August 2015 - ISSUE 7

WKMJ

World Korean Medical Journal

Cover Story

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World Korean Medical Journal is published bi-monthly by W Medical Strategy Group, 210B Sylvan Ave., Englewood Cliffs, NJ 07632. Tel. 201.402.1400, Fax. 201.430.2472, Email. info@wmedicalstrategy.org, Website www.wmedicalstrategy.org. Please send inquiries, subscription requests and address changes to the above address.

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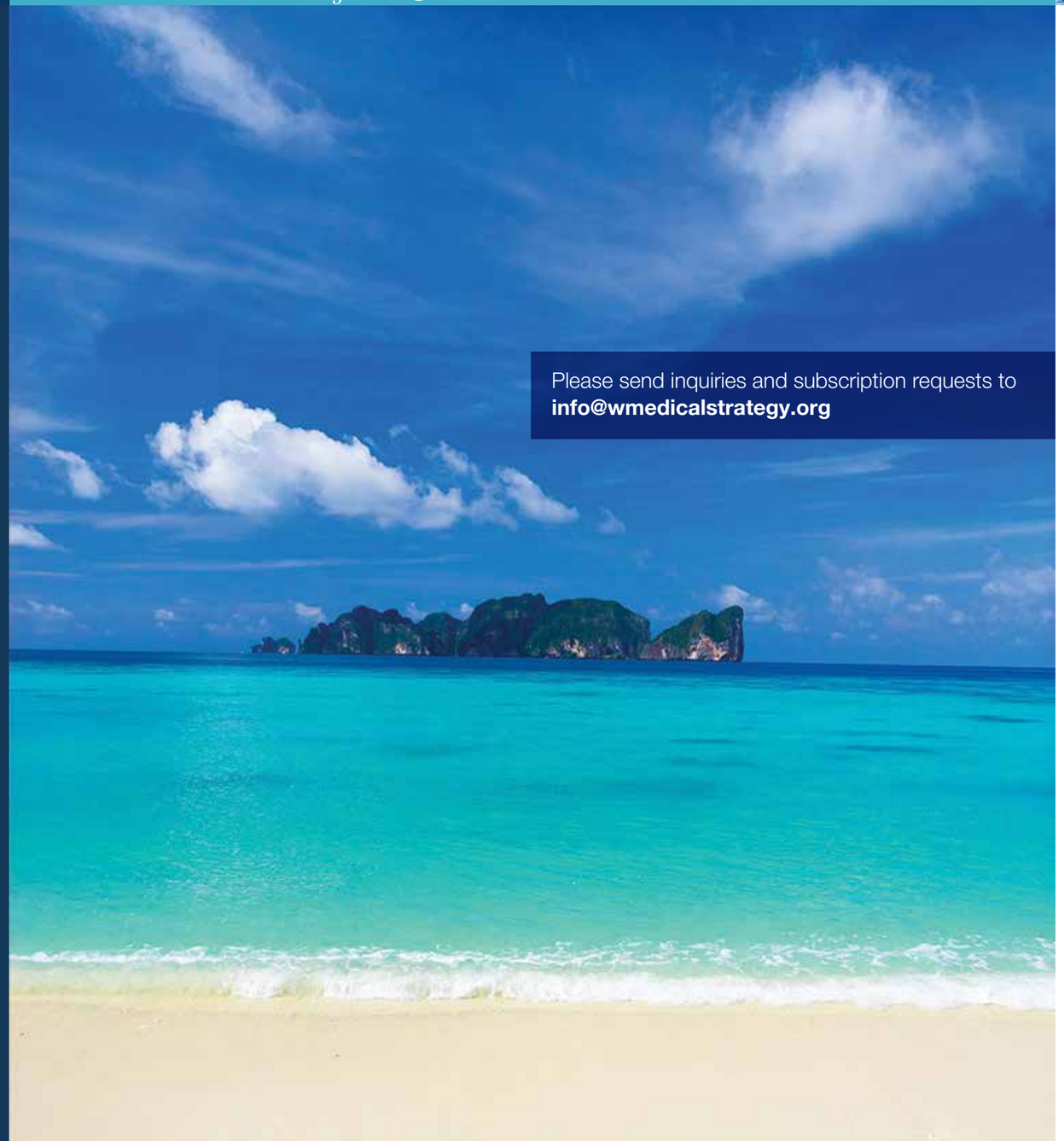

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FROM THE PUBLISHER

Dear Colleagues,

Greetings! First I want to thank the speakers and sponsors including lead Samsung that made the 4th WKMO Annual Convention a success. It was good to see many of you in LA. The speakers all had interesting topics and the TED style talks were informative and entertaining. Dr Charlie Cho of Stanford spoke on research on living longer and mentioned the million dollar prize his group is offering http://paloaltoprize.com toward immortality. A deep felt thank you goes to Congressman Mike Honda for supporting WKMO, as he is leader in the hepatitis campaign in Asian Americans as well as issues involving Korea. A special thanks goes to Dr Chul Hyun and his family who made the meeting a top notch event as always.

It is only appropriate that this issue cover story is Dr. Chul Hyun. It is through the vision of Dr Hyun and many other Korean physician leaders that WKMO was founded 4 years ago. Dr. Sanghoo Kim deserves a special word of thanks for his legwork of making contact with Korean physician groups throughout the world. Dr. Hyun as President has worked tirelessly to have the WKMO get off the ground and have the regional and annual convention which is no small feat. Gathering an international group is challenging logistically and financially but he always held an informative and productive meeting with focused agendas. His energy and dedication in trying to network Korean heritage physicians is boundless. Dr. Hyun has done so much for WKMO including getting 501C non-profit organization designation. Dr. Hyun is also the founding publisher of the WKMJ, a great new vehicle to reach Korean physicians worldwide and disseminate news, notes and activities of many bright, energetic doctors in many worthwhile efforts and endeavours.

Much has been accomplished with the inception of WKMO but there is much more work to be done with the strengthening the WKMO base and increasing the outreach to many Korean physician in all corners of the world. WKMO is a unique medical organization not to supplant a national or regional Korean physician groups but to supplement networking on an international level. As physicians we wear many hats and we want to leverage our resources and capabilities to enhance healthcare through international interaction. WKMO can be a vehicle for scientific exchange, but also for medical education as the new International medical school in North Korea is now being built there are unprecedented opportunities to educate and interact with the next generation of North Korean physician leaders who work in harsh conditions with limited resources. We want to get North Korean doctors to become members of WKMO medical community. WKMO's goal is to foster interaction on a global scale, as there are Korean physicians literally in all corners of the world. I am honored to be elected President of WKMO and I ask that everyone gets involved as the organization success depends on everyone's participation.

David Y. Ko, MD
Publisher
Board Director of WKMO
Keck School of Medicine of USC

FROM THE EDITOR IN CHIEF

Dear Readers,

In his enthralling book, "The Lexus and the Olive Tree (2000)", a prominent journalist of the New York Times Thomas Friedman explained the impact in which globalization is making on our lives throughout the world. He puts it as "It enables us to reach into the world as never before and it enables the world to reach into each of us as never before." One and a half decades had been passed since Thomas Friedman wrote this book, and globalization has been processed more intensively than ever before in all segments of human lives, spreading into healthcare as well. Under such circumstances, World Korean Medical Journal was founded and published to feature the most relevant issues on the global healthcare arena while introducing the most influential and inspirational healthcare leaders.

In this August edition, Dr. Chul S. Hyun, Inaugural president of World Korean Medical Organization (WKMO) is introduced in the cover story. He is a man of belief and enthusiasm, and an inspiration to the Korean physician community. As a physician, his achievements in the areas of gastroenterology and hepatitis in needed communities are significant. He has navigated arduous and formidable pathways to address ethnic disparities and cultural healthcare issues and to present measurements to overcome such challenges in the communities. As a healthcare leader, his visions on global health became a true legacy inspiring the young generations. He has accomplished tremendously through his 3 years as the president of the organization.

New trends and issues of bio-health industry are featured in the articles. In the article from BioCentury, the reporter emphasizes competitiveness of gene therapy on orphan diseases. In another article, US rheumatologists' enthusiasm and concerns over biosimilar products are viewed. Patent extension and litigation issues are addressed as well as efficacy and safety aspects.
An article about Green Alley, the eco-luxe beauty store and its skincare products, provides interesting information on chemical vs. natural ingredients that our readers may find delightful to read.

Many eminent experts shared their knowledge and insights as authors in this edition. I wish that our readers would find this exciting selection of articles to be helpful and inspiring.

As I newly step up to the position of Editor-in-Chief, I hope my humble contribution would nourish the contents and bring a small joy to our readers.

Thank you.

DoHyun Cho, PhD
Editor in Chief
President & CEO of W Medical Strategy Group
Chairman of New York Health Forum

WKMJ RECAP OF MAY ISSUE

Cover Story
Inspirational Korean Healthcare Leader "Dr. Kwang Tae Kim, President of International Hospital Federation"

Dr. Kwang Tae Kim is the president of International Hospital Federation, the first Asian to be elected as the leader of the organization. He is also the president of a private general hospital named, Daerim St. Mary's Hospital. The hospital was established in 1969 in Seoul, Korea. In the interview, he emphasizes on healthcare delivery system facing a major challenge due to the aging population with chronic conditions. Read our Issue 6 to find out more about the inspirational Korean Healthcare Leader.

Entrepreneur Interview
Chul Kyoon Park, President of It's a wig

Chul Kyoon Park, the president of It's a wig, his company distributed wigs in the U.S for more than 40 years. His wig donation first started in 2009, and he donates 2000 wigs per year in 20 different locations for cancer patients who have lost hair during the chemotherapy treatment. He supports them by donating wigs to make them feel more confident about their looks and have better self-esteem. In 2012, It's a wig has been selected as the best wig supporting company. Read our Issue 6 to find out more about Chul Kyoon Park and his campaign.

Special Report
New York Health Forum: "The Pacific Connection: U.S-East Asia Pharma Collaboration"

On February 11th, 2014, the 2nd New York Health Forum titled, "The Pacific Connection: US-East Asia Pharma Collaboration" was held in Yale Club of New York City. Over 100 individuals including investors, industry leaders, and physicians attended this forum. The forum was co-hosted by W Medical Strategy Group and New York Pharma Forum and it was sponsored by Green Cross, Life Sciences Queensland, SLI Production Corp, Rivkin Radler, and etc. For more detailed report on the 2nd New York Health Forum, please refer to our Issue 6 to find out more.

Biopharmaceutical Report: Spark's LCA2 gene therapy is likely to have greater benefit for younger patients

Experts announced that Spark Therapeutics' (NASDAQ:ONCE) subretinal gene therapy injection of SPK-RPE65, is likely to restore vision most effectively in younger Leber's Congenital Amaurosis (LCA2) patients. Although the younger patients are likely to experience better treatment results because they tend to have more viable retinal area to salvage, they have higher risk of performing surgery. For more detailed report, read our Issue 6 to find out more.

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KOREAN MEDICAL PIONEER

Inspirational Korean Healthcare Leader

"Dr. Chul S. Hyun, Inaugural President of World Korean Medical Organization"

1. Dr. Hyun, you are a successful physician and a respected member of the community. What was your particular background that motivated you to pursue your career? As a doctor, you may have gone through various obstacles; can you share some of the most difficult moments during your career?

- I was originally trained as a basic research scientist. In both undergraduate and graduate years, I had an interest in basic science, specifically in the field of cell membrane transport. After my PhD in Biophysics, I pursued postdoctoral studies in cell physiology. I was fascinated by numerous underlying cellular mechanisms, regulating electrolyte and nutrient transport, which are essential for survival. I studied these mechanisms in both health and diseased states, which often manifest as diarrhea. Clinical implications of these studies are obvious if we consider that diarrhea is one of the top disease threats. Root of the problems for many diarrheal disorders is found in the altered mechanisms of transport, and understanding the mechanisms and regulations provide a key to solution. I decided to pursue my career in medicine during my postdoctoral years. So, I began my medical school years, followed by medical residency and gastroenterology fellowship.

After gastroenterology fellowship, I had a busy life as a physician scientist at a university medical center, doing both clinical medicine and bench research. As a physician scientist, one has to keep up with the latest tools and treatments, and at the same time, face an unprecedented explosion of scientific discoveries. While it was quite challenging, it brought me a unique perspective to biomedical research because it inspired me with my personal experiences in caring for patients.

It wasn't until I contact with the Korean American community in New York, which led me to a new career path as a full-time clinician in a private practice. The transition from physician scientist to a full-time clinician was not easy. However, there was a strong need for medical expertise in our community which overlapped with my focus and interest. Subsequently, I began to discover the 'clinician in me' and enjoy taking care of patients.

Dr.Hyun speaking about hepatitis B diseases among Asians at The 3rd WKMO Annual Conference

Dr. Chul Hyun

2. You've served as the president for Korean American Medical Association (KAMA) for two consecutive terms. Also, you are the founding president of World Korean Medical Organization (WKMO) and have contributed tremendously to the public welfare. What is your reasoning and motivation to create and operate such activities? Additionally, you've led numerous WKMO activities such as expanding regional chapters in over 10 countries. Where does your underlying strength come from?

- Throughout the world, Korean medical communities have great resources and we are in the position to lead the future of medicine and matters of global health. This can only be achieved if and only if we unite and work for the same goal! Our successes rely on vibrant networks amongst Korean physicians and their communities. Networking is equivalent to continuing education because the more we learn, the greater chance we have at succeeding. We often hear education being compared to 'filling of a bucket' in providing students with information and data. However, real education is not only filling up the bucket, but also making the bucket bigger to accommodate more creative thoughts and information. This is what networking is and what it can offer. We make the bucket bigger to embrace the greater diversity. Networking is also about making relationships. It is a collective movement that can empower all of us in every aspect of our lives.

Group photo at The 3rd WKMO Annual Conference

KAMA and WKMO are only two examples of these networks. Each one of them has uniquely different roles and potential to contribute to our community. KAMA is a nationwide networking organization promoting collegiality among the Korean American physicians and empowering them to serve the community. WKMO is an international network, connecting Korean physicians and their organizations throughout the world. WKMO's goal is to create a synergy through collaboration between different nations. KAMA and WKMO ultimately share common goals in their efforts to strengthen and facilitate the network of Korean physicians. The scopes and approaches of our organizations, however, are different and can be tailored to the different leaderships.

I am energized and motivated when I think of the potentials of Korean physicians and our roles in the community. The vision of global leadership and the difference we can make give great meanings to me and my core identity.

3. We have heard that you are interested in competitiveness of Korean healthcare systems. As a physician practicing in the US, what is the reason to have interests in global competiveness of Korean medical industry and its advance into global markets?

- The scope of achievements in medicine and science demonstrated in Korea was remarkable during the past five decades. Modern medicine and bio-health industry in Korea represent a clear symbol of cutting edge medical research and advanced clinical care. In an era of globalization, the modern medical progress in Korea offers an unprecedented potential to enhance global health.

There are over 36,000 overseas Korean physicians outside the Korean peninsula, many of whom are international experts in their own fields. One may consider WKMO as a bridge connecting these vast human resources to Korea and vice versa. This leads to mutually beneficial experiences for both WKMO and Korea. Since, they share the same goals to promote awareness of the Korean medical sector and to contribute to the advancement of global healthcare.

WKMO Board members(Bottom, left to right): Dr. David Ko, Dr. Hyung Kwon Kim, Dr. Sang Choon Cha, Dr. Kyung Ryul Lee. (Top, left to right): Mrs. Hyun, Dr. Chul Hyun, and Mrs. Lee

For example, WKMO held 2nd Annual Convention in Las Vegas in 2013 under the theme named, 'Partnership between Physicians and Health Industry'. We featured two specialty forums to evaluate and demonstrate the various roles physicians have in the advancement of the biomedical industry and the healthcare business. The first forum was called 'Role of physicians in Drug development', which consisted of Korea's pharmaceutical CEOs and experts in the United States. It covered various areas of drug development and the role of physicians in the pharmaceutical industry. The second forum titled 'Advances in medical Imaging' featured radiology faculty from different institutions who touched on various tools and technologies, and provided important insights into modern medical imaging. We also heard from Samsung Medison and Electronics regarding on their current and future plans in biomedical technology. Additionally, similar imaging forums held during in 2014 and 2015 Conventions in New York and Los Angeles.

Dr. Hyun receiving appreciation award by WKMSO(left to right): Andrew Lee, Dr.Hyun, and Soyoun Kim

KOREAN MEDICAL PIONEER

4. You've successfully completed the first term as president of WKMO and Dr. David Ko is elected as the next president. What is the future plan and vision of WKMO along with the new leadership and your support?

WKMO Board members(left to right): Dr. David Ko, Dr. Hyun, Dr. Hyun Kwon Kim, Dr. Sang Choon Cha

- Dr. Ko is a highly respected physician in both America and the international community. He was the president of The Korean American Medical Association (KAMA) in 2014. Most recently, he served as the Chair for the 2015 WKMO Annual Convention in Los Angeles. His interest, hard work and passion for the Korean physician network in the United States and the rest of the world are highly regarded. Dr. Ko's educations, experiences, and particularly, his dedicated services and leaderships in WKMO and other various academic societies make him eminently qualified to lead WKMO as the president.

It has been a great honor and privilege for me to serve as the president of WKMO for the past three years. I am thankful to be a part of an organization that contributes to the careers and lives of many physicians, and the community at large. It has been quite a journey for me and I am grateful to all those who stood by me with their encouragement and support.

I see tremendous potential for growth and prosperity for WKMO. We have enormous resources in the background of multicultural identity. Immediate goals of WKMO include advocacy for health equity in our communities, and promotion of outreach activities in the underdeveloped communities throughout the world.

5. You worked in a university hospital for several years and moved on to a private practice for the Korean community. What is your vision and philosophy about health services in community and healthcare in general?

- The transition from physician scientist to a full time clinician was challenging. Private practice brought me the new perspectives. The practice of medicine in a community setting is very different from an academic center. Being in private practice, I learned how critical it was to get to know a patient as a whole before attempting to diagnose their medical problems. I learned how to communicate effectively with patients to get to the root of the problem. Oftentimes, patients and their illnesses are reflections of what their community has. As a result, it became critical that I understand the community.

As our society becomes more racially and ethnically diverse, physicians need to respond to patients' various needs, values, and behaviors concerning health. Failure to understand the socio-cultural differences can have significant health consequences and management for minority groups. For instance, there are over two million Koreans living in the United States. Health issues of Korean Americans are diverse, and are often overlooked because of language and cultural barriers. Healthcare providers have the responsibility to work with the community to resolve these issues.

We also have to understand that current healthcare has evolved as a complex and challenging interdisciplinary field. Physicians have to go beyond the usual boundary of medicine, and interact with scientists, engineers, businessmen, lawyers, policy makers, and others so together we can safely navigate healthcare in today's ever-expanding multi-cultural and multi-ethnic society. We need to integrate the various expertise and develop new perspectives. Organizations like WKMO provides a platform for us to explore, interact, and establish a wholesome network through which we can find innovative approaches to deal with the myriad of today's healthcare issues.

Dr. Hyun giving a speech

6. You are the founder of Asian Liver Center at Holy Name Hospital and have established another non-profit organization, Center for Viral Hepatitis (CVH). Why are you continuously emphasizing the importance of awareness of Hepatitis diseases in the community?

- The most frequent cause of liver diseases for Korean people, viral hepatitis B, is also a crucial topic of ethnic disparity. There is a marked disparity between Asian Americans and White Americans in the prevalence of chronic hepatitis B and its complications. For instance, approximately 3-10 % of all Asian Americans have HBV infection compared with 0.1% of White Americans. Patient-related obstacles mostly consist of lack of awareness about the disease, language and cultural barriers, and Insurance issues. Additionally, providers and healthcare systems currently available in the US lack the understanding of the significance of chronic hepatitis B. Specifically, there is a lack of public health systems to meet the needs of multicultural populations. There is also a poor communication between providers and patients of different racial, ethnic, or cultural backgrounds.

The Center for Viral Hepatitis (CVH) is a non-profit organization with the following missions: (A) to increase the screening for chronic hepatitis B (CHB) in high risk populations; and (B) to develop strategies to provide and maintain the efficient linkage to clinical care for Asian American CHB patients. CVH aims to reduce the impact of Hepatitis B Virus (HBV) infection and to limit the progression and complications from HBV-related liver diseases, thereby reducing morbidity and mortality associated with CHB.

With a serious lack of good health access models available for minority populations in the United States, the need of CVH and similar organizations is crucial to fight ethnic disparities and to promote culturally competent healthcare.
scientists, engineers, businessmen, lawyers, policy makers, and others so together we can safely navigate healthcare in today's ever-expanding multi-cultural and multi-ethnic society. We need to integrate the various expertise and develop new perspectives. Organizations like WKMO provides a platform for us to explore, interact, and establish a wholesome network through which we can find innovative approaches to deal with the myriad of today's healthcare issues.

Family photo: Mrs. Hyun, Dr. Hyun, Sarah Hyun

7. As a highly experienced physician, do you have any words of advice to medical students? And for other healthcare providers who are not currently participating in Korean Medical associations like WKMO, what is your advice?

- I can think of at least three good reasons of why healthcare providers should join WKMO. First, it is the identity. We join because it says 'something' about us, about our roots, and very special commonness we share linguistically, culturally and historically. Second, we join WKMO, so that we can connect and build relationships because through this connection, we feel the power of belongingness. Third, we join for the sake of community. We want to belong to the community that is not only Korean, but also global community, so that our children can also re-identify with that same commonness we share.

Whether it is WKMO or KAMA, we serve to build a vibrant community. Be a part of the community with a purpose to share with others that we have been blessed with.

Dr. Chul S. Hyun

Inaugural President of World Korean Medical Organization

DR. CHUL S. HYUN obtained his B.A. from the Johns Hopkins University in 1977. After earning an M.D. from the University of Miami School of Medicine, he underwent internship and residency in Internal Medicine at Georgetown University Medical Center. Subsequently, he completed Gastroenterology and Liver Fellowship at Yale University School of Medicine. He is Board certified in Internal Medicine and Gastroenterology and has been an attending gastroenterologist in New York Presbyterian Hospital where he currently serves as a clinical faculty in the Division of Gastroenterology and Hepatology at the Weill Cornell Medical College. Dr. Hyun has served as the president of Korean American Medical Association (KAMA, 2011-2013) and is currently the President of World Korean Medical Organization (WKMO), a global network of 140,000 physicians of Korean descent. He is also the director general of CVH(Center for Viral Hepatitis).

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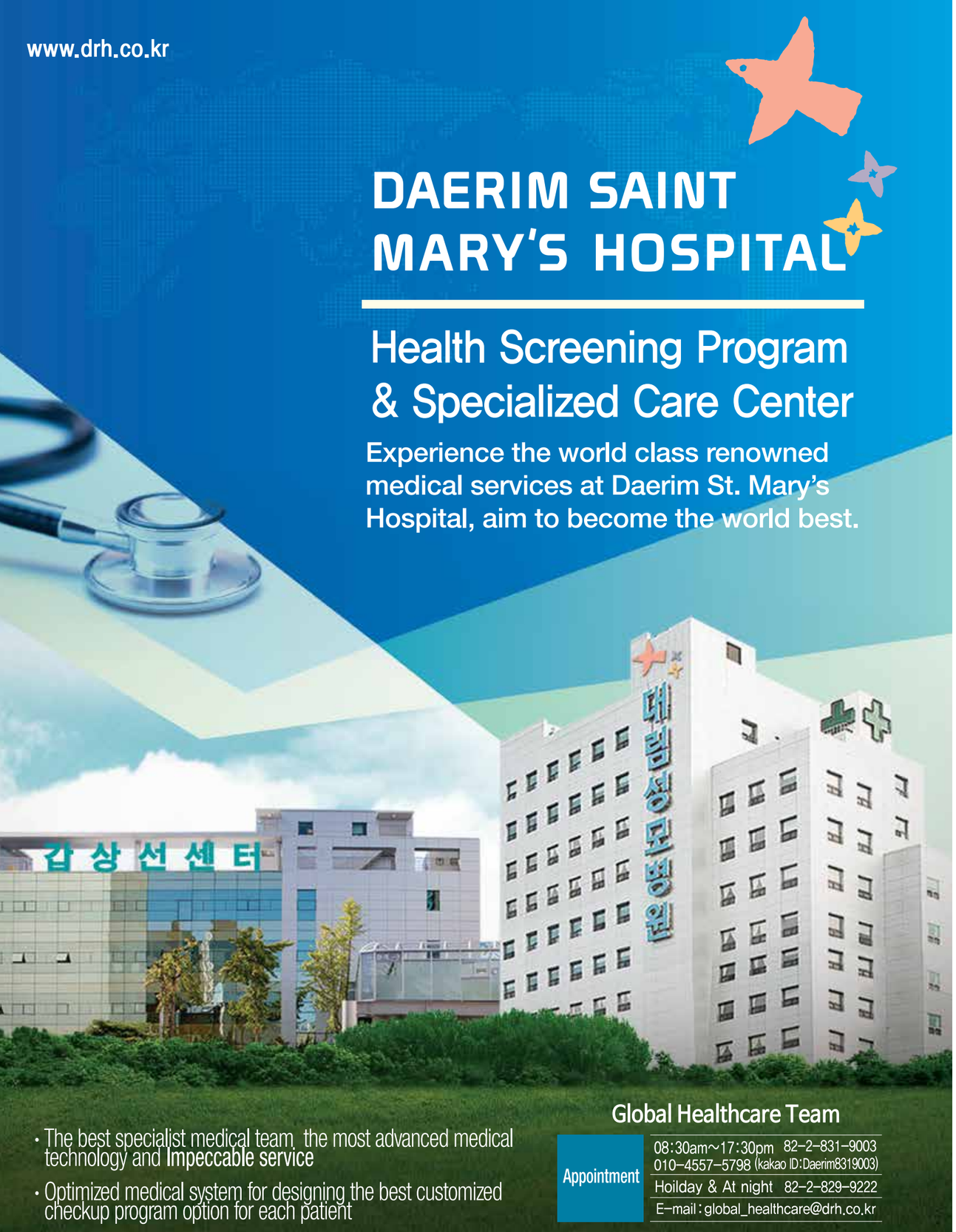

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SPECIAL REPORT I

GREEN ALLEY:
YOUR SKIN SAYS, I AM SO SICK OF
CHEMICAL PRODUCTS

SPECIAL REPORT II

NEW YORK HEALTH FORUM:
ERA OF MOBILE HEALTH

Special Report I

Your skin says, I am so sick of chemical products

Green Alley's Natural Ingredients Skincare

Skincare often is focused on targeting women, but nowadays both men and women concerns about their skin and show interests in skincare. Especially while going through the puberty or during lifetime, almost every men and women experience skincare problems, called acne. There are some who are lucky enough to pass by the puberty without any skin troubles; however, he/she all faces skin challenge called 'Aging skin'. There are different types of skin troubles including: acne, dark spots, wrinkles, dry skin, redness, dull skin, dark circles, and etc. Although there are millions of skincare products from all over the country, there is not a single product that can completely solve the skin troubles yet. Taking care of skin is lifelong homework. It's often said that 70 percent of human skin is from genetic and the rest, 30 percent is from skincare management. So, this means that even if one has genetically great looking skin when he/she is young, he/she will soon face the aging skin problems such as sun damage, wrinkles, and dark spots. On the other hand, it could mean that if one can manage the troubles with careful skincare, he/she has a good chance to improve his/her skin condition.

GREEN ALLEY
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Though there are tremendous amount of cosmetic products, everyone's skin type,living environment, and/or skincare routine can be different and it's not so easy to find the right products for each one. It's hard to understand chemical words listed on the ingredient list if one is not a Chemist. Also, it's hard to afford and try all the expensive products being a lab rat. Green Alley, the new skincare brand in the beauty market is established for this purpose. There are numerous products out there in the world, but consumers do not really know which ones are actually good for their skin. Some of the products are full of hazardous chemicals that will eventually damage the skin instead of solving skin problems. So, instead of having self-human trial with number of products, Green Alley filters out all harmful products for consumers.

Green Alley (www.GreenAlleyShop.com), a natural cosmetic multi-brand shop is opened on June 19, 2015. Green Alley finds skincare solutions in Korea's skincare products with natural ingredients. Green Alley is all about high-end, natural skin care collections from South Korea, a new global hub of innovative beauty and skin care trends. Green Alley will provide a great opportunity for the U.S customers to experience brand new healthy skin products powered by Korea's finest non-GMO beauty brands who only use natural ingredients that are clinically tested and validated for its safety and effectiveness.

All Green Alley's staffs are referred as "Beauty Hunters". Beauty hunters' major missions are to build direct connections between customers and high performance, and boutique cosmetic manufacturers. Beauty hunters selectively discover 'Forever Item' meaning one will be willing to use the product forever. Once beauty hunters discover a suitable candidate, they take detailed ingredient examinations, clinical data validations, professional advices and personal testing for more than 6 months. After 6 months of examination period, only a few of the products satisfy the rigorous inspection and are carefully selected. Currently, Green Alley exclusively distributes 4 new and trendy cosmetic brands including Kicho, CU Nature, Vant 36.5, and Dermafirm, and plans on adding10 more qualified brands by the end of this year. With growing consumer's awareness of risks of using chemicals in cosmetics and demand for natural cosmetics, Green Alley's collection carries products using naturally driven ingredients, no animal testing, and formulated without any harmful chemicals. Most of cosmetic products are made of more than 50 ingredients, and it's not easy for consumers to check whether all ingredients are natural. So, as a cosmetic business professional, Green Alley carefully selects brands, reviews their ingredients, and visits manufacturers before introducing a new brand to consumers.

Green Alley's skincare cosmetics are sold online @ www.greenalleyshop.com. For customers who would like to physically experience the cosmetics can visit the showroom located @ 210B Sylvan Ave. Englewood Cliffs, New Jersey. Customers can meet professional cosmetologist and consultants for personal skincare consultation. Also to offer a chance to meet with Green Alley to New Yorkers, Green Alley had recently opened up a 'Pop-up store' in K-Town, NYC on July 17 &18. Number of fans and beauty bloggers of K-Beauty who had already heard about Green Alley's great products visited the pop-up store to personally try Green Alley's selections. At this 2 day pop-up shop, Beauty hunters also gave personal consultation to the customers based on each customer's skin concerns, skin type, and current skin condition.

Anita Depta

Cosmetologist, Green Alley

Anita is a licensed Cosmetologist at Green Alley. She is a skincare specialist offering personalized consultation on daily skincare and special skincare treatment based on individual's skin condition. She is creative and detail-orientated cosmetologist with experience in providing all-encompassing, quality skincare services and consultation.

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Special Report II

New York Health Forum: “Can Smartphones Become The New Stethoscopes?”

Expert Insights Into The Future Of Mobile Health

One of the hottest topics for speculation in healthcare today is the unrealized potential for mobile health defined as technologies that use mobile devices, apps or telehealth to connect patients and physicians to transform the way healthcare is sought and delivered. Twothirds of Americans own a smartphone (http://www.pewinternet.org/factsheets/mobiletechnology-factsheet/), and companies are eager to tap this widespread technology for the benefit of patients, doctors and hospitals. But expert say it’s not yet obvious how exactly mobile services might be leveraged in the bureucratic world of healthcare with its highly sensitive privacy issues.

“The fact is that consumers are mobile so healthcare has to respond to that,” Shira D’Erasmo, a communications director at the insurance company Humana, said at a panel discussion (http://www.nypharmaforum.org/events/thefutureisnowtheeraofmobilehealth/) on mobile health held on Thursday as part of the Third New York Health Forum at the Explorer’s Club in Manhattan.

Already, some companies have launched mobile services focused on easing the inconvenience for patients of dealing with the healthcare system. ZocDoc, Inc. (https://www.zocdoc.com/) is an online doctorbooking service that has been adapted for mobile. Kevin Kumler, the company’s vice president, points out that it takes 18 days on average (http://www.everydayhealth.com/news/doctorwillseeyoufewweeks/) for a patient to book a primary health care appointment in

Most companies that promise to offer mobile health solutions are small, private enterprises that are still trying to raise money. But the largest insurers and pharmaceutical companies in America are also keeping a close eye on this trend. Wikimedia Commons/Intel Free Press

the U.S. The service grants patients access to a physician’s calendar to schedule their appointment right away much like consumers can use Seamless to order food online or Uber to call a driver.

Most companies that promise to offer mobile health solutions are small, private enterprises that are still trying to raise money. But the largest insurers and pharmaceutical companies in America are also keeping a close eye on this trend. Wikimedia Commons/Intel Free Press

Unity Stoakes, founder of StartUp Health (https://www.startuphealth.com/), which provides consultation to healthcare entrepreneurs, said he is most excited by the notion that mobile health can apply elegant solutions to everyday problems for both patients and their caregivers. “Sensors can be embedded into and onto and around everything to understand really important and simple things like, ‘Did Grandma get out of bed today?’” he said.

The nation’s largest companies are just as eager as its smallest to explore these possibilities D’Erasmo says Humana’s (https://www.humana.com/) home care division, which provides at home health services for elderly patients, has experimented with placing sensors in patients’ homes and using Skype or other virtual services to enable remote caregivers to attend doctors visits with a loved one.

Pharmaceutical companies have also begun to use mobile tech such as Fitbits or Garmin activity trackers to measure patient data during clinical trials. These tools and other such devices might allow researchers to constantly track vital signs, log a patients’ heartbeat pattern or trace the effects of a medicine, rather than only collecting this information during a checkup.

Even though some companies have begun to use trackers in their trials, the Food and Drug Administration has not yet approved any drug based on a result measured by a mobile health device. Kara Dennis, managing director of Medidata, (https://www.mdsol.com/en)which provides software support for pharmaceutical companies conducting trials, predicts this could soon change.

While she is optimistic about the future, Dennis said that there is still a ways to go to get there. “Mobile technology is still very new in the clinical research space,” she said.

Additionally, a pharmaceutical company has a far more rigorous standard for data collection than a consumer who is planning their workout a device must be worn almost constantly in a clinical trial and measure data with extreme precision. It’s also recommended that a device can be worn in the shower which is not recommended (http://help.fitbit.com/articles/en_US/Help_article/Can-Iswimorshowerwithmytracker)for Fitbit and has a

long battery life. “Those considerations become very serious when you’re considering using it in clinical trials,” said Dennis.

A recent lawsuit (http://arstechnica.com/tech-policy/2015/05/lawsuitsaysfitbitoverestimates sleepby67minutespernight/) from a Florida man alleging Fitbit gadgets overestimate the amount of sleep that wearers receive by 67 minutes per night are also problematic. “If you’re overestimating sleep duration, we can’t use that in a trial,” Dennis said. “We need to know how much the patient actually slept.”

Les Funtleyder, a portfolio manager at Esquared Asset Management (http://www.esquaredconsulting.co.uk/Capabilities/business_consultant_capabilities_asset_management.html), said investors would be wise to keep a clear head when considering the potential of each new mobile health application. He sees five or six mobile health companies seeking investment a week and worries that many are overvalued. “I think mobile health is reminiscent of a bubble,” he said. But “I don’t think they’re in a bubble yet.”

One of the current limitations, as Stoakes of Startup Health sees it, is that each mobile health company is independently trying to build its own hardware and software to deliver its services. The arrival of platform tools such as Apple’s ResearchKit, which developers may leverage to collect health data or conduct experiments, could absolve companies of this need and allow them to focus on perfecting their product or service.

Paula Wilson, president of Joint Commission International, (http://www.jointcommissioninternational.org/)which provides accreditation for hospitals, says that while mobile health could lead to great advances in healthcare, it will inevitably bring new risks. The vast majority (http://www.ibtimes.com/datasecurity29millionpatientrecords compromisedhealthcarebreachesstudyshows1881245)of major healthcare data breaches that have occurred in recent years took place through electronic networks.

Still, Stoakes at StartUp Health believes that these technologies will soon become an essential part of all healthcare services. “Very soon, there won’t be a separate category called mobile health,” he said. Instead, Stoakes said mobile devices will be fully integrated into the way that healthcare is designed and delivered. W

Amy Nordrum

Reporter, International Business Times

Amy Nordrum is a science/business writer at International Business Times. In the past, her work has been featured by Scientific American, Smithsonian Magazine, IEEE Spectrum and The Atlantic. Amy holds a master’s degree from the Science, Health and Environmental Reporting Program at New York University.

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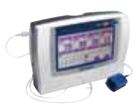
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Happy smile and hope after pain

D.K. Lee has related to It's A Wig that she will promote to cancer patients about the beauty classes and healing programs she attended. The beauty classes are held at Kyung Hee Medical Center and it is for cancer patients to help them feel more womanly during their hard times. She would like to thank all the people who gave her hope. "Thank you for giving me a second chance to live as a woman. With the hopes and gifts that I have received, it encourages me to work harder to volunteer my time for the people who are fighting against cancer."

Kyung Hee Medical Center patient
D. K. Lee

Cancer-free D.K. Lee

D.K. Lee attending
beauty classes while chemotherapy treatment

WKMO Report

The 4th World Korean Medical Organization's annual convention

The 4th World Korean Medical Organization's annual convention was held in Los Angeles, California this year on July 2nd to July 4th at the Intercontinental Los Angeles Century City. The convention focused on a theme: "Trans-cultural Healthcare and Global Initiatives" and featured four specific forums and distinguished speakers to learn and identify the roles and needs of physicians in various aspects of healthcare.

a. Congressman Mike Honda giving a keynote speech

On July 2nd, starting with an opening performance, registration and opening reception started. Congressman Mike Honda came over to give keynote speech which was titled as "Hepatitis B: role of WKMO, Take It Global!" There were four great forum sessions throughout two days. Session A: "The Brain" was organized by neurologists aiming to navigate a wide spectrum of disorders including epilepsy, stroke, Alzheimer's and other neurological issues; Session B: "The Mental Health Issues of Korean Americans" was designed to discuss various mental health issues of Korean immigrants in the U.S.; Session C: "Imaging and Digital Technology in Health" to discuss new advances in imaging sciences and their application in clinical medicine and Session D: "Distance Care around the World" was organized by representatives from different countries who overviewed telehealth and related healthcare issues in respective nations. Thanks to all the speakers, every session was rich and fruitful making the convention as another influential achievement of WKMO.

At the end of July 4th, there was WKMO Gala Dinner where Consul General Hyun Myung Kim came to give congratulatory remarks and Dr. Chan Hie Kim spoke as a keynote speaker. Also, WKMO held an award ceremony in two different aspects: one in WKMO Global Leadership and the other one in Appreciation Awards.

b. From left: Dr. Chul Hyun, Congressman Mike Honda, Dr. Helen Kang, Dr. David Ko, and Dr. Jeffery Suh

c. From left: Dr. Sang Hoo Kim, Dr. Chul Hyun, Dr. Helen Kang, Dr. Chan Hie Kim, and Dr. David Ko

WKMO was privileged this year to honor Dr. Ui Hwa Chung, the Speaker of National Assembly of Korea and Congressman Mike Honda. These distinguished guests are WKMO Global Leadership awardees.
Their achievements and leadership in global health and healthcare industry, and their insights into how we can better serve the world as physicians are inspiring. The Appreciation Awards recognized individuals who have made unique contributions to the promotion and advancement of the WKMO and its vision. Awardees included: Dr. Sang Choon Cha, Dr. Tai P. Yoo, Mr. Soo-In Cho and Dr. Joe McMenamin.
One additional thing that made this year's convention special and meaningful was that at the end of the award ceremony, Dr. David Ko received a gavel from Dr. Chul S. Hyun celebrating WKMO's new president. Dr. Chul S. Hyun, the first president of WKMO, made countless achievements and contributions to WKMO with his great passion towards WKMO's vision and goals. Now Dr. David Ko, new president of WKMO, is handed the baton and will continue to develop and nurture WKMO.

d. Dr. Chul Hyun and Dr. David Ko, new president of WKMO

e. The 4th WKMO Annual Convention -Trans Cultural Healthcare & Global Initiatives: Program Brochure

SESSION A July 3rd, 8:30am - 12:00pm

8:30- 8:40 AM	Introduction David Ko, MD, USC Keck School of Medicine
8:40-9:10 AM	Advances in the Treatment of Acute Ischemic Stroke May Kim, MD, USC Keck School of Medicine
9:10-9:40 AM	Diet and Brain Function John Rho, MD, University of Calgary
9:40- 10:10 AM	New Imaging in Cerebrovascular Disease Paul Kim, MD, USC Keck School of Medicine
10:10-10:40 AM	Epilepsy Treatment: Yesterday, Today, Tomorrow Steve Chung, MD, Banner University medical Center
10:40-11:10 AM	The Rise of Immune-Oncology John Yu, MD, Cedars-Sinai Medical Center
11:10-11:40 AM	Autonomic dysfunction and longevity Charlie Cho, MD, Stanford University
11:40- 12:00 PM	Q & A

SESSION B July 3rd, 1:15pm - 3:40pm

1:15- 1:20 PM	Introduction Tai P Yoo, MD, MSBA, UCLA Medical Center
1:20- 1:50 PM	The Korean Americans; History, Culture and MH issues Tai P Yoo, MD, MSBA, UCLA Medical Center
1:50- 2:20 PM	East meets the West: Influence of Cultural Factors in Korean American Mental Health Soni Kim, PsyD, Horbor-UCLA Medical Center
2:20- 2:50 PM	What is the most common psychiatric condition in the Korean American community in Los Angeles area Susan Chung, MD, USC Keck School of Medicine
2:50- 3:20 PM	Overcoming Challenges and Implementing Effective Strategies to the Treatment of Asian Americans with mental health Austina Cho, MD
3:20-3:40 PM	Q & A

SESSION C July 4th, 8:30am - 11:20am

8:30- 8:35 AM	Introduction Paul E. Kim, MD, USC Keck School of Medicine
8:35- 9:05 AM	Why you may already have Alzheimer's Disease and if not, what can you do to prevent it? Meng Law, MD, USC Keck School of Medicine
9:05-9:35 AM	Contrast-enhanced ultrasound for liver tumors Tae Kyoung Kim, MD, PhD, University of Toronto
9:35-10:05 AM	Multi-modality imaging for hepatocellular carcinoma Hyun Jung Jang, MD, PhD, University of Toronto
10:05-10:35 AM	Lung cancer screening with low dose CT Chris Lee, MD, USC Keck School of Medicine
10:35- 11:05 AM	Introduction to Premium Ultrasound Technology of SAMSUNG Joon Sunwoo, MD, MBA, Samsung Medison
11:05- 11: 20 AM	Q & A

SESSION D July 4th, 1:00pm - 4:00pm

1:00- 1:05 PM	Introduction Joe McMenamin, MD, JD, W Medical Strategy Group
1:05- 1:35 PM	Telemedicine in the United States- Patient and Physician Engagements Joe McMenamin, MD, JD , W Medical Strategy Group
1:35- 2:05 PM	The Affordable Care Act and the Korean American Community Paul Song, MD , Cedars-Sinai Medical Center
2:05-2:35 PM	ICT-Engaged Hospital Service: Patient-Engagement, Chronic & Acute Disease Telemonitoring: SNUBH Cases Hee Hwang, MD, PhD, Seoul National University
2:35-3:05 PM	mHealth and Teleradiology in Canada Tae Kyoung Kim, MD, PhD, University of Toronto
3:05-3:35 PM	How Can Medical Education Be Effectively Used to Reach Third World Countries David Roh, MD, PUST DMS School of Medicine
3:35- 4:00 PM	Q & A

Biopharmaceutical Report I

US Rheumatologists' View on Biosimilars

Rheumatologists in the US eagerly anticipate biosimilars for pricey anti-TNFs and other biologics used to treat rheumatic diseases but have expressed concern over perceptions of not having full prescribing power. Others say physicians should not be concerned, as they will still have ultimate discretion, and biosimilars will not be used interchangeably.

Experts agreed they are not concerned about biosimilars having unanticipated adverse effects. Their concern lies in the belief that, until biosimilars have entered the market on a large scale, it will be difficult to determine the extent of their bioequivalence.

The PLANETRA study showed there is no justification for physician fears that biosimilars will perform worse than their originator biologic counterparts, said Dr Daniel Furst, director, rheumatology clinical research center, UCLA, Los Angeles, California. The PLANETRA study was a randomized-double-blind parallel group study to demonstrate equivalence in efficacy and safety of CT-P13 to its originator, Horsham, Pennsylvania-based Janssen Biotech's Remicade when co-administered with methotrexate in patients with active rheumatoid arthritis (RA) [Yoo, DH. Annals of the Rheumatic Diseases. 2013 Oct; 72(10):1613-20].

In the study, CT-P13 demonstrated equivalent efficacy to Remicade at week 30 with a comparable pharmacokinetic profile and immunogenicity and comparable safety profile, according to the Journal.

Efficacy more of a concern than safety

More rheumatic disease biosimilars are also coming up for EMA decision in 2H15, including Samsung Bioepis' Remicade biosimilar, SB2, and its biosimilar of Amgen (NASDAQ:AMGN), Pfizer (NYSE:PFE) and Takeda's (TYO:4502) Enbrel (etanercept), SB4, according to company press releases.

SB4 and SB2 both met their primary endpoints in pivotal Phase III studies, demonstrating equivalence to their originators and equivalent safety profiles, according to a 10 June press release.

Substitution concerns

A drug that's exactly the same but less expensive is great as long as the physician gets to decide when to prescribe it, a rheumatologist said. Still, these are theoretical concerns at this point, she said, adding it's a matter of waiting to see how it plays out once biosimilars enter the US market.

Europe has 20 biosimilars on the market, including anti-TNFs, which have had no unexpected adverse effects, said Brenda Huneycutt, director, Avalere's FDA Regulatory, Strategy and Policy Practice.

Despite the PLANETRA study's positive findings for biosimilars, the fear is pharmacies having the power to substitute biologics with biosimilars without appropriate identification, said Furst, noting that would make it impossible to track side effect profiles, should negative side effects arise.

No laws currently exist that allow for automatic substitution of biologics with biosimilars in the pharmacy and, while such a law could theoretically be drafted, it would be shocking, noted Huneycutt. Under the 2009 Biologics Price Competition and Innovation Act (BPCIA), only interchangeable biologics could be substituted at the pharmacy, and the FDA has still not laid out a clear path for having biosimilars approved as interchangeable, Huneycutt explained. To date no biosimilar has been approved as an interchangeable, she added.

Pending legislation in at least 30 states includes provisions that biosimilar manufacturers would also have to apply for interchangeability status--similar to existing legislation for generics--before pharmacy substitution could occur, according to the National Conference of State Legislature.

Ultimately, it's uncertain whether pharmacy interchangeability laws would be enacted at the state or federal level, said Huneycutt.

The rheumatologist agreed that pharmacy substitution at the pharmacist's discretion would be a major concern. Another concern is insurance companies mandating switching patients from biologics to biosimilars or interchangeables

Price reduction similar to Europe anticipated

when patients are doing perfectly well on brand name medication, and that's a major worry that rheumatologists have, she said.

Physicians always have the option of having medications dispensed as written, so the physician still has a level of control, even if interchangeables were approved, explained Huneycutt. Physicians' concerns about interchangeables are not completely unfounded though as, while there should be no clinical difference between a biosimilar and the reference product, it's hard to believe that a product is 100% the same as the originator, she said. Every batch might not be the same, and physicians may have different comfort levels depending on the sensitivity of their patients or the nuances of different indications when it comes to interchangeability, she said.

Oncologists would typically be more open to switching their patients from a biologic to a biosimilar than rheumatologists whose patients have stabilized on a treatment, said Huneycutt. Rheumatologists are likely to try biosimilars on new patients, rather than switching patients who are stabilized on treatment, Huneycutt said.

When generic substitution became commonplace, there were physician concerns that generics were potentially not as good as originator drugs, and biologics raise a similar concern, said Huneycutt.

Anti-TNFs like Remicade are also more complex than granulocyte colony-stimulating factor (G-CSF) analogs like Amgen's (NASDAQ:AMGN) Neuopgen (filgrastim), for which the only biosimilar is approved in the US, making immunogenicity possibly a greater concern for the more complex drug, Huneycutt noted.

Further, the administration of many biologics for rheumatic diseases, for instance infusions, happens in the hospital setting, so the drugs

the hospital has available comes into play, said Huneycutt.

While physicians largely agree that fear surrounding biosimilars is unwarranted, it's hard to know what impacts there might be in terms of immunogenicity, or the ability of a drug to provoke an immune response, until the drugs are out on the market and being used in large populations, explained Jean Sathish, lecturer, molecular and clinical pharmacology, University of Liverpool, UK.

Getting a patient to respond to an anti-TNF, especially for a period of time, is a delicate balance, the rheumatologist explained. If a patient is switched to a biosimilar and does not respond to the biosimilar as well as the originator, and you try to put them back on the original anti-TNF, it might not work for them again, and then you've missed the boat if they don't respond to either, she noted. Still, the perception is that safety issues and immunogenicity are less of a concern than they used to be, said Sathish.

Price and uptake in the US

It's important to remain conservative at the moment while sorting out regulatory issues around biosimilars in the US, but it's a fervent hope that in the long run, there will be RA biosimilars that, when prescribed appropriately, will have a 25-30% cut in cost without any downsides, said Furst.

A 20% savings is likely on US biosimilars, which is not huge, but is a pretty good deal as these biologics are so expensive to start off with and so many people are on anti-TNFs, said Sathish.

It's hard to imagine why there would be uptake for rheumatology biosimilars in the US, especially if there is no automatic substitution at the pharmacy as with small molecules, said Arti Rai, professor of law, Duke Institute for Genome Sciences & Policy, Durham, North Carolina. The price reduction is not dramatic enough, she said, adding that it will also hurt if biosimilars are not approved for all the same indications as their originators.

It's difficult to predict what uptake will look like in the US and the European model is not necessarily the most accurate, explained Sathish. The UK, for instance, has publicly funded healthcare, and will conduct a cost/benefit analysis and view any biosimilar favorably, he said, noting that the US tends to be more individualistic when it comes to healthcare.

It may be a number of years before the US sees major anti-TNF biosimilars approved and launched due to ongoing litigation surrounding the BPCIA, this news service previously reported on 29 May. The Korean manufacturer Celltrion (KOSDAQ: 068270) is attempting to bring Remsima, a Remicade biosimilar, to market, but it could be tangled up in a legal battle with Remicade originator Janssen Biotech until at least 2018, this news service reported. Enbrel, another major anti-TNF, was also given a patent extension of an additional 16 years in the US in 2012. Furst said he is holding out hope for a biosimilar for Biogen's (NASDAQ:BIIB) Rituxan (rituximab) to enter the US market. The patent on Rituxan expires in the US in September 2016. W

Alissa Fleck

Reporter, New York

Alissa is a former freelance editor and journalist who has been a regular contributor for Bankrate, the Huffington Post, Truthout, Global Post and three Straus News publications in Manhattan. She has written medical and health copy for websites including SF Gate (the San Francisco Chronicle online) and Livestrong as well as for private clients.

Biopharmaceutical Report II

Seattle Genetics/Takeda's Adcetris, likely to get label expansion

Seattle Genetics (NASDAQ:SGEN) and Takeda Pharmaceutical's (TYO:4502) Adcetris (brentuximab vedotin) will likely get a Hodgkin's lymphoma (HL) label expansion from the FDA based on results of the AETHERA study, experts said.

The Phase III trial's (NCT01100502) positive results on the primary endpoint of progression-free survival (PFS) in patients who are at high risk of relapse following autologous stem cell transplant (autoSCT) make approval likely, they said. The current practice is not to treat high-risk patients and to wait for them to relapse before receiving allogeneic SCT (alloSCT), some experts said, noting that alloSCT is a difficult procedure to undergo. As such, an expert added, forestalling relapse is valuable for those patients.

Topline results of the study were presented at the American Society of Hematology's (ASH's) 2014 annual meeting in December, and this news service reported 11 September 2014 that AETHERA had potential to expand the Adcetris label in the US and EU.

Seattle Genetics did not respond to requests for comment.

Strong uptake prospects in post-autologous transplant, high-risk patients

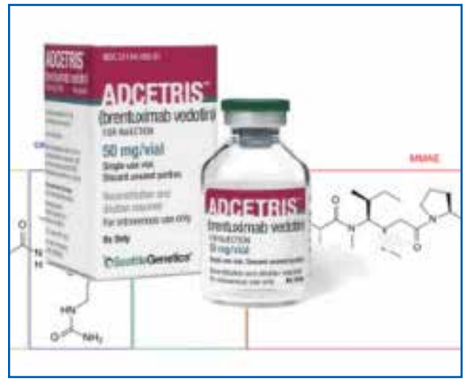
Label expansion likely

The AETHERA data will likely drive an expansion of Adcetris' label in HL to include use in the consolidative setting post-autoSCT and result in widespread use of the drug, said Dr David Peace, professor, medicine, University of Illinois College of Medicine, Chicago; Dr Nam Dang, deputy chief, Division of Hematology and Oncology, University of Florida College of Medicine, Gainesville; and Dr Elizabeth Budde, assistant professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope, Duarte, California. Median PFS by independent review was 43 months for the Adcetris group and 24 months for the placebo group, according to an 18 February Seattle Genetics press release.

The data looks compelling and is likely to lead to FDA approval, said Dr David Aboulafia, section head, Department of Hematology/Oncology, Virginia Mason Clinic, Seattle, Washington. On the other hand, he said,
it raises the question of how to sequence the drug because a lot of the patients get Adcetris before transplant, but for high-risk patients who have not received it pre-transplant, it will likely become a post-transplant maintenance standard of care. This news service reported 11 September 2014 that even if AETHERA was positive for PFS and OS, the results may not apply to patients getting Adcetris in first- or second-line therapy, and while the drug is not routinely used in those settings, that could change going forward. The study excluded patients previously treated with Adcetris, according to ClinicalTrials.gov.

The FDA has accepted Seattle Genetics' sBLA based on the AETHERA data, the company said in a 20 April press release. Currently, the drug has accelerated approval for HL patients after failure of autoSCT or patients who are not autoSCT candidates and have failed at least two prior multi-agent chemotherapy regimens, as well as for systemic anaplastic large-cell lymphoma (ALCL) after failure of at least one multi-agent chemotherapy regimen.

AETHERA enrolled high-risk patients with a high-risk disease, noted Dr Nishitha Reddy, associate professor, medicine, Vanderbilt-Ingram Cancer Center, Nashville, Tennessee. With HL curable in 80-85% of patients, those being taken to transplant represent a small percentage, while those meeting the criteria for high-risk are an even small percentage, maybe 7-8%.



The study included patients considered at high-risk of residual HL post-autoSCT, including 196 refractory to frontline therapy, 107 who had relapsed less than 12 months after frontline therapy and 26 who had relapsed at least 12 months after frontline therapy with extranodal disease, according to published results (Moskowitz, et al. Lancet. 2015 May 9;385(9980):1853-62). The current practice is not to do anything for those patients, and to simply wait until they relapse before giving them allogeneic stem cell transplant (alloSCT), noted Reddy and Budde. Yet, alloSCT after autoSCT is not a trivial procedure and is very hard on patients, they added. Frontline HL treatments include radiation and chemotherapy-combination regimens like doxorubicin/bleomycin/vinblastine/dacarbazine (ABVD) and bleomycin/etoposide/doxorubicin/cyclophosphamide/vincristine/procarbazine

Targeted population small, usually does not receive treatment

(BEACOPP), according to the American Society of Clinical Oncology.

It would be very helpful to be able to delay alloSCT by a couple of years, Reddy said. Watching and waiting after autoSCT without maintenance can be nerve-wracking for patients, so Adcetris maintenance therapy will definitely benefit them, Budde said.

Given Adcetris' extensive use in HL and ALCL and her center's ample experience with the administration and side-effect profile of the drug, Budde said she saw herself giving it widely in the post-autoSCT high-risk setting. Approval in that setting will also likely change practice in the sense that community oncologists will be more comfortable giving the drug, Dang said, explaining that academic oncologists such as he tend to be more liberal in their usage of drugs like Adcetris.

In AETHERA, the most frequent adverse events included peripheral sensory neuropathy and neutropenia, according to the results.

Yet, usage in the community setting may not be so likely because most oncologists who deal with post-transplant relapses are more or less in the academic setting, Reddy said, adding that she did not foresee a huge increase in Adcetris' usage following FDA approval of the label expansion.

AETHERA's lack of OS difference between the arms, could be due to patients in the placebo arm crossing over to receive Adcetris, Dang noted. This news service reported 11 September 2014 that OS improvement may be needed for doctors to use Adcetris in post-transplant maintenance or for the drug to change practice, though HL is a difficult disease in which to show OS benefit. However, commenting on the most recent data, Budde said the goal of post-transplant maintenance is to keep patients in remission, making PFS a more important endpoint.

A pre-specified analysis showed no statistically significant difference in OS between the two arms, according to a 29 September 2014 Seattle Genetics and Takeda press release, but a further analysis for OS is expected in 2016. For the pooled study population at 24 months, the Kaplan-Meier estimate for OS was 88%, according to the ASH abstract (abstract no. 673).

Seattle Genetics' market cap is USD 5.8bn. W

Alaric DeArment
Reporter, New York

Alaric DeArment covers cancer drugs and vaccines for BioPharm Insight. Previously, he was associate editor at Drug Store News, covering retail and specialty pharmacy, pharmaceuticals, biologics and regulatory affairs. A native of Seattle, he graduated with honors with a bachelor degree in journalism from Ball State University and also lived in China from 2001-2004.

Biopharmaceutical Report III

RULES OF COMPETITION

Competing in gene therapy is unlikely to follow the same rules as competing in other therapeutic categories where — even in Orphan diseases — a better product can steal market share. The reason is that if the first gene therapies to market deliver on the promise of a functional cure, there may not be any patients left to treat.
Investors have poured at least $3 billion into 20 companies developing gene therapies for Orphan indications that have one or more competitors working on the same gene — including $1 billion to bluebird bio Inc. alone. Most of these companies have touted potential benefits of their products over more advanced competitors targeting the same genes.

But in Orphan indications, if the first-to-market therapy addresses a large proportion of the prevalent patient population, it could be difficult for followers to even enroll clinical trials. And it is unknown whether the risk of immunogenicity to the vector or the transgene protein product would preclude re-treating patients who received a first-generation product.
"If there is an approved gene therapy that is providing a functional cure, I think it will be hard for some of these companies to enroll trials," Spark Therapeutics Inc. CFO Stephen Webster told BioCentury.

However, when the gene therapy delivers a therapeutic protein that doesn't address the underlying pathology of the disease — and therefore isn't a cure — improvements in efficacy or safety can potentially supplant first-in-class therapies.

And even in Orphan indications, there could be room for followers with new vectors if the first to market uses a vector to which a large enough proportion of the population has a pre- existing, natural immunity.

For companies pursuing larger indications, the rules of competition should be similar to those in other drug classes. Here, followers may be able to compete based on advances in vectors, gene expression levels, gene selection, administration or using more advanced technologies like CRISPR.
The 30
gene therapy companies that are focused on large indications have received at least $3 billion since inception.

WINNER TAKES ALL?

Most gene therapy companies have shied away from competing with each other in Orphan diseases. According to BioCentury's BCIQ database, out of 166 gene therapy products in development, 133 (80%) are being developed for indications where there is no competition, are using different genes than competitors for the same indication, or are intended for a patient population large enough to support multiple players.

The other 33 products (20%), however, are in competitive Orphan indications (see "Crowding the Gene Pool").
According to Venrock's Bong Koh, whether a second-in-class gene therapy will have a market will likely depend on how big a head start the first-in-class product has.
"How quickly can you rapidly identify and penetrate the patients and cure them? My guess is if you have a one-year lead, it probably doesn't mean all that much. But on the other end of the spectrum a 10-year lead probably means a lot," said Koh.
He added that for indications where there is a rapid decay due to disease, such as in spinal muscular atrophy (SMA), penetration is likely to be faster, potentially leaving a smaller opportunity for follow-on therapies.
Koh has invested in four gene therapy companies, of which three have a chance at being first to market or are working in indications with room for competition: Audentes Therapeutics Inc., AveXis Inc. and RegenxBio Inc.

Audentes' lead program is AT001, an adeno-associated viral serotype 8 (AAV8) vector encoding the myotubularin 1 (MTM1) gene that is in preclinical testing to treat X-linked myotubular myopathy. AveXis has chariSMA, a self-complementary AAV9 vector encoding the survival motor neuron (SMN) gene that is in Phase I testing for SMA. RegenxBio's lead program is RGX- 501, an AAV8 vector encoding the low-density lipoprotein receptor (LDLR) that is expected to enter the clinic in 1H16 to treat homozygous familial hypercholesterolemia (HoFH).
Koh's fourth investment, Celladon Corp., was working in heart failure but has ceased R&D and is looking to sell itself or its assets, including Mydicar gene therapy, which failed a Phase IIb trial in April.
Venrock's one gene therapy investment that is in a competitive Orphan indication is Avalanche Biotechnologies Inc. The biotech's AVA-311, an optimized AAV that encodes the retinoschisis X-linked juvenile 1 (RS1; XLRS1) gene, is in preclinical development to treat X-linked juvenile retinoschisis and is partnered with Regeneron Pharmaceuticals Inc. Applied Genetic Technologies Corp. (AGTC) is ahead with its XLRS, a recombinant AAV encoding RS1 that is in a Phase I/II trial for the indication.
Koh wouldn't discuss how Avalanche might compete as a follow-on gene therapy in X-linked juvenile retinoschisis. However, the biotech's lead program is AVA-101, an AAV that encodes soluble VEGF receptor 1 (sFLT1; sVEGFR-1). The product has completed a Phase IIa trial for wet age-related macular degeneration (AMD) and is in preclinical testing for diabetic macular edema (DME) and retinal vein occlusion (RVO).

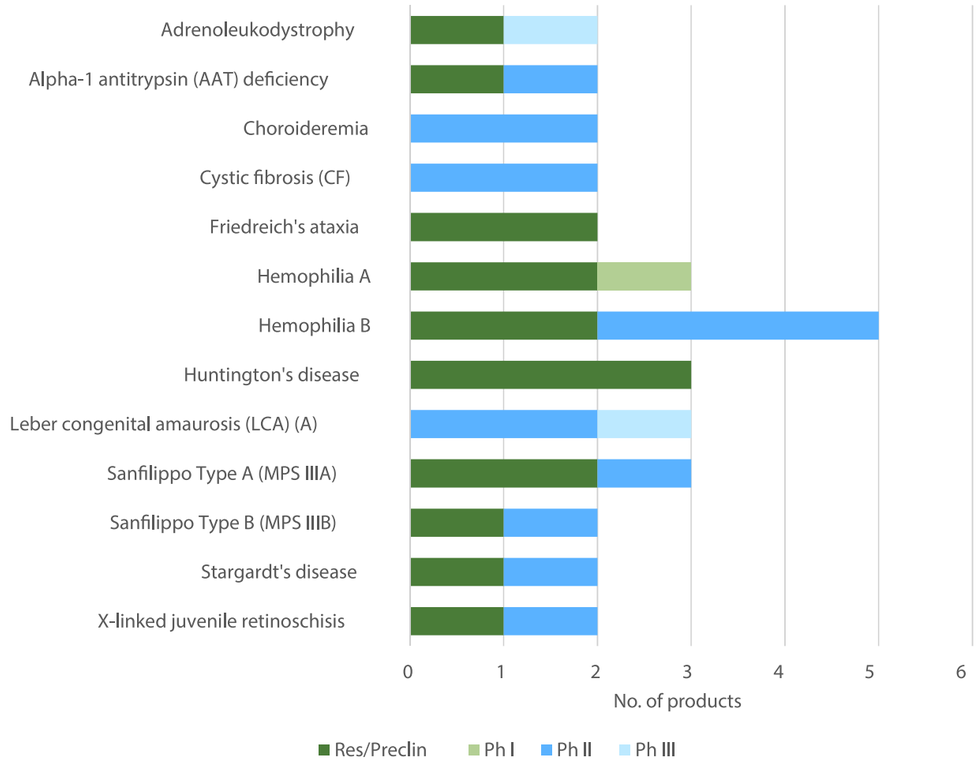
UNKNOWN TERRITORY

While second-to-market drugs in other therapeutic modalities might hope to treat patients who had failed the first-generation drug, it isn't clear whether that will be possible with gene therapies.
According to Webster, Spark has decided not to test re-dosing patients with its gene therapies due to the risk of an immune response against the protein product expressed by the transgene.
"The fear scientifically is that if there is an immune response to the second dose, you could lose the benefit that the first dose conferred," he said.

However, AGTC President and CEO Sue Washer said the risk of immunogenicity in re-treating human patients is actually unknown, and concerns are primarily derived from non-human primate studies, not clinical trials.
Still, until more data are gathered on the risks of immunogenicity, follow-on therapies may be limited to gene therapy-naïve patients.
Webster added that patients may be reluctant to enroll in a clinical trial of a new gene therapy if the risk of immunogenicity might preclude them from being re-treated with an approved gene therapy.
"The informed consent for that will be brutal," he said. "Who is going to volunteer for a clinical trial? Why would you chance an experimental therapy that may or may not be marginally better instead of receiving one that is approved?"
Most gene therapy company executives who spoke to BioCentury said they think an improved duration of response compared with a more advanced product could allow a follower to compete. However, if the first product to market has a long enough head start and a duration of response lasting several years — even if not a lifetime — demonstrating an improvement could be a practical impossibility.
uniQure N.V. CEO Jörn Aldag noted his company's lipoprotein lipase deficiency product Glybera alipogene tiparvovec has demonstrated a duration of response of five years — so far. By the time another company could generate five years of response data, "we may have shown a benefit that lasts 10 years. So you haven't proven anything if you wait five years
in your clinical trial. Proving superior durability of response will be very difficult,"Aldagsaid.

CROWDING THE GENE POOL

There are 33 gene therapy products being developed in Orphan indications where there is more than one competitor developing a therapy encoding the same gene. The most competitive indication is hemophilia B, with five candidates targeting the Factor IX gene. (A) Only gene therapies encoding the RPE65 gene; Source: BCIQ: BioCentury Online Intelligence



THE LCA EXAMPLE

Of course, in some Orphan indications, the competition may shake itself out before any products get to market due to natural attrition, or as companies reprioritize their investments.
The latter appears to be the case in Leber congenital amaurosis (LCA), a form of retinitis pigmentosa that has about 3,500 patients in the U.S. and Europe. Three gene therapies that express the retinal pigment epithelium- specific protein 65kDa (RPE65) gene have been in development for the indication.
Spark's SPK-RPE65, an AAV2 encoding RPE65, is in Phase III testing to treat LCA, with data expected this year.

The other two completed Phase I/II trials, but neither is in active development: rAAV2-CB-rhRPE65 from AGTC and HORA-RPE65 from Horama S.A.S.
According to Washer, AGTC decided to discontinue its product based on a combination of factors, including the ultra-Orphan nature of the indication, difficulties in identifying patients and the degenerative nature of the disease pathology.

"We decided there were other ophthalmic diseases better suited for us to pursue even before Spark existed as a company," she said.

Horama, however, decided to deprioritize its RPE65 product because Spark was so much further ahead. Horama is seeking a development partner for HORA-RPE65 and is instead focusing its internal efforts on two ophthalmic gene therapies that have no competitors.
Spark's co-founder, President and CSO Katherine High noted, "The question I'm wondering about is if there are over 200 genes involved in vision and many of them fit into an AAV vector, why would someone go after something where somebody else already had a product in Phase III?"
Koh agreed. "You have to ask yourself how big is LCA really? My understanding is other gene therapy companies have looked at that indication and passed on it because of its size," he said.
He added that with 7,000 rare diseases, small gene therapy plays may be better off focusing on untapped indications.

ROOM TO IMPROVE

In some indications a gene therapy might provide a significant benefit to patients but not a functional cure, potentially leaving room for follow-on therapies to provide improved efficacy.
Hemophilia B, the most competitive of the Orphan diseases for gene therapy, may be an example. The less common of the two forms of hemophilia has a prevalence of about 4,000 patients in the U.S. and 80,000 worldwide.
There are at least six companies and one academic group developing gene therapies for hemophilia B. Three compounds are either in or about to start Phase I/II testing: Baxalta Inc.'s BAX 335, Spark and Pfizer Inc.'s SPK-FIX and uniQure's AMT-060.
St. Jude Children's Research Hospital and University College London have scAAV2/8-LP1-hFIXco in a Phase I trial. Two others are in preclinical development, including DTX101 from Dimension Therapeutics Inc. and Sangamo BioSciences Inc.'s zinc finger DNA-binding protein nuclease (ZFN) therapeutic.
Despite the small patient population, given differences in the degrees of efficacy that could be attained in hemophilia, executives felt it could be possible for a follower to replace a first-in-class product. Whether there would be a large enough patient population left to provide a return on investment for a follow-on gene therapy would depend on the uptake of the first-in-class therapy.
Increased efficacy is part of the rationale behind Spark's decision to use the Padua variant of Factor IX in its SPK-FIX therapy. The variant has 5-10 times the activity of wild-type Factor IX, meaning a similar expression level of the gene variant could significantly improve efficacy.
According to High, 5% expression levels would convert severe hemophilia to mild hemophilia, which would provide a benefit to patients. Expression levels close to 50% would bring a patient within the normal limits for Factor IX expression. But High noted it's not clear how much of a gain within the 5-50% range would be meaningful.
"Is 10% expression clinically better than 5%? That would be debatable," she said.
There are other indications where there could be an opportunity to meaningfully improve efficacy. The question is whether it would be as straightforward to demonstrate efficacy in those

indications as it is in hemophilia, where clotting factor is easy to measure.

For example, in retinopathies, companies can't simply measure expression levels of the protein of interest. "You have to look at downstream effects of it on various visual and retinal functional measures," said High.
Koh said he expects there will be both big and small indications where better expression or better vectors will make a difference for follow-on gene therapies. But he added, "there are going to be quite a few indications where it just doesn't matter. The expression the first product has is good enough and provides a functional cure, and whatever sort of side effects exist are just going to be well managed."

DIFFERENTIATING FACTORS

Development of non-immunogenic vectors could allow follow-on therapies to gain market share in either large or Orphan indications. Many patients have a natural, pre-existing immunity to some of the most common AAV vectors. For instance, Aldag said as much as 40% of the population has a natural immunity against AAV8, and patients can be screened for the presence of neutralizing antibodies against a relevant AAV serotype.
In that example, if the first product to market uses an AAV8 vector, a sizable portion of the patient population would be ineligible for treatment, and better suited for a lentiviral vector or an AAV with lower rates of pre- existing immunity.
"If someone comes to market first with an AAV8 hemophilia product, there is still a significant market left for someone with an AAV5 for example," Aldag said.
Both Spark's AAV8-hFIX19 and Baxalta's BAX 335 use an AAV8 vector. uniQure's AMT-060 uses an AAV5 vector.
Oxford BioMedica plc CEO John Dawson agreed, noting that lentiviral vector-based gene therapies would provide a potential alternative for patients with pre-existing immunity to AAV vectors.
However, such opportunities would likely be limited to diseases where there is systemic exposure to the gene therapy. High noted pre-existing immunity against AAV is less of a concern in ophthalmology, because the eye is immuno-privileged.

"IF THERE IS AN APPROVED GENE THERAPY THAT IS PROVIDING A FUNCTIONAL CURE, I THINK IT WILL BE HARD FOR SOME OF THESE COMPANIES TO ENROLL TRIALS."
STEPHEN WEBSTER, SPARK THERAPEUTICS

DIVIDE AND CONQUER

In larger indications like congestive heart failure (CHF) or Parkinson's disease (PD), companies see enough patients to support multiple gene therapies and expect the competitive paradigm would be similar to other therapeutic categories.
Thus technologies that increase efficacy, such as self-complementary transgenes that have higher expression profiles, or approaches that improve safety, such as vectors that can better target the tissue of interest, could provide differentiation for a follow-on product.
These large indications are also typically diseases in which gene therapies are used as delivery vehicles for a protein product that may provide a clinical benefit but does not address the underlying pathology of disease and therefore does not represent a cure.
For instance, in Parkinson's there are at least five companies working on gene therapies that aim to stimulate the production of dopamine or other neurotrophic factors.
Wet AMD is another crowded indication, with seven companies developing gene therapies that encode a VEGF inhibitor or some other anti-angiogenic protein.
Both diseases have populations estimated at more than 1 million patients in the U.S. alone.

"PROVING SUPERIOR DURABILITY OF RESPONSE WILL BE VERY DIFFICULT."
JÖRN ALDAG, UNIQURE

BEYOND 'FUNCTIONAL'

In the long term, most gene therapy companies said they were looking beyond the current generation of gene therapy — in which a functional gene is simply added to the cell alongside the mutated gene — to gene editing technologies like CRISPR that could instead repair the endogenous gene.
According to Fulvio Mavilio, scientific director at Genethon, the next wave of gene therapies will be the in vivo application of gene editing technologies. "Gene editing is the next generation, because we don't add things, we fix things," he said.
Genethon's lead gene therapy uses autologous CD34-positive cells transduced with a lentiviral vector encoding human Wiskott-Aldrich syndrome gene to treat Wiskott-Aldrich syndrome.
The next wave may be coming sooner than most expected. While gene editing technologies are already in man in ex vivo settings such as in CAR T cell therapies, the problem for in vivo applications has typically been that the CRISPR construct has been too large to fit into a delivery vector.
Abeona Therapeutics Inc. CEO Tim Miller said his company is working on a modified CRISPR construct that can be delivered using an AAV vector, and the company expects to complete preclinical proof-of-concept studies within the next year.
Miller said the AAV-delivered CRISPR program will first target the rare blood disorder Fanconi anemia.

Stephen Hansen
Associate Editor, BioCentury

COMPANIES AND INSTITUTIONS MENTIONED

Abeona Therapeutics Inc. (NASDAQ:ABEO), Dallas, Texas
Applied Genetic Technologies Corp. (NASDAQ:AGTC), Alachua, Fla.
Audentes Therapeutics Inc., San Francisco, Calif.
Avalanche Biotechnologies Inc. (NASDAQ:AAVL), Menlo Park, Calif.
AveXis Inc., Dallas, Texas
Baxalta Inc. (NYSE:BXLT), Deerfield, Ill.
bluebird bio Inc. (NASDAQ:BLUE), Cambridge, Mass.
Celladon Corp. (NASDAQ:CLDN), San Diego, Calif.
Dimension Therapeutics Inc., Cambridge, Mass.
Genethon, Evry, France
Horama S.A.S., Paris, France
Oxford BioMedica plc (LSE:OXB), Oxford, U.K.
Pfizer Inc. (NYSE:PFE), New York, N.Y.
Regeneron Pharmaceuticals Inc. (NASDAQ:REGN), Tarrytown, N.Y.
RegenxBio Inc., Washington, D.C.
Sangamo BioSciences Inc. (NASDAQ:SGMO), Richmond, Calif.
Spark Therapeutics Inc. (NASDAQ:ONCE), Philadelphia, Pa.
St. Jude Children's Research Hospital, Memphis, Tenn.
uniQure N.V. (NASDAQ:QURE), Amsterdam, the Netherlands University College London, London, U.K.

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UNITED KINGDOM +44 (0)1865-512184; Fax: +1 650-595-5589

Not an actual patient, but is representative of a real patient type. Models are used for illustrative purposes only.

IN THE TREATMENT OF CHRONIC HEPATITIS B (CHB) IN ADULTS WITH COMPENSATED LIVER DISEASE

TAKE A CLOSER LOOK AT LAMIVUDINE (LAM) RESISTANCE

MORE THAN 50% of Americans living with CHB are Asian and Pacific Islanders[1]

NEARLY 70% of Asian Americans were born or have parents born in countries where CHB is common[1]

70% of patients receiving lamivudine develop resistance at 5 years[2]

2% of patients in the United States use lamivudine; **up to 88%** in Asia[3]

Indication and Usage

VIREAD® (tenofovir disoproxil fumarate) is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older.

The following points should be considered when initiating therapy with VIREAD for the treatment of HBV infection:

- The indication in adults is based on data from treatment of subjects who were nucleoside–treatment-naïve and treatment-experienced with documented resistance to lamivudine. Subjects were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease
- VIREAD was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease
- The numbers of subjects in clinical trials who had adefovir resistance-associated substitutions at baseline were too small to reach conclusions of efficacy

Important Safety Information

BOXED WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals**
- **Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted**

Warnings and Precautions

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of VIREAD. In all patients, assess estimated creatinine clearance (CrCl) prior to initiating and during therapy. In patients at risk for renal dysfunction, including those who previously experienced renal events while receiving adefovir dipivoxil, additionally monitor serum phosphorus, urine glucose, and urine protein. In patients with CrCl <50 mL/min, adjust dosing interval and closely monitor renal function. Avoid concurrent or recent use with a nephrotoxic agent. Cases of acute renal failure, some requiring hospitalization and renal replacement therapy, have been reported after initiation of high dose or multiple NSAIDs in HIV-infected patients with risk factors for renal dysfunction; consider alternatives to NSAIDs in these patients. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function
- **Coadministration with other products:**
  - Do not use in combination with other products containing tenofovir disoproxil fumarate
  - Do not administer in combination with adefovir dipivoxil
- **Patients coinfected with HIV-1 and HBV:** Due to the risk of development of HIV-1 resistance, VIREAD should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with VIREAD
- **Bone effects:** Decreases in bone mineral density (BMD) and mineralization defects, including osteomalacia, have been seen in patients treated with VIREAD. Consider assessment of BMD in adult and pediatric patients who have a history of pathologic bone fracture or other risk factors for bone loss. In a clinical trial conducted in pediatric subjects 12 to <18 years of age with chronic hepatitis B, total body BMD gain was less in VIREAD-treated subjects as compared to the control group. In patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms, hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered

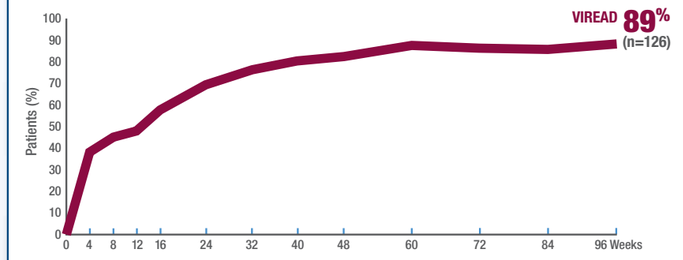
Adverse Reactions

- **In HBV-infected subjects with compensated liver disease:** Most common adverse reaction (all grades) was nausea (9%). Other treatment-emergent adverse reactions reported in >5% of patients treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash

TAKE A CLOSER LOOK AT VIREAD

LAM-resistant VIREAD patients (Study 121)

achieving viral suppression (HBV DNA <400 copies/mL) at 96 weeks of treatment[4,5]



Study 121 was a randomized, double-blind, active-controlled 96-week trial evaluating the safety and efficacy of VIREAD (n=141) compared to an unapproved antiviral regimen (n=139) in subjects with CHB, persistent viremia (HBV DNA ≥1000 IU/mL), and genotypic evidence of LAM resistance. The primary endpoint in Study 121 was HBV DNA <400 copies/mL (69 IU/mL) at Week 96.[4,5]

- As a secondary endpoint, **no HBV resistance (0%)** was detected at **96 weeks** in CHB patients with LAM resistance[4]

Important Safety Information (cont'd)

- **In HBV-infected subjects with decompensated liver disease:** Most common adverse reactions (all grades) reported in ≥10% of patients treated with VIREAD were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%)

Drug Interactions

- **Didanosine:** Coadministration increases didanosine concentrations. Use with caution and monitor for evidence of didanosine toxicity (e.g., pancreatitis, neuropathy). Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD and in patients weighing <60kg, the didanosine dose should be reduced to 200 mg once daily when coadministered with VIREAD
- **HIV-1 protease inhibitors:** Coadministration decreases atazanavir concentrations and increases tenofovir concentrations; use atazanavir given with ritonavir. Coadministration of VIREAD with atazanavir and ritonavir, darunavir and ritonavir, or lopinavir/ritonavir increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity
- **Drugs affecting renal function:** Coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir

Dosage and Administration

- Recommended dose, in adults and pediatric patients ≥12 years of age (≥35 kg), for the treatment of chronic hepatitis B: one 300 mg tablet, once daily, taken orally, without regard to food
- In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown
- Safety and efficacy in pediatric patients <12 years of age or weighing <35kg with chronic hepatitis B have not been established
- The dosing interval of VIREAD should be adjusted (using recommendations in the table below) and renal function closely monitored in patients with baseline creatinine clearance <50 mL/min

Dosage Adjustment for Patients with Altered Creatinine Clearance

	Creatinine clearance (mL/min)[a]			Hemodialysis patients
	≥50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis[b]

[a]Calculated using ideal (lean) body weight.

[b]Generally once weekly assuming three hemodialysis sessions a week of approximately 4 hours duration. VIREAD should be administered following completion of dialysis.

- The pharmacokinetics of tenofovir have not been evaluated in non-hemodialysis patients with creatinine clearance <10 mL/min; therefore, no dosing recommendation is available for these patients
- No dose adjustment is necessary for patients with mild renal impairment (creatinine clearance 50-80 mL/min). Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein should be performed in these patients
- No data are available to make dose recommendations in pediatric patients with renal impairment

Please see Brief Summary of full Prescribing Information, including **BOXED WARNING**, on the adjacent pages.

References: 1. CDC Web site. CDC Features-August 2011: Chronic hepatitis B and Asian & Pacific Islanders. Centers for Disease Control and Prevention. http://www.cdc.gov/Features/ChronicHepatitisB/. Accessed June 26, 2013. **2.** European Association for the Study of the Liver. EASL Clinical Practice Guidelines: Management of chronic hepatitis B virus infection. *J Hepatol.* 2012;57:167-185. **3.** Data on file, Gilead Sciences, Inc. Gilead HBV LAM assessment, IMS MIDAS data. May 2013. **4.** Data on file, Gilead Sciences, Inc. 0121 CSR. **5.** VIREAD Prescribing Information, Foster City, CA: Gilead Sciences, Inc.; October 2013.

300mg tablets®
Viread®
tenofovir disoproxil fumarate

VIREAD® (tenofovir disoproxil fumarate) tablets

Brief summary of full Prescribing Information. Please see full Prescribing Information including Boxed WARNING. Rx only

WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS

- **Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals *(See Warnings and Precautions)***
- **Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including VIREAD. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VIREAD. If appropriate, resumption of anti-hepatitis B therapy may be warranted *(See Warnings and Precautions)***

INDICATIONS AND USAGE: VIREAD is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older

The following points should be considered when initiating therapy with VIREAD for the treatment of HBV infection:

- The indication in adults is based on safety and efficacy data from treatment of subjects who were nucleoside-treatment-naïve and subjects who were treatment-experienced with documented resistance to lamivudine. Subjects were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease *(See Adverse Reactions)*
- VIREAD was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease *(See Adverse Reactions)*
- The numbers of subjects in clinical trials who had adefovir resistance-associated substitutions at baseline were too small to reach conclusions of efficacy

DOSAGE AND ADMINISTRATION: For the treatment of chronic hepatitis B the recommended dose, in adults and pediatric patients ≥12 years of age (≥35 kg), is one 300 mg tablet, once daily, taken orally, without regard to food. In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown. Safety and efficacy in pediatric patients <12 years of age with chronic hepatitis B weighing <35 kg have not been established. **Dose Adjustment for Renal Impairment in Adults:** Significantly increased drug exposures occurred when VIREAD was administered to subjects with moderate to severe renal impairment. Therefore, the dosing interval of VIREAD tablets 300 mg should be adjusted in patients with baseline creatinine clearance <50 mL/min using the recommendations in Table 1. These dosing interval recommendations are based on modeling of single-dose pharmacokinetic data in non-HIV and non-HBV infected subjects with varying degrees of renal impairment, including end-stage renal disease (ESRD) requiring hemodialysis. The safety and effectiveness of these dosing interval adjustment recommendations have not been clinically evaluated in patients with moderate or severe renal impairment, therefore clinical response to treatment and renal function should be closely monitored in these patients *(See Warnings and Precautions)*. No dose adjustment of VIREAD tablets 300 mg is necessary for patients with mild renal impairment (creatinine clearance 50–80 mL/min). Routine monitoring of estimated creatinine clearance, serum phosphorus, urine glucose and urine protein should be performed in patients with mild renal impairment *(See Warnings and Precautions)*.

Dosage Adjustment for Adult Patients with Altered Creatinine Clearance

	Creatinine clearance (mL/min)[a]			Hemodialysis patients
	≥50	30-49	10-29	
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72 to 96 hours	Every 7 days or after a total of approximately 12 hours of dialysis[b]

a. Calculated using ideal (lean) body weight.
b. Generally once weekly assuming three hemodialysis sessions a week of approximately 4 hours duration. VIREAD should be administered following completion of dialysis.

The pharmacokinetics of tenofovir have not been evaluated in non-hemodialysis patients with creatinine clearance <10 mL/min; therefore, no dosing recommendation is available for these patients. No data are available to make dose recommendations in pediatric patients with renal impairment.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS: Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with VIREAD should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations). **Exacerbation of Hepatitis after Discontinuation of Treatment:** Discontinuation of anti-HBV therapy, including VIREAD, may be associated with severe acute exacerbations of hepatitis. Patients infected with HBV who discontinue VIREAD should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, resumption of anti-hepatitis B therapy may be warranted. **New Onset or Worsening Renal Impairment:** Tenofovir is principally eliminated by the kidney. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of VIREAD *(See Adverse Reactions)*. It is recommended that estimated creatinine clearance be assessed in all patients prior to initiating therapy and as clinically appropriate during therapy with VIREAD. In patients at risk of renal dysfunction, including patients who have previously experienced renal events while receiving adefovir dipivoxil , it is recommended that estimated creatinine clearance, serum phosphorus, urine glucose, and urine protein be assessed prior to initiation of VIREAD, and periodically during VIREAD therapy. Dosing interval adjustment of VIREAD and close monitoring of renal function are recommended in all patients with creatinine clearance <50 mL/min *(See Dosage and Administration)*. No safety or efficacy data are available in patients with renal impairment who received VIREAD using these dosing guidelines, so the potential benefit of VIREAD therapy should be assessed against the potential risk of renal toxicity. VIREAD should be avoided with concurrent or recent use of a nephrotoxic agent (e.g., high-dose or multiple non-steroidal anti-inflammatory drugs (NSAIDs)) *(See Drug Interactions)*. Cases of acute renal failure after initiation of high dose or multiple NSAIDs have been reported in HIV-infected patients with risk factors for renal dysfunction who appeared stable on tenofovir DF. Some patients required hospitalization and renal replacement therapy. Alternatives to NSAIDs should be considered, if needed, in patients at risk for renal dysfunction. Persistent or worsening bone pain, pain in extremities, fractures and/or muscular pain or weakness may be manifestations of proximal renal tubulopathy and should prompt an evaluation of renal function in at-risk patients. **Coadministration with Other Products:** VIREAD should not be used in combination with the fixed-dose combination products ATRIPLA®, COMPLERA®, STRIBILD® or TRUVADA® since tenofovir disoproxil fumarate is a component of these products. VIREAD should not be administered in combination with adefovir dipivoxil *(See Drug Interactions)*. **Patients Coinfected with HIV-1 and HBV:** Due to the risk of development of HIV-1 resistance, VIREAD should only be used in HIV-1 and HBV coinfected patients as part of an appropriate antiretroviral combination regimen. HIV-1 antibody testing should be offered to all HBV-infected patients before initiating therapy with VIREAD. It is also recommended that all patients with HIV-1 be tested for the presence of chronic hepatitis B before initiating treatment with VIREAD.

Bone Effects

Bone Mineral Density: In clinical trials in HIV-1 infected adults, VIREAD was associated with slightly greater decreases in bone mineral density (BMD) and increases in biochemical markers of bone metabolism, suggesting increased bone turnover relative to comparators. Serum parathyroid hormone levels and 1,25 Vitamin D levels were also higher in subjects receiving VIREAD *(See Adverse Reactions)*.

Clinical trials evaluating VIREAD in pediatric and adolescent subjects were conducted. Under normal circumstances, BMD increases rapidly in pediatric patients. In HIV-1 infected subjects aged 2 years to less than 18 years, bone effects were similar to those observed in adult subjects and suggest increased bone turnover. Total body BMD gain was less in the VIREAD-treated HIV-1 infected pediatric subjects as compared to the control groups. Similar trends were observed in chronic hepatitis B infected adolescent subjects aged 12 years to less than 18 years. In all pediatric trials, skeletal growth (height) appeared to be unaffected *(See Adverse Reactions)*.

The effects of VIREAD-associated changes in BMD and biochemical markers on long-term bone health and future fracture risk are unknown. Assessment of BMD should be considered for adults and pediatric patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Although the effect of supplementation with calcium and vitamin D was not studied, such supplementation may be beneficial for all patients. If bone abnormalities are suspected then appropriate consultation should be obtained.

Mineralization Defects: Cases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to fractures, have been reported in association with the use of VIREAD *(See Adverse Reactions)*. Arthralgias and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy. Hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms while receiving products containing tenofovir DF *(See Warnings and Precautions)*.

ADVERSE REACTIONS: Clinical Trials in Adult Subjects with Chronic Hepatitis B and Compensated Liver Disease: *Treatment-Emergent Adverse Reactions:* In controlled clinical trials in subjects with chronic hepatitis B (0102 and 0103), more subjects treated with VIREAD during the 48-week double-blind period experienced nausea: 9% with VIREAD versus 2% with adefovir dipivoxil. Other treatment-emergent adverse reactions reported in >5% of subjects treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash. No significant change in the tolerability profile was observed with continued treatment with VIREAD for up to 240 weeks.

Laboratory Abnormalities: in Studies 0102 and 0103 (0–48 Weeks) laboratory

Brief Summary (cont'd)

abnormalities (Grades 3–4) reported in ≥1% of subjects treated with Viread (n=426) and adefovir dipivoxil (n=215), respectively, were: any ≥Grade 3 laboratory abnormality (19%, 13%); creatine kinase (M: >990 U/L; F: >845 U/L) (2%, 3%); serum amylase (>175 U/L) (4%, 1%); glycosuria (≥3+) (3%, <1%); AST (M: >180 U/L; F: >170 U/L) (4%, 4%); and ALT (M: >215 U/L; F: >170 U/L) (10%, 6%). Laboratory abnormalities (Grades 3–4) were similar in subjects continuing VIREAD treatment for up to 240 weeks in these trials.

The overall incidence of on-treatment ALT flares (defined as serum ALT >2 × baseline and >10 × ULN, with or without associated symptoms) was similar between VIREAD (2.6%) and adefovir dipivoxil (2%). ALT flares generally occurred within the first 4-8 weeks of treatment and were accompanied by decreases in HBV DNA levels. No subject had evidence of decompensation. ALT flares typically resolved within 4-8 weeks without changes in study medication. The adverse reactions observed in subjects with chronic hepatitis B and lamivudine resistance who received treatment with VIREAD were consistent with those observed in other hepatitis B clinical trials in adults. *Clinical Trial in Adult Subjects with Chronic Hepatitis B and Decompensated Liver Disease:* In a small randomized, double-blind, active-controlled trial (0108), subjects with CHB and decompensated liver disease received treatment with VIREAD or other antiviral drugs for up to 48 weeks. Among the 45 subjects receiving VIREAD, the most frequently reported treatment-emergent adverse reactions of any severity were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%). Two of 45 (4%) subjects died through Week 48 of the trial due to progression of liver disease. Three of 45 (7%) subjects discontinued treatment due to an adverse event. Four of 45 (9%) subjects experienced a confirmed increase in serum creatinine of 0.5 mg/dL (1 subject also had a confirmed serum phosphorus <2 mg/dL through Week 48). Three of these subjects (each of whom had a Child-Pugh score ≥10 and MELD score ≥14 at entry) developed renal failure. Because both VIREAD and decompensated liver disease may have an impact on renal function, the contribution of VIREAD to renal impairment in this population is difficult to ascertain. One of 45 subjects experienced an on-treatment hepatic flare during the 48 week trial.

Clinical Trials in Pediatric Subjects 12 Years of Age and Older with Chronic Hepatitis B: Assessment of adverse reactions is based on one randomized study (0115) in 106 pediatric subjects (12 to less than 18 years of age) infected with chronic hepatitis B receiving treatment with VIREAD (N = 52) or placebo (N = 54) for 72 weeks. The adverse reactions observed in pediatric subjects who received treatment with VIREAD were consistent with those observed in clinical trials of VIREAD in adults. In this study, both the VIREAD and placebo treatment arms experienced an overall increase in mean lumbar spine BMD over 72 weeks, as expected for an adolescent population. The BMD gains from baseline to Week 72 in lumbar spine and total body BMD in VIREAD-treated subjects (+5% and +3%, respectively) were less than the BMD gains observed in placebo-treated subjects (+8% and +5%, respectively). Three subjects in the VIREAD group and two subjects in the placebo group had significant (greater than 4%) lumbar spine BMD loss at Week 72. At baseline, mean BMD Z-scores in subjects randomized to VIREAD were −0.43 for lumbar spine and −0.20 for total body, and mean BMD Z-scores in subjects randomized to placebo were −0.28 for lumbar spine and −0.26 for total body. In subjects receiving VIREAD for 72 weeks, the mean change in BMD Z-score was −0.05 for lumbar spine and −0.15 for total body compared to +0.07 and +0.06, respectively, in subjects receiving placebo. As observed in pediatric studies of HIV-infected patients, skeletal growth (height) appeared to be unaffected *(See Warnings and Precautions)*.

Postmarketing Experience: The following adverse reactions have been identified during postapproval use of VIREAD. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: allergic reaction, including angioedema, lactic acidosis, hypokalemia, hypophosphatemia, dyspnea, pancreatitis, increased amylase, abdominal pain, hepatic steatosis, hepatitis, increased liver enzymes (most commonly AST, ALT gamma GT), rash, rhabdomyolysis, osteomalacia (manifested as bone pain and which may contribute to fractures), muscular weakness, myopathy, acute renal failure, renal failure, acute tubular necrosis, Fanconi syndrome, proximal renal tubulopathy, interstitial nephritis (including acute cases), nephrogenic diabetes insipidus, renal insufficiency, increased creatinine, proteinuria, polyuria, asthenia. The following adverse reactions listed above, may occur as a consequence of proximal renal tubulopathy: rhabdomyolysis, osteomalacia, hypokalemia, muscular weakness, myopathy, hypophosphatemia.

DRUG INTERACTIONS: Didanosine: Coadministration of VIREAD and didanosine should be undertaken with caution and patients receiving this combination should be monitored closely for didanosine-associated adverse reactions. Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. When administered with VIREAD, C_{max} and AUC of didanosine increased significantly. The mechanism of this interaction is unknown. Higher didanosine concentrations could potentiate didanosine-associated adverse reactions, including pancreatitis and neuropathy. Suppression of $CD4^+$ cell counts has been observed in patients receiving VIREAD with didanosine 400 mg daily. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD. In patients weighing <60 kg, the didanosine dose should be reduced to 200 mg once daily when it is coadministered with VIREAD. When coadministered, VIREAD and didanosine EC may be taken under fasted conditions or with a light meal (<400 kcal, 20% fat). For additional information on coadministration of VIREAD and didanosine, please refer to the full Prescribing Information for didanosine.

HIV-1 Protease Inhibitors: VIREAD decreases the AUC and C_{min} of atazanavir. Viread should not be coadministered with atazanavir without ritonavir. Lopinavir/ritonavir, atazanavir coadministered with ritonavir, and darunavir coadministered with ritonavir have been shown to increase tenofovir concentrations. Tenofovir disoproxil fumarate is a substrate of P-glycoprotein (Pgp) and breast cancer resistance protein (BCRP) transporters. When tenofovir disoproxil fumarate is co-administered with an inhibitor of these transporters, an increase in absorption may be observed. Patients receiving VIREAD concomitantly with lopinavir/ritonavir, ritonavir-boosted atazanavir, or ritonavir-boosted darunavir should be monitored for VIREAD-associated adverse reactions. VIREAD should be discontinued in patients who develop VIREAD-associated adverse reactions. **Drugs Affecting Renal Function:** Since tenofovir is primarily eliminated by the kidneys, coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of tenofovir and/or increase the concentrations of other renally eliminated drugs. Some examples include, but are not limited to cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides (e.g., gentamicin), and high-dose or multiple NSAIDs *(See Warnings and Precautions)*. In the treatment of chronic hepatitis B, VIREAD should not be administered in combination with adefovir dipivoxil.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category B:* There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, VIREAD should be used during pregnancy only if clearly needed. *Antiretroviral Pregnancy Registry:* To monitor fetal outcomes of pregnant women exposed to VIREAD, an Antiretroviral Pregnancy Registry has been established. Healthcare providers are encouraged to register patients by calling 1-800-258-4263. *Animal Data:* Reproduction studies have been performed in rats and rabbits at doses up to 14 and 19 times the human dose based on body surface area comparisons and revealed no evidence of impaired fertility or harm to the fetus due to tenofovir. **Nursing Mothers: The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers not breast-feed their infants to avoid risking postnatal transmission of HIV-1.** Samples of breast milk obtained from five HIV-1 infected mothers in the first post-partum week show that tenofovir is secreted in human milk. The impact of this exposure in breastfed infants is unknown. Because of both the potential for HIV-1 transmission and the potential for serious adverse reactions in nursing infants, **mothers should be instructed not to breast-feed if they are receiving VIREAD. Geriatric Use:** Clinical studies of VIREAD did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for the elderly patient should be cautious, keeping in mind the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. **Patients with Impaired Renal Function:** It is recommended that the dosing interval for VIREAD be modified in patients with estimated creatinine clearance <50 mL/min or in patients with ESRD who require dialysis *(See Dosage and Administration)*.

For detailed information, please see full Prescribing Information. To learn more call 1-800-GILEAD-5 (1-800-445-3235) or visit www.VIREAD.com.

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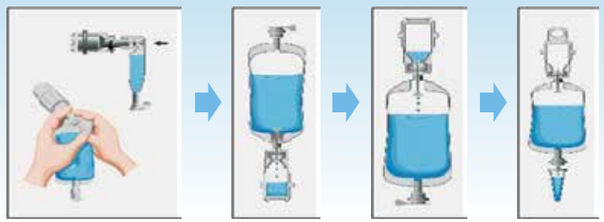

- ✓CLOSED SYSTEM APPLICABLE FOR USP CHAPTER <797>
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- ✓REDUCE THE NEEDLE INJURY AND ANTIBIOTIC ALLERGY OF PRACTITIONER
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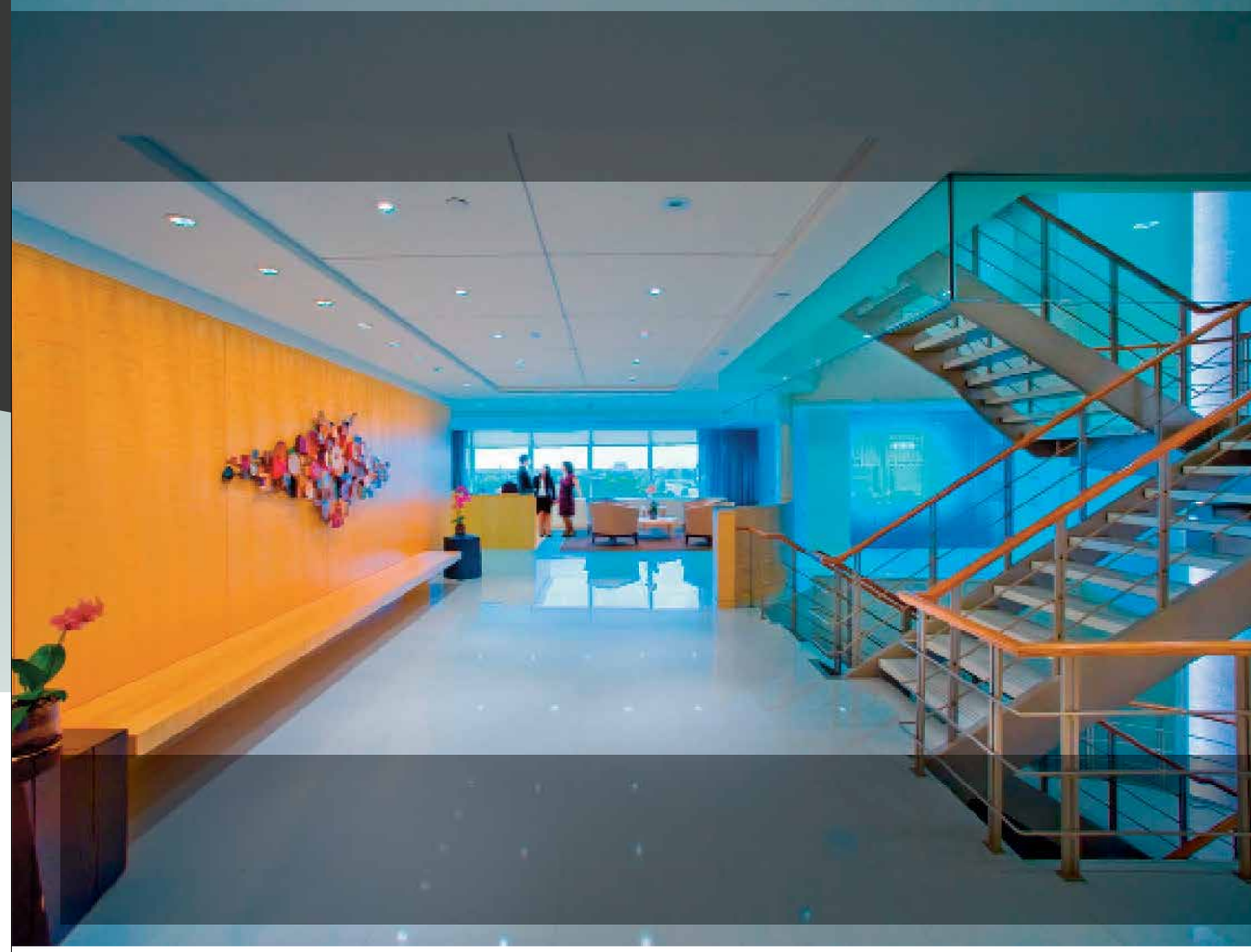


Conference Alerts

Asia

The 66th Annual Meeting of Korean Society of Food Science and Nutrition: International Conference of Food Science and Nutrition
August 24th to 26th 2015 Pyeongchang, Korea (south)

Conference
Website: http://event.kfn.or.kr/
Contact person: kfn3@kfn.or.kr

Abstract submission Open June 1, 2015 Abstract submission Deadline June 30, 2015 Early registration Deadline July 15, 2015

ISERD -9th International Conference on Medical and Health Sciences (ICMHS)
September 26th 2015 Tokyo, Japan

Conference
Website: http://iserd.co/Conference/Japan/ICMHS/
Contact person: COORDINATOR

ISERD -9th International Conference on Medical and Health Sciences (ICMHS) aimed at presenting current research being carried out in that area and scheduled to be held on September 26, 2015 in Tokyo,Japan.
Organized by: ISERD
Deadline for abstracts/proposals: August 20th 2015

Third International Conference on Global Public Health 2015
December 10th to 11th 2015 Colombo, Western, Sri Lanka

Conference
Website: http://www.health3000.org
Contact person: Prabhath Patabendi

Global Public Health 2015 is an interactive platform to connect and reconnect colleagues around the world. Meet 2012, 2014 participants as well as new participants in our conferences. GPH 2015 conference is the premier knowledge building event in GPH
Organized by: Umeå University, Sweden and International Center for Research & Development, Sri Lanka
Deadline for abstracts/proposals: August 15th 2015

North America

American Pharma Congress
August 3rd to 5th 2015 Philadelphia, Pennsylvania, United States of America

Conference
Website: http://american.pharmaceuticalconferences.com
Contact person: Richard Marcos

OMICS Group Conferences invites all the participants across the globe to attend American Pharma Congress during August 03-05, 2015 in Philadelphia, USA which includes prompt keynote presentations, Oral talks, Poster presentations and Exhibitions.
Organized by: OMICS

5th International Conference and Exhibition on Pharmaceutical Regulatory Affairs
August 3rd to 5th 2015 Orlando, Florida, United States of America

Conference
Website: http://regulatoryaffairs.pharmaceuticalconferences.com/
Contact person: Kasper Dave

OMICS Group is organizing 5th International Conference and Exhibition on Pharmaceutical Regulatory Affairs during August 03-05, 2015 Florida, USA with the theme of Share and Enhance the Aspects on Novel Policies in Regulatory Affairs.

5th Digital Marketing for Medical Devices
August 10th to 12th 2015 Minneapolis, United States of America

Conference
Website: http://atnd.it/25931-0
Contact person: Sarah Gordon-Goldsmith

Once more the industry's ONLY device-specific digital marketing conference brings an extraordinary lineup of the most innovative device marketers to Minneapolis. Time: 8:30 - 15:45 Price: USD1795 - USD2895
Organized by: ExL Events
Deadline for abstracts/proposals: August 9th 2015

3rd International Conference on Alzheimer's Disease & Dementia
August 31st to September 2nd 2015 Toronto, ontario, Canada

Conference
Website: http://alzheimers-dementia.conferenceseries.com/
Contact person: Michael Clarke

It's our pleasure to welcome you to the 3rd International Conference on Alzheimer's Disease & Dementia during Aug 31 - Sept 02, 2015 Toronto, Canada.
Organized by: Omics International
Deadline for abstracts/proposals: December 22nd 2014

BIOMARKERS-2015
August 31st to September 2nd 2015 Toronto, Ontario, Canada

Conference
Website: http://biomarkers.conferenceseries.com/
Contact person: Michael Smith

OMICS International is pleased to announce the 6th International Conference on Biomarkers and Clinical Research from August 31 to September 02, 2015 at Toronto, Canada with a theme "Lab to Industry as Biosignatures to Therapeutic Discovery".
Organized by: OMICS International
Deadline for abstracts/proposals: July 8th 2015

THE 22ND ANNUAL NEWSMAKERS IN THE BIOTECH INDUSTRY
September 10th, 2015
Millennium Broadway Hotel & Conference Center New York City, United States of America

Conference
Website: http://www.biocentury.com/conferences/newsmakers/dates

NewsMakers presents a hand-picked group of public biotech companies whose corporate and regulatory milestones will drive stock prices. NewsMakers is recognized as the industry's key venue for companies to take their story to Wall Street each Fall. Thus, NewsMakers remains the best opportunity for business development executives and key members of the institutional investment and analyst communities to compare notes and assess the industry landscape.
Last year, more than 500 delegates congregated at NewsMakers, including money managers who controlled more than $480 billion in equity assets, with over $50 billion dedicated to healthcare and $15 billion dedicated to biotech.

2015 PHARMA CI USA CONFERENCE & EXHIBITION
September 10th to 11th 2015 Hilton Parsippany Hotel New Jersey, United States of America

Conference
Website: http://pharmaciconference.com

The Pharma CI Conference & Exhibition (September 10-11, 2015,www.pharmaciconference.com) is THE INDUSTRY'S GOLD STANDARD for senior level pharmaceutical, biotechnology, medical device, and diagnostics professionals seeking the latest news and the rare chance to network with all the industry's luminaries. This is the biggest and best gathering of pharmaceutical competitive intelligence thought leaders (75 speakers)!
Join us at this premier gathering and network with other key decision makers as you learn about the most pressing and relevant issues facing the industry today. Enjoy the highest ratio of industry practitioners (pharma, biotech, medical device and diagnostics) of any pharma intelligence conference! For more information, please go tohttp://pharmaciconference.com/ , call 1-212-228-7974, or emailinfo@pharmaciconference.com
Organized by: Pharma CI Conference

3rd International Conference on Bioprocess and Biosystems Engineering Balitmore, Maryland U.S.A
September 14th to 15th 2015 Hotel Double tree Hilton by Baltimore Baltimore, MD United States of America

Conference
Website: http://bioprocess.conferenceseries.com

OMICS Group announces all the Biotechnology enthusiasts across the globe to attend the 3rd International Conference on Bioprocess and Biosystems Engineering during September 14-15, 2015 Baltimore, USA with the theme"Bringing latest technological developments of bioprocess in to real world scenario "OMICS will continue Bioprocess conference series to explore new innovative researches, thoughts, new bioprocess. fermentation technologies to the world.
Organized by: OMICS International Conferences

4th International Conference on Nephrology & Therapeutics
September 14th to 16th 2015 Maryland, United States of America

Conference
Website: http://nephrology.conferenceseries.com/
Contact person: James Crawler

Nephrology-2015 scheduled during September 14-16, 2015 at Maryland, Baltimore, in USA .
Organized by: OMICS International

Functional and Medical Foods for Chronic Diseases: Bioactive Compounds and Biomarkers
September 15th to 16th 2015 Boston, Massachusetts, United States of America

Conference
Website: http://functionalfoodscenter.net/18th-international-conference.html
Contact person: Conference Secretary

The 18th International Conference of FFC will bring together experts in medicine, biology, and the food industry to discuss the functional foods with bioactive compounds as dietary interventions for chronic diseases at Harvard Medical School.
Deadline for abstracts/proposals: July 31st 2015

8th Annual International Partnering Conference BioPharm America 2015 U.S.A
September 15th to 17th 2015 Boston, MA United States of America

Conference
Website: http://www.ebdgroup.com/bpa/index.php

BioPharm America™ is where biotech industry partnerships get started. Meet face-to-face with biotech and pharma executives from around the world to identify and enter strategic relationships. Equipped with partneringONE®, the world's leading web-based partnering system for the life science industry, BioPharm America is the only event in North America based on the same reputable formula as EBD Group's acclaimed European events BIO-Europe® and BIO-Europe Spring®.

Redefining Early Stage Investments (RESI) Conference
September 17th to 19th 2015 Boston, Massachusetts, United States of America

Continuing professional development event
Website: http://www.criticalmedboston.com
Contact person: HMS-DCE

This course is intended to provide core clinical critical care skills to health care providers who are not trained as Intensivists, but whose clinical duties involve taking care of critically ill patients.
Organized by: Harvard Medical School

Echo in the City of Rivers: Practical Review of Myocardial and Ischemic Heart Disease
September 19th to 20th 2015 Pittsburgh, PA, United States of America

Continuing professional development event
Website: http://ce.mayo.edu/echo3rivers
Contact person: cvcme

This course will provide the sonographer with a practical review of the current uses and limitations of two-dimensional echocardiography, Doppler and color flow imaging in the assessment of ischemic and myocardial disease.
Organized by: Mayo Clinic

International Conference and Expo on Biopharmaceutics
September 21st to 23rd 2015 Baltimore, Maryland, United States of America

Conference
Website: http://biopharmaceutics.pharmaceuticalconferences.com
Contact person: Anusha

Biopharma-2015 program will comprise of keynote sessions, workshops and symposiums. The major sessions include: Approaches to assess BABE studies, applied biopharmaceutics, biowaiver approaches, nanoparticle mediated pulmonary drug delivery and innovation
Organized by: OMICS Group

Discovery on Target
September 21st to 24th 2015 Boston, MA, United States of America

Conference
Website: http://www.discoveryontarget.com/
Contact person: Bethany Gray

This event will showcase current and emerging “hot” targets for the pharmaceutical industry & attracts 1,000+ attendees (from 21 countries), composed of scientists/technologists and excutives from biopharma, academic,and healthcare organizations.
Organized by: Cambridge Healthtech Institute

Targeting Ocular Disorders
September 22nd to 23rd 2015 Boston, MA, United States of America

Conference
Website: http://www.healthtech.com/targeting-ocular-disorders/
Contact person: Kerri Kelley

The third annual Targeting Ocular Disorders will cover some of the most promising emerging therapies in the treatment of ocular diseases. Special focus with be given to age-related macular degeneration and retinopathy.
Organized by: Cambridge Healthtech Institute

The 9th Annual Pain & Migraine Therapeutics Summit
September 23rd to 24th 2015 Washington DC, District of Columbia, United States of America

Conference
Website: http://www.paintherapeuticsummit.com
Contact person: John Waslif

US’s premier pain conference covering pain research and therapeutics. Leaders from the pharmaceutical, biotech, device and medical communities attend this conference to learn about the latest advances in the treatment of various types of pain.

Organized by: Arrowhead Publishers

Big Data in Pharma USA 2015
September 22nd to 24th 2015 Boston, MA, United States of America

Conference
Website: http://big-datapharma.com/
Contact person: Charlotte Parnaby

Big DiP USA is back for the 3rd year running and the 2015 meeting will accelerate the development of your therapies and inform your commercial decision making through enhanced data interpretation.
Organized by: Hanson Wade

6th World Bispecific Antibody Summit
September 22nd to 24th 2015 Boston, Massachusetts, United States of America

Conference
Website: http://bispecific.com/
Contact person: Katie Draper

Over 3 days, 27 leading experts will share transferable insights to accelerate the development of your lead bispecific candidate, and see more in the clinic.
Organized by: Hanson Wade

Mayo Clinic Nutrition and Wellness in Health and Disease
September 25th to 26th 2015 Washington DC, District of Columbia, United States of America

Continuing professional development event
Website: http://ce.mayo.edu/nutrition/node/1276
Contact person: Mayo School of Continuous Professional Development

Nutrition, physical activity and other healthy lifestyle behaviors are vital components in the promotion of health and in the treatment of disease. This program will highlight ambulatory, nutrition, and wellness topics with multidisciplinary faculty.

2015 PDA/FDA JOINT REGULATORY CONFERENCE
September 28th to 30th 2015
Renaissance Washington DC Hotel Washington DC, District of Columbia, United States of America

Conference
Website: https://www.pda.org/conference/2015-pda-fda-joint-regulatory-conference/home
Do you know if you’re meeting regulatory requirements? More importantly, do you know how to meet them? Plan to network with the experts in this leading forum that integrates science, technology and regulation! Join us at the 2015PDA/FDA Joint Regulatory Conference and take the unique opportunity to dialogue with FDA representatives and industry experts face-to-face to discover firsthand how to comply with regulatory global strategies and industry strategic initiatives from leaders and advocates who are shaping the global regulatory compliance landscape and take home best practices for compliance. Ask questions of the experts, influence direction and take home innovative and pragmatic solutions that will drive compliance in your business. Each year, FDA speakers provide updates on the current state of efforts impacting the development of global regulatory strategies; while industry professionals from some of today’s leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes. You won’t find this level of direct information exchange with FDA at any other conference!

Predictive Analytics World for Healthcare 2015
September 28th to October 1st 2015 Boston, Massachusetts, United States of America

Conference
Website: http://www.predictiveanalyticsworld.com/health/2015/
Contact person: Conf Info

Predictive Analytics World Healthcare Conference in Boston, focuses on real-world examples of deployed predictive analytics. Attend and witness today's emerging movement to fortify healthcare with big data's biggest win: The power to predict.
Organized by: Predictive Analytics World for Business

9th Digital Pharma East
September 29th to October 2nd 2015
Pennsylvania Convention Center, 1101 Arch Street, Philadelphia, 19107, Pennsylvania, United States of America

Conference
Website: http://atnd.it/29339-0
Contact person: Warren Drysdale

Join what will be the world's largest gathering of life science digital marketers in order to leverage solutions. Time: 3:45 am - 10:45 am Price: USD1795 - USD3395
Organized by: ExL Events

American Global Summit and Expo on Vaccines & Vaccination
October 5th to 7th 2015 San Francisco, Califonia, United States of America

Conference
Website: http://vaccines.global-summit.com/america/index.php
Contact person: vankatesh

9th Global Summit and Expo on Vaccines & Vaccination (American Vaccines-2015). which will be held during November 30-December-02, 2015 in San Francisco, USA
Organized by: Omicsonline.org
Deadline for abstracts/proposals: August 28th 2015

3rd Antibody & Protein Therapeutics Conference
October 22nd to 23rd 2015 Boston, United States of America

Conference
Website: https://www.gtcbio.com/conferences/antibody-protein-therapeutics-overview
Contact person: Kristen Starkey

This conference strives to connect industry and academic researchers in the protein therapeutics field to facilitate discussion on the current state of the industry and discuss recent studies and challenges involved in therapeutic development.
Organized by: GTCbio
Deadline for abstracts/proposals: September 22nd 2015

THEIIER-14th International Conference on Recent Advances in Medical Science (ICRAMS-2015)
October 23, 2015 New York, United States of America

Conference
Website: http://theiier.org/Conference/NewYork/2/ICRAMS/
Contact person: CONFERENCE COORDINATOR

2015 is the Second year of ICRAMS, it will be held every year since 2014, the conference will be an international forum for the presentation of technological advances and research results in the fields of Science, Innovation and Management.
Organized by: THEIIER
Deadline for abstracts/proposals: September 17th 2015

IASTEM -The 4th International Conference on Medical, Biological and Pharmaceutical Sciences (ICMBPS-2015)
October 25, 2015 Boston, United States of America

Conference
Website: http://iastem.org/Conference/USA/ICMBPS/
Contact person: CONFERENCE COORDINATOR

The IASTEM -The 4th International Conference on Medical, Biological and Pharmaceutical Sciences (ICMBPS-2015) will be held on October 25th 2015, 2015 at Boston, USA.
Organized by: IASTEM
Deadline for abstracts/proposals: September 16th 2015

2015 Aging Conference: Inter-Generaltional Relationships - A Common Ground Conference
November 5th to 6th 2015 Washington DC, United States of America

Conference
Website: http://agingandsociety.com/the-conference-2015
Contact person: Conference Producer

This interdisciplinary conference and its companion journal discuss the dramatic changes in the world's population, including the growing length of the average lifespan.
Organized by: Aging and Society / Common Ground Publishing

UPDATE IN INTERNAL MEDICINE - 2015
December 6th to 12th 2015 Boston, Massachusetts, United States of America

Conference
Website: http://www.updateinternalmedicine.com
Contact person: Jennifer Agri

This intensive CME course will provide you with a comprehensive review of the most important advances that have recently been made in internal medicine.
Organized by: Harvard Medical School

Seventh International Workshop on HIV Persistence, Reservoir and Cure
December 8th to 11th 2015 Miami, FL, United States of America

Workshop
Website: http://www.hiv-persistence.com
Contact person: Alain Lafeuillade

Workshop topics are: -Models of HIV persistence -Basic science of HIV latency -Assays to measure HIV persistence -Drug discovery -Clinical trials of HIV cure Workshop area: mechanisms of HIV persistence

Organized by: CHITS
Deadline for abstracts/proposals: September 6th 2015

Infectious Diseases in the Adult Patient: A Primary Care Update
December 28th to 31st 2015 Sarasota, Florida, United States of America

Continuing professional development event
Website: http://www.ams4cme.com/www/LiveSeminars/SEMLA-3020151228.aspx
Contact person: Tara or Anthony

American Medical Seminars, Inc. presents this Live CME Conference in Sarasota, FL. The course is free of Commercial Support and is approved for 20 AMA PRA Category 1 Credits™. Course details and other CME courses can be found at www.ams4cme.com.

Organized by: American Medical Seminars

Europe

International Conference and Expo on Drug Discovery & Designing
August 11th to 13th 2015 Frankfurt, Germany

Conference
Website: http://drug-discovery.pharmaceuticalconferences.com
Contact person: James Abraham

Drug Discovery-2015 would lay a perfect platform for the interaction among specialists, directors, professors, faculties, experts, and research fellows around the world reputed research institutes, universities and companies, agencies & associations.

World Congress on Beneficial Microbes: Food, Pharma, Aqua and Beverages Industry
August 24th to 26th 2015 Valencia, Spain

Conference
Website: http://beneficialmicrobes.conferenceseries.net/
Contact person: James Roberts

Beneficial Microbes-2015 is the premier event which brings together different sectors of industrial microbiology such as Food, Pharma, Aquaculture and Beverages Industry. And it provides platform for researcher around the globe to share their views.

30th International Papillomavirus Conference & Clinical and Public Health Workshops
September 17th to 21st 2015 Lisbon, Portugal

Conference
Website: http://www.hpv2015.org/
Contact person: Charlotte Boskila

HPV 2015's international forum enables the exchange of knowledge between the research and clinical communities showcasing the latest scientific HPV advances.
Organized by: Kenes International
Deadline for abstracts/proposals: May 6th 2015

Fairness in the Delivery of Health Care: An Examination of Pricing, Technology and People Issues
September 16th to 19th 2015 Barga, Italy

Conference
Website: http://www.engconf.org/conferences/biotechnology/fairness-in-the-delivery-of-health-care-an-examination-of-pricing-technology-and-people-issues/
Contact person: Arlene Conway

The delivery of health care is a major international issue. Not only is the cost of the provision of this service increasingly burdensome, the way in which it is apportioned has become the subject of both ethical and practical consideration

Organized by: Engineering Conferences International
Deadline for abstracts/proposals: June 15th 2015

6th International Conference on Healthcare and Life Science Research (ICHLSR)
September 18th to 19th 2015 London, United Kingdom

Conference
Website: http://ichlsrlondon.com/
Contact person: Dr. D Lazarus

Venue: Imperial College London Excellent opportunity for international peer-reviewed publication and to meet academicians from world over.
Deadline for abstracts/proposals: September 15th 2015

5th Annual Pharma Marketing Summit - Digital Marketing & CEM
October 6th to 8th 2015 Berlin, Germany

Conference
Website: http://globalpharmamarketing.com/
Contact person: Margareta Nociarova

Join us and uncover new potential ways of improving, defining and designing your digital marketing strategy, explore what Social Media channels are most effective for your business and what does Big Data mean for customer experience in 2015.

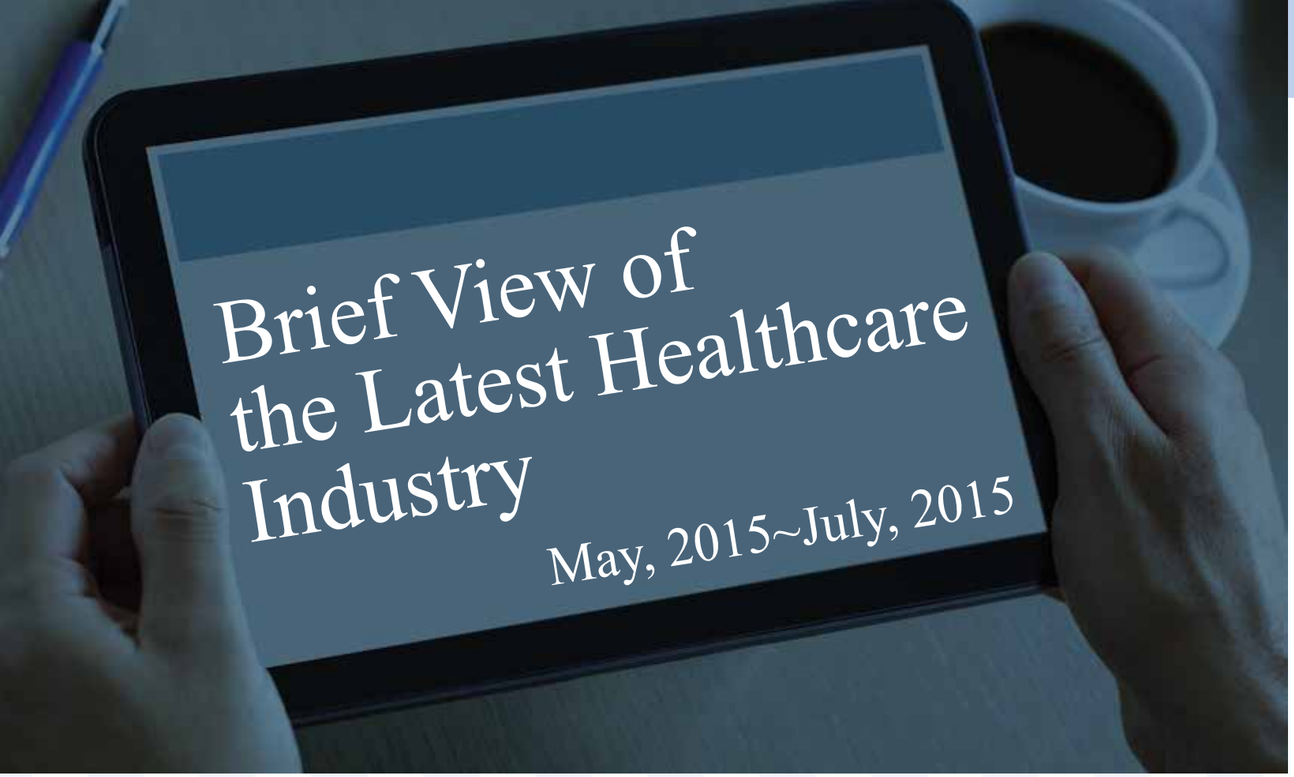
Organized by: Allan Lloyds group

International Conference On Health Informatics And Computer Assisted Medicine (Health IT 2015)
December 7th to 8th 2015 London, United Kingdom

Conference
Website: http://www.c-mric.org/hi-2015
Contact person: Organising Chair

International Conference on Health Informatics and Computer Assisted Medicine (Health IT 2015) is an international referred conference dedicated to the advancement of Health Informatics, Computer Assisted Medicine and Tele-Health.

Organized by: C-MRiC.ORG
Deadline for abstracts/proposals: July 6th 2015



May

1. A practical gel that simply 'clicks' for biomedical applications 5/5/15

Hydrogels are commonly used in our daily lives such as contact lenses and it is made up of polymer chains that can absorb water which allow oxygen pass through in contacts. Biomedical engineers have found that turning the composition of shape and their physical properties can form other things. However, because hydrogels are easily damaged during the encapsulation processes, it is very difficult to form. Before, as it seen above, hydrogel was not biocompatible, but Wyss Core Faculty member Neel Joshi, Ph.D., developed biocompatible hydrogel, so it can now from without damaging them.
http://www.medicalnewstoday.com/releases/293411.php

2. Global oncology spending reached $100 billion in 2014 5/6/15

Early cancer findings, treatments, and improvements helped on to the greater demand for oncology. Although in 2014, the cost of global oncology market reached $100 billion, the cost of global oncology increase was not significant as it compared with five largest European countries. However, the increasing of early cancer findings, treatments, and improvements helped on to the greater demand for oncology.
http://www.medicalnewstoday.com/articles/293555.php

3. Global financial injection 'needed to transform development of antibiotics' 5/15/15

Economist named Jim O'Neill, chairman of the Review on Antimicrobial Resistances states that the world needs to develop new antibiotics because no new antibiotics have been found for the past decades. Although many drugs are manufactured, not all drugs are treatments for diseases. He also argues that spending $100 trillion costs will save millions of lives. GlaxoSmithKline's President of Pharmaceuticals R&D Patrick Vallance supports the economists the idea because it encourages people to research and show improvements on drug industry.
http://www.medicalnewstoday.com/articles/293959.php

May

4. Investing in hepatitis C drugs could save the economy billions, researchers suggest 5/18/15

Researchers suggested that higher improvement rate and treatment of hepatitis C will have to save economies more than $3.2 billion a year of the U.S and five largest European countries, which include France, Germany, Italy, Spain and the UK. Although there are other treatments of hepatitis C, developing newer and improvement version would help not only patients, but also save billions of dollars and economy. If they develop newer version and help on curing hepatitis C could save $2.67 billion for the U.S and $556 million for five largest European countries.
http://www.medicalnewstoday.com/articles/294041.php

5. Study in Nigeria finds 1 in 10 malaria drugs are poor quality 5/28/15

Nigeria is top one of people diagnosis malaria: 48 million malaria cases and 180,000 deaths annually. The research published by PLOS ONE found out of 3,000 antimalarials, 9.3% are poor quality. The problem is not only from the drug, it also comes from not giving correct treatment or dosage for those drugs that treat malaria. The poor quality drugs that are identified, they were mixed with other chemical ingredients that do not help to treat malaria. The reason why this is dangerous is most patients in Nigeria go to drug stores rather than pharmacies and these drugs are commonly found in drug shops. They are expose to dangerous situations.
http://www.medicalnewstoday.com/releases/294506.php

June

6. Will 'the female Viagra' really help women? 06/04/15

UK – 92480 is treatment for angina and high blood pressure that Pfizer began developing during the 1990s. "The drug worked by inhibiting an enzyme that causes the inside of blood vessels to contract". The theory behind this drug was if the process was interrupted, the cells would play lessening in their roles, while improving blood flow and relieving blood pressure. However, recent study found that the drug, UK-92480, is not working as it supposed to be because it causes blood pressure to fall too low. Moreover, there are side effects such as muscle aches and they are now looking this drug as a treatment for erectile dysfunction.
http://www.medicalnewstoday.com/articles/294903.php

7. Eating nuts, peanuts daily could lower death risk from cancer, other diseases 6/11/15

The article talks about consuming peanuts and nuts may prevent from diseases such as cancer, heart disease, and diabetes. According to Prof. Piet van den Brandt and colleagues from Maastricht University in the Netherlands, they stated, "Peanuts and nuts are a good source of omega-3, fiber, vitamin E, antioxidants and "good" fats. They had an experiment with 120,000 people and resulted that people who had 15g of nuts or peanuts everyday lowered the risk of diseases such as cancer, diabetes, and heart diseases. However, peanut butter had no effect because it contained other ingredients such as salt, vegetable oil and trans fatty acids.
http://www.medicalnewstoday.com/articles/295124.php

June

8. The top 10 leading causes of death in the US 6/16/15

1,254,978 males and 1,260,480 females, in total of 2,515,458 people die annually. This article focuses on the diseases that leads to death: Heart disease, Cancer (malignant neoplasms), Chronic lower respiratory disease, Stroke (cerebrovascular diseases), Accidents (unintentional injuries), Alzheimer's disease, Diabetes (diabetes mellitus), Influenza and pneumonia, Kidney disease (nephritis, nephrotic syndrome, and nephrosis), and suicide. Top one death is caused by heat disease and it had the highest rate for both males and females. This article mainly focuses on major warning signs and symptoms and how to protect you from the disease.
http://www.medicalnewstoday.com/articles/282929.php

9. Chocolate: is it really good for our health? 6/18/15

Average Americans take around 4.5 kg of chocolate each year. Chocolates taste delicious and it stimulates the release of endorphins. This article focuses on whether chocolate is really good for our health as what we have known for years. Researchers from United Kingdom stated earlier that consuming 100g of chocolate in a daily life prevent from having heart attack or stroke. However it contains questions from other people saying, how does chocolate actually prevent from diseases when they contain high levels of fat and sugar. Chocolate is made from cacao beans that are from Central and South America. These cacao beans include flavonoids and flavanols; they are known to be antioxidants that are to destroy free radicals in the body. They also contain dopamine, phenylethylamine and serotonin that are known to enhance mood and promote feelings of well-being. Most people recommend taking dark chocolate rather than white or milk chocolate because the darker the chocolate, the more flavonoids and flavonols are included. So far, chocolate has only positive effects, but it has also negative effects. The problem of consuming too much chocolate is from additional ingredients that are included in the actual chocolate bar. Since, these additional ingredients change the structure and component of flavonoids and flavanols that are in the chocolate. If they changed the structure and component, it lessens the effect and does not fully do its job.
http://www.medicalnewstoday.com/articles/295615.php

10. Blood pressure medication could prevent alcohol, drug addiction 6/24/15

Alcohol and drug addictions are the most problematic in the society and this article examines how high blood pressure treatment can prevent these addictions. The research team, led by Hitoshi Morikawa has suggested that the treatment of high blood pressure drug named isradipine can prevent alcohol and drug addiction. They had an experiment with addicted rats with rooms and gave a high dose of Isradipine and see whether or not the drug actually expunge the addiction memories. A few days later, behaviors in rats changed; they no longer went to the addicted room. The blood pressure medication named Isradipine is FDA approved drug that lowers blood pressure by blocking calcium channels in the heart and blood vessels.
http://www.medicalnewstoday.com/articles/295797.php

11. Skin cancer risk linked with grapefruit and orange juice 6/30/15

The most dangerous form of skin cancer, these cancerous growths develop when unpaired DNA damage to skin cells (most often caused by ultraviolet radiation from sunshine or tanning beds) triggers mutations (genetic defects) that lead the skin cells to multiply rapidly and form malignant tumors. The most serious type of skin cancer develops in the cells (melanocytes) that produce melanin – the pigment that gives your skin its color. It can form in your eyes, rarely in internal organs such as your intestines. The exact cause of all melanomas isn't clear, but exposure to UV radiation from sunlight or tanning lamp and beds increases your risk of developing melanoma. By limiting your exposure to UV radiation can help reduce your risk of melanoma. Moreover, by consuming large amounts of grapefruit and orange juice can lead to higher risk of melanoma. For those consume large amount of grapefruit and orange juice have higher chances of risking melanoma than those who consume less. 73,870 people will diagnose from melanoma and 9,940 people will die from skin cancer.
http://www.medicalnewstoday.com/articles/296087.php

12. 'Over 184,000 global deaths each year' caused by sugary drinks 6/30/15

Many Americans favor sugary drinks, but consuming too much sugary drinks can lead to death. Sugary drinks include sports/energy drinks, fruit drinks, sweetened ice teas, and any type of beverages that contain sugar. Over the past 30years, sugary drink consumptions haven risen. The death is caused by obesity, diabetes, cardiovascular disease and cancer and the study found out that 184,000 people die from sugary drinks annually. Moreover, the American Heart Association (AHA) is recommending people to consume 450calories of sugary drinks in a week, that would be about 2 cans of soda.
http://www.medicalnewstoday.com/articles/296035.php
http://well.blogs.nytimes.com/2015/07/01/sugary-drinks-take-a-deathly-toll/?ref=health

July

13. New study reveals dangers of opioid abuse for chronic back pain sufferers 7/12/15

Chronic back pain is treated with opioid, but this drug is leading to psychiatric disorders such as depression or anxiety. In Anesthesiology, the official medical journal of the American Society of Anesthesiologists (ASA), researchers stated that 55 patients who take opioids for back pain experienced psychiatric disorders. The danger part of this is that 46 people die from overdosing of prescription painkillers.
http://www.medicalnewstoday.com/articles/296498.php

14. WHO says the international community must do more to take action against rabies 7/17/15

The WHO report, 'The Control of Neglected Zoonotic Diseases: from advocacy to action' states that it is possible to eliminate rabies by using our knowledge and techniques that are available. Dr. Louise Taylor from The Global Alliance for Rabies Control (GARC) said rabies can be eliminated by mass dog vaccination and other techniques and application that are available now will help those people who risk of rabies.
http://www.medicalnewstoday.com/releases/296935.php

15. Anthem Nears Deal to Buy Cigna for $48 Billion 7/22/15

Anthem Inc. is planning to buy Cigna Corp. for more than $48 billion and expect to pay about $188 a share for Cigna. The companies are combining together for more cost efficiency and its scale because of the Affordable Care Act and other factors. The largest health insurer group by revenue would UnitedHealth Group. In 2015, UnitedHealth projected $154 billion while Anthem-Cigna and Aetna-Humana projected about $115 billion. Although combining two companies together would rise up the revenue, the issue brought up: who will be running the combined company. However, the agreements have not been signed yet and it can be delayed and contracts may be changed. The final announcement will be made during Thursday afternoon.
http://www.wsj.com/articles/anthem-nears-deal-to-buy-cigna-1437604564

July

16. FDA approve new daily pill for common skin cancer 7/27/15

The US Food and Drug Administration (FDA) had an experiment with patients who cannot receive surgery or radiotherapy or recurrence of tumor and a new drug and it reduced tumors of 58 percent of patients. People who have locally advanced basal cell carcinomas do not respond to treatments. However, Odomzo, generic name is sonidegib, which is marketed by Novrtis AG works for those patients. The study showed that tumors reduced for 58% of patients who took 200mg of Odomzo a day and the effect lasted for 1.9 to 18.6 months. Moreover, for those who consume more than 200mg of Odomzo had similar response, but side effects such as hair loss, nausea, and headaches are shown.
http://www.medicalnewstoday.com/articles/297323.php

17. FDA approves non-surgical temporary balloon device to treat obesity 07/29/15

There is a new balloon device that is used to treat obesity without surgery and the U.S Food and Drug Administration has approved it. The device is named as ReShape Integrated Dual Balloon System and it mainly to lose weight and for obese adult patients. It works by occupying space in the stomach to feel fullness or other mechanisms. The procedure does not take long and it approximately takes 30 minutes. Moreover, once the device takes in place in the stomach, it does not change or alter the stomach's natural anatomy.
http://www.medicalnewstoday.com/releases/297488.php

18. Mindfulness meditation may help smokers quit – even those with no willpower 07/31/15

Experts announced that behavior training like mindfulness meditation may help smokers to quit smoking and this may be effective way even for people who are not planning to quit smoking.
The review of addiction research, published in the journal Trends in Cognitive Sciences states that "smoker's intention to quit smoking is not always needed to reduce cigarette cravings:. It is always hard to motivate and influence smokers to quit smoking. Moreover, even if they try to quit, some smokers restart smoking again. However, experts say that behavior training will help to quit smoking because it makes you to control your brain and yourself. The article states that "Even though many of the students said they had smoked the same number of cigarettes before and after the training, for those who had received mindfulness meditation, an objective measure of carbon dioxide percentage in their lungs showed a 60% reduction in smoking in the 2 weeks after the study".
http://www.medicalnewstoday.com/articles/297536.php

19. Drone transport 'does not affect blood samples' 07/30/15

The collaboration between pathologists and engineers published the journal, PLOS ONE, it said that drone transport does not affect blood samples and it could be a way to deliver. The study suggests that carrying blood samples with these medical drones could help health providers shorten the time to do lab tests that is needed for diagnoses and treatments. The main purpose of this study is to find whether using medical drone could be one of efficient way of transport blood and find out whether the blood samples arrive in good condition for diagnostic testing. The team found that if the common and routine blood test sample is carried on the hobby-sized drones will not be affected up to 40 minutes.
http://www.medicalnewstoday.com/articles/297498.php

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