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WKMJ

World Korean Medical Journal

Cover Story
Inspirational Korean Healthcare Leader
Terry Kim, MD, Vice President and President-Elect, American Society of Cataract and Refractive Surgery (ASCRS)

Special Report
New York Health Forum at a Glance

Biopharmaceutical Report
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Aclaris' Phase II Results for ATI-502 and ATI- 501 in Alopecia May Lack Cosmetic Significance

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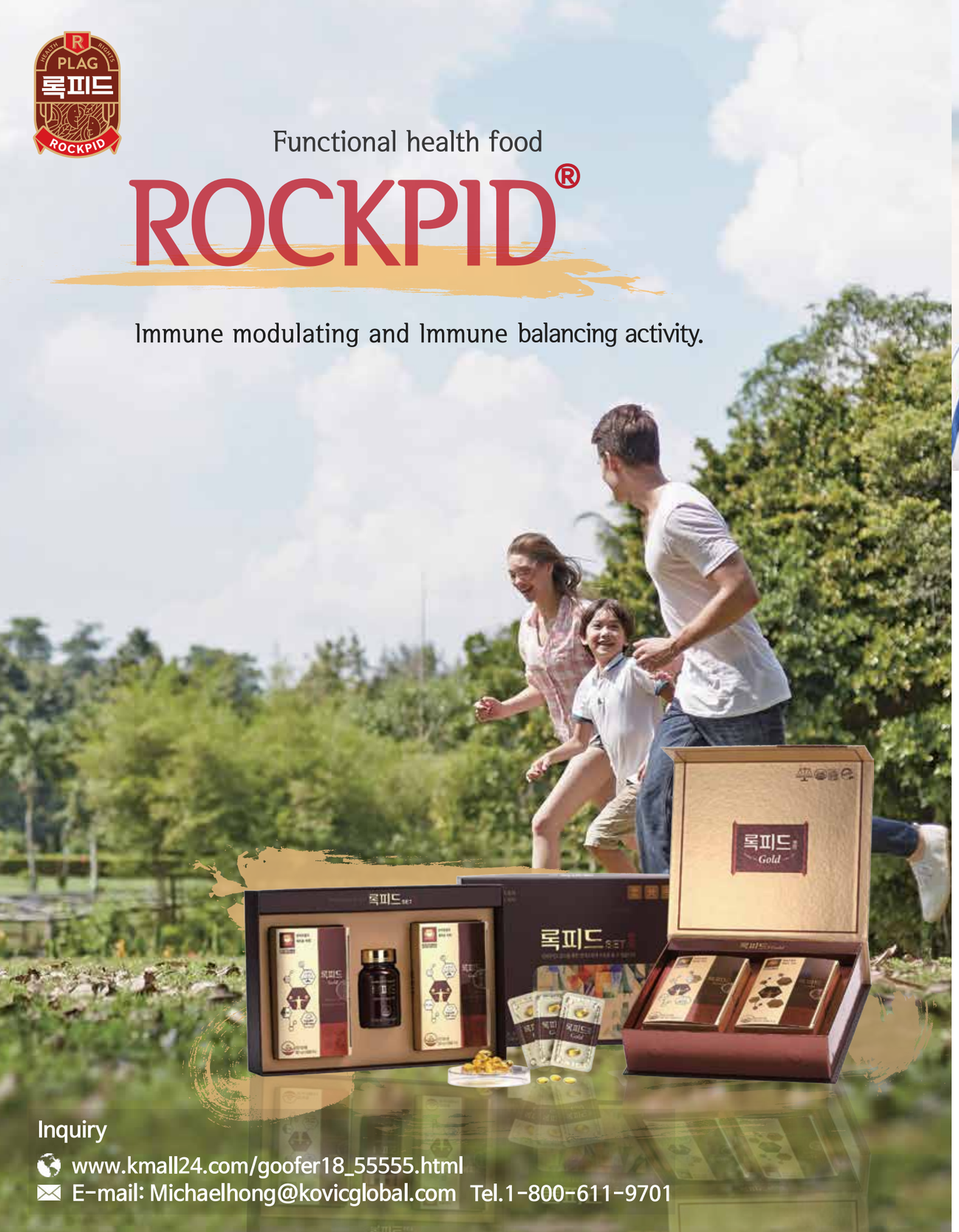

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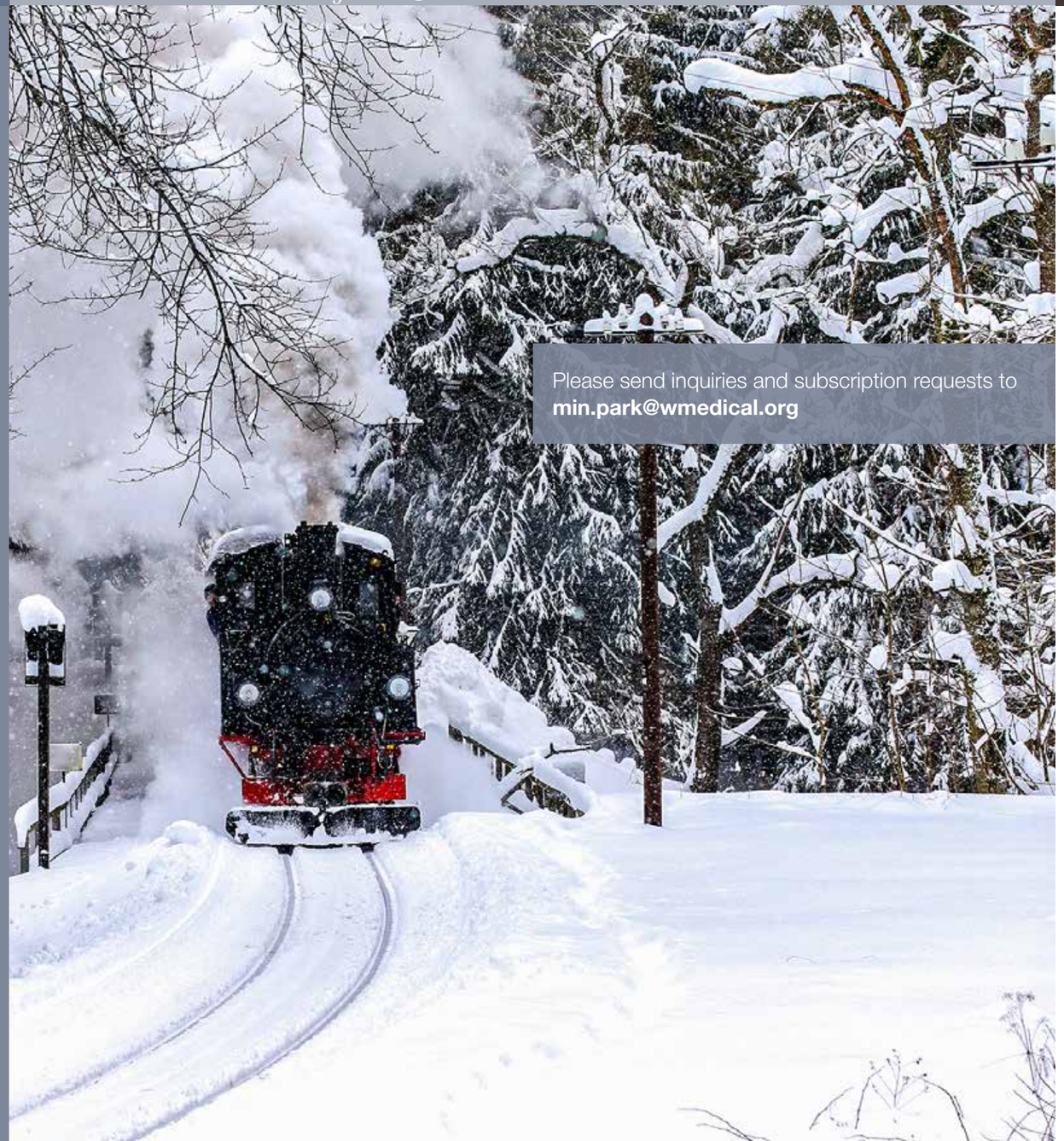

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Cover Story

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TABLE OF CONTENTS

05 OUR EDITORIAL BOARDS

07 TABLE OF CONTENTS

08 FROM THE PUBLISHER

09 FROM THE EDITOR-IN-CHIEF

11 WKMJ RECAP OF THE LAST ISSUE

14 COVER STORY
Inspirational Korean Healthcare Leader
Terry Kim, MD, Vice President and President-Elect,
American Society of Cataract and Refractive Surgery (ASCRS)

24 SPECIAL REPORT
New York Health Forum at a Glance

32 BIOPHARMACEUTICAL REPORT I
Aldeyra's Reproxalap has Experts Mixed on Seasonal
Allergic Conjunctivitis Focus in Phase III

40 BIOPHARMACEUTICAL REPORT II
Aclaris' Phase II Results for ATI-502 and ATI- 501 in
Alopecia May Lack Cosmetic Significance

52 CONFERENCE ALERTS

58 BRIEF VIEW OF THE LATEST HEALTHCARE INDUSTRY

FROM THE PUBLISHER

Our 18th issue marks the end of 2018, a year full of changes, challenges and controversies regarding healthcare, especially in the United States. Surviving numerous contestations by the incumbent presidential administration, the Patient Protection and Affordable Care Act has proven to be a formidable fixture of federally funded healthcare, and with several bold policy decisions and agendas—including the Food and Drug Administration's crackdown on e-cigarette use—the focus on health, and the maintenance of it, is as significant as ever.

For our cover story, we met with Dr. Terry Kim, a professor of Ophthalmology at the Duke University Eye Center who has dedicated his life to improving and preserving vision, one of the most delicate senses. As Chief of Duke's Cornea and External Disease Service and Director of the Refractive Surgery Service, Dr. Kim is a triple threat: a prominent surgeon continuously listed and voted one of the top doctors in the U.S., a principal investigator with award-winning research and a dedicated teacher to young, aspiring doctors. We explore Dr. Kim's passion for mentorship and extensive work within the national and international ophthalmology communities. We were also able to glean some insight into the ongoing integration of artificial intelligence (AI) in ophthalmology, such as the introduction of the brain-computer interface (BCI) to restore loss of vision from retinitis pigmentosa, in conjunction with the FDA-approved Argus retinal prosthesis system. The burgeoning field of BCI has incredible potential, promising so many new ways to approach medicine that even Elon Musk is interested, with his own neurotechnology company looking to develop implantable BCIs.

Touching on the theme of exciting, fresh developments in healthcare, this issue also highlights the upcoming 11th New York Health Forum (NYHF) with the theme "Healthcare/Life Sciences Industry: Preparing for 2019." Akin to how translational research brings experts from various backgrounds together to improve health outcomes, the NYHF brings together hundreds of healthcare stakeholders—from academia, clinics, pharmaceutical companies, Wall Street and other institutions and fields—to address current and future healthcare issues and trends. We explore how the triannual conference promotes synergistic collaboration and discourse within an industry that is as multi-faceted and ever-changing as its constituents.

2018 was a remarkable year. At WKMJ, we wish all our readers a festive holiday season and look forward to a healthy and prosperous 2019.

David Y. Ko, MD
Publisher
President of WKMO
Loma Linda University

FROM THE EDITOR-IN-CHIEF

Pulitzer-winning investigative reporter John Carreyou examines the breathtaking rise and subsequent collapse of Theranos—the infamous blood-testing startup once valued at $9 billion—in his book "Bad Blood: Secrets and Lies in a Silicon Valley Startup." In its review for the nationally acclaimed bestseller, Publisher Weekly praises Carreyrou's skillful integration of "lucid descriptions of Theranos's technology and its failures with a vivid portrait of its toxic culture and its supporters' delusional boosterism. The result is a bracing cautionary tale about visionary entrepreneurship gone very wrong." Visionary leadership can often make or break an organization, playing a crucial role in its success. Nonetheless, Theranos warns entrepreneurs that vision should always be built around a foundation of truth and principles.

Including "Bad Blood," I have read about 20 books this year. With about a month left in 2018, I believe I will be reaching my goal of completing 2 books every month. The volumes I chose have been diverse in both subject and author, but the emphasis on the importance of two things—people and purpose— has remained consistent. At WKMJ, we strive to find those who also believe in the value of these two organizational components for our covers. Every issue explores what it means to be a great leader with equally invaluable purpose.

For this issue, we feature another passionate and inspiring leader in the medical arena. Dr. Terry Kim, a professor of Ophthalmology at Duke's medical school, is also on the executive boards of the American Society of Cataract and Refractive Surgery (ASCRS), American Academy of Ophthalmology (AAO) and the Cornea Society. Dr. Kim, who will serve as Vice President of ASCRS next year and President of the organization in 2020, shared with us his various experiences as a leader who has lived through, and continues to see, groundbreaking advancements in medical technology and surgical techniques.

Our Special Report features the New York Health Forum, a quarter yearly, one-day event that draws innovators from all areas of the global medical and life sciences industries to discuss the next big healthcare trends and concerns. The report focuses on the people and purpose of the unique platform, in addition to its initiatives and progress. I believe the New York Health Forum will become one of the key players in cross-border collaborations and transactions.

We also discuss new developments in the bio-health industry in this edition of the WKMJ. I always thank my writers and partner media organizations who endeavor to share important stories with our readers. Their contributions provide valuable knowledge and insights. As the year draws to a close, I hope you will find both information and inspiration within these pages.

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

WKMJ RECAP OF THE LAST ISSUE

Cover Story
Inspirational Korean Healthcare Leader "Eun Sook Lee, MD, PhD, President of the Korean National Cancer Center"

Dr. Eun Sook Lee is the first female president of the Korean National Cancer Center (NCC Korea), one of the world's largest centers for cancer prevention, detection, and treatment in South Korea. With over 100 research papers, five patents, and more than 30 years of medical experience, Dr. Lee has spent her celebrated career testing limits and breaking boundaries; as a surgical oncologist specializing in breast cancer, she has advanced Korea's knowledge of breast cancer surgery and patient care, and as the first female surgeon from the Korea University Medical College and the first female director of the Korean Surgical Society. To learn more about Dr. Lee, please refer to Issue 17 of WKMJ.

Special Report
Ductal Carcinoma in Situ: Current Status and Future Perspectives

Although ductal carcinoma in situ is considered non-invasive as 70-80% of cases do not progress to invasive carcinoma, it is often treated surgically, sometimes accompanied by systemic or adjuvant radiation therapy. With DCIS accounting for an increasingly large percentage of breast cancer diagnoses and a comparatively marginal reduction in advanced female breast cancer. The report discusses promising research, including that of Dr. Eun-Shil Shelley Hwang of the Duke Cancer Institute, to create individualized treatment options for patients with DCIS. To find out more about the future of DCIS treatment, please refer to Issue 17 of WKMJ.

Biopharmaceutical Report
Immunomedics' Sacituzumab Has Insufficient Dataset to Pursue Accelerated Approval

Sacituzumab govitecan, the lead investigational antibody-drug conjugate (ADC) of biopharmaceutical company Immunomedics, Inc., is unlikely to receive accelerated approval from the U.S. Food and Drug Administration (FDA) with current Phase I/II data for hormone receptor positive (HR+) Her2-negative breast cancer. According to experts, while the early Phase I/II data looks promising—with an overall response rate (ORR) of 31%—because not all patients in the dataset were previously treated with CDK4/6 inhibitors, which influence responses to sacituzumab treatment, and because the full impacts of CDK4/6 inhibitor treatment also remain unknown, the data will most likely be ruled insufficient. To read more about the future of sacituzumab in the more competitive HR+ breast cancer space, head over to Issue 17 of WKMJ.

Biopharmaceutical Report III
Eisai's Lenvima for First-Line HCC is Approvable but Noninferiority Data to SOC May Slow Uptake

Lenvima (lenvatinib), an oral multikinase inhibitor by Eisai Inc., is widely expected to be approved by the U.S. FDA for first-line hepatocellular carcinoma (HCC) after a positive Phase III noninferiority trial versus Bayer's Nexavar (sorafenib). The prediction of approval is due to the fact that Lenvima is the first to succeed in first-line HCC versus Nexavar, the established standard-of-care (SOC), in a decade. However, even if Lenvima is approved, experts anticipate that Eisai will have difficult persuading clinicians to switch from Nexavar. To learn more about the battle between Lenvima and Nexavar, refer to Issue 17 of WKMJ.

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INSPIRATIONAL KOREAN HEALTHCARE LEADER

Dr. Terry Kim

Terry Kim, MD, Vice President and President-Elect, American Society of Cataract and Refractive Surgery (ASCRS)

Professor of Ophthalmology, Chief of the Cornea and External Disease Service at Duke University Eye Center

COVER STORY

1. Dr. Kim, you are a successful ophthalmologist and a respected member of the medical community. What motivated you to specialize in ophthalmology?

- Many of us who go into medicine know that serendipity and timing have a lot to do with finding a specialty. In my case, I was fortunate to receive advice and guidance from my parents, who were both in the healthcare field. They were both graduates of Yonsei University and Yonsei School of Medicine and boldly emigrated to the U.S. in 1965 to pursue a new life. I witnessed firsthand the hardships that my parents experienced in raising my sister and I in a country that was foreign to them. My father, who was a very hard-working and well-respected community obstetrician-gynecologist, encouraged me to take a different path than he did and to look into academic ophthalmology as a specialty.

As a sophomore at Duke University, I had an opportunity to volunteer at Duke Eye Center where I met Dr. Robert Machemer. I was first exposed to ophthalmic surgery when he invited me to the operating room to observe him perform a retinal vitrectomy procedure. During the 3rd year at Duke University School of Medicine, I decided to pursue my research year in the laboratory of Dr. Gordon Klintworth studying corneal neovascularization with a grant from the Research to Prevent Blindness Foundation. This experience not only opened my eyes to the field of ophthalmology but also to the importance of translational research. Inevitably, I interacted with the residents, fellows, and faculty there, all of whom helped me decide to pursue ophthalmology as a specialty, and I haven't looked back since.

2. As an acclaimed physician with more than 20 years of experience, what do you enjoy most about being in the field of ophthalmology? What have been some of the highlights and honors in your career? Also, what are the most challenging aspects?

Dr. Kim giving the KSCRS Award Lecture in Seoul, Korea

- One of the joys of ophthalmology that became evident to me was being able to benefit from the many advancements in technology and surgical techniques that are ubiquitous in our field. From Dr. Charles Kelman's introduction to the revolutionary concept of phacoemulsification by using ultrasound energy to remove cataracts, to Dr. Ramon Castroviejo's first series of successful human corneal transplants, and Machemer's and Thomas Aaberg's pioneering efforts to launch the vitrectomy procedure, the field continues to remain at the cutting edge of innovation as we now use femtosecond and excimer lasers for cataract and refractive surgical procedures as well as new microscopic devices for glaucoma surgery to help restore sight and prevent blindness.

Through the generous support of research grants from the National Institutes of Health, Fight for Sight/Research to Prevent Blindness, and the Heed Ophthalmic Foundation, as well as corporate support from Alcon and Allergan, I have also immensely enjoyed my research career, which focused on corneal wound healing and eventually led to the commercialization of a wound sealant to decrease the need for sutures in ophthalmic surgery. But to me, the single greatest joy of working in my field has been the pleasure and privilege of giving the gift of sight to many of my patients. Not only until one loses his/her vision does one really appreciate it, as

I have personally witnessed the tears and emotions expressed by children who can see for the first time through their new corneal transplant, by adolescent military serviceman who can now see without contact lenses or glasses after their LASIK surgery, or by grandparents who with their restored sight after cataract surgery can resume their normal daily activities and hobbies.

Of course, some of the greatest challenges lie in treating the diseases for which we currently don't have ideal therapies, such as macular degeneration. And for this, I'm confident that the field of ophthalmology will continue to advance and innovate to eventually eliminate blindness altogether.

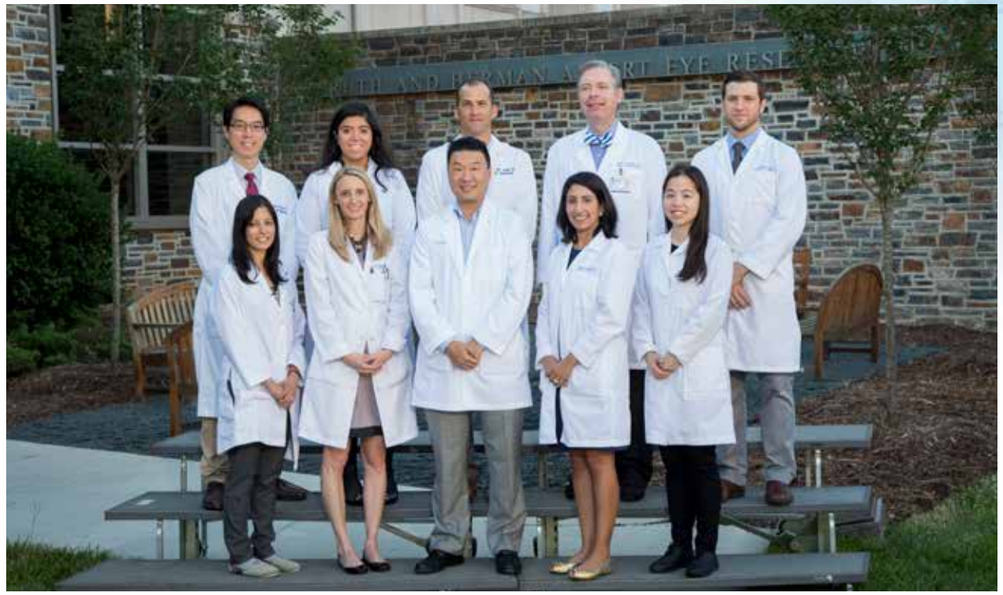
Dr. Kim receiving the KSCRS Award in Seoul, Korea

As far as some of the honors in my career, I have been the recipient of the Achievement Award and the Senior Achievement Award from the American Academy of Ophthalmology (AAO) and the American Society of Cataract and Refractive Surgery (ASCRS) Film Festival Award. I have also been invited to give numerous named lectures, including the Wilfred E. Fry lecture, the Don Boyaner lecture, the Dong Shin memorial lecture, the Edward Zirm lecture, the Richard C. Troutman lecture, the Gavin Herbert lecture, as well as several memorial lectures at Yonsei and Asan Medical Centers. Certainly, one of the highlights of my career include my nomination to the Executive Committee of ASCRS, where I'm excited to serve as President in the year 2020.

> "I'm confident that the field of ophthalmology will continue to advance and innovate to eventually eliminate blindness altogether"

3. Dr. Kim, you are currently the Professor of Ophthalmology at Duke University Eye Center, the Division Chief of Cornea and Refractive Surgery, as well as the former Director of the Residency Program and Ophthalmology Fellowship Programs. How do you view yourself as an educator? What are your principles or philosophies as a teacher?

- It has been an honor and privilege to be part of the faculty at Duke Eye Center, which has consistently been ranked as one of the top 10 ophthalmology departments in the country by U.S. News and World Report for the last 20 years. An extremely rewarding part of my ophthalmology career here at Duke has been the role I've played in teaching and training many of the undergraduate/medical students, residents, fellows, and visiting professors and scholars with whom I've been so fortunate to interact. Just as many of my teachers and mentors have done for me, I have tried to learn by example and teach not only the diagnostic or surgical skills that are directly relevant to becoming a proficient ophthalmologist, but also the values and life skills that are important in becoming a caring and compassionate physician. I am still thankful to my residency program director Dr. Geoffrey Broocker and my fellowship director Dr. Peter Laibson for the ophthalmic education I received, but also and just as importantly, for all the valuable advice and guidance they have given me throughout my career.



Dr. Kim with cornea faculty at Duke Eye Center

I view education as a career-long and mutually beneficial and gratifying process, as I continue to learn myself from all the students, trainees, and faculty that teach and stimulate me with their questions, observations, concepts, hypotheses, and so on. One of the principles or philosophies I strongly believe in is a mentoring process where I encourage both my trainees and junior colleagues to find mentors on several levels, be it a fellow senior student, an upper level resident or fellow, or a mid or senior level faculty member. I also encourage them to seek out mentors in different fields or areas of interest, which may include a PhD in a laboratory or a CMO of an ophthalmic company. Under the leadership of my previous chairman Dr. David Epstein and my current chairman Dr. Edward Buckley, we have been able to maintain a successful mentoring department for our residents and faculty at Duke Eye Center.

4. You currently serve on the Executive Committee for the American Society of Cataract and Refractive Surgery (ASCRS) as Treasurer and are slated to be President in the year 2020. Please introduce ASCRS to our readers. What are your key roles and responsibilities in the organization? Also, what are the long-term goals and visions you hope to see at ASCRS?

- ASCRS is an international, educational society with more than 8,000 members. Its mission is to advance the art and science of ophthalmic surgery and the knowledge and skills of ophthalmic surgeons by providing clinical and practice management education and by working with patients, government, and the medical community to promote the delivery and advancement of high-

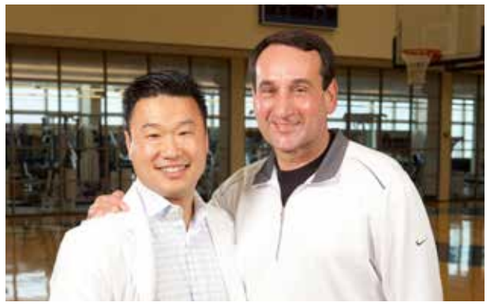
Dr. Kim with ASCRS Executive Committee

quality eye care. Since its founding in 1974, ASCRS has led the field through significant advances in technology and clinical science through its educational programs, publications and online resources. ASCRS has become the surgeons' primary source of up-to-date clinical information, published research, and regulatory information affecting the practice of medicine.

As a supporter and believer in ASCRS's mission, I have served the organization in different key roles and responsibilities over the past 15 years and have so many people at ASCRS to thank for my involvement (but not enough space to list here). After working as an ASCRS Cornea Clinical Committee member for 4 years, I was chosen to serve as its Chair for the next several years. I was then nominated to the Executive Committee, fulfilling my duties as Secretary in 2017 and Treasurer this current year, followed by Vice President in 2019 and President of ASCRS in 2020. It has been a tremendous honor to serve an organization that has done so much for ophthalmology. My long-term goals include helping to expand ASCRS's domestic membership base by specifically engaging the young to middle-aged ophthalmologist and also expand educational opportunities, such as web-based learning and virtual conferences, that it offers beyond its annual meeting. I envision ASCRS to be the core organization that offers all the essential tools and resources for the cataract and refractive surgeon to become more proficient in his/her profession.

5. Dr. Kim, you have extensive publications in over 300 journal articles, textbook chapters, and scientific abstracts and 4 textbooks. As an eminent opinion leader in ophthalmology who has delivered over 300 invited lectures both nationally and internationally, what are some significant changes or trends you have noticed in the field of ophthalmology? What do you forecast in the next five years?

- I have been fortunate to have collaborated with so many of my trainees and colleagues on clinical and research projects that have resulted in these scholarly publications. I am also appreciative of the numerous invitations I have received to lecture on my clinical and research work all over the nation and the world. Over the years, I have published and lectured on a wide variety of topics that encompass clinical observations, diagnostic modalities, surgical techniques and complications, technological advances and instrumentation, and management strategies. Some trends I have noted in our field is the increasing emphasis on outcomes-based research and translational medicine. More than ever, patients have a higher expectation with their surgical procedures and seek out more information about the quality of the care they are receiving. Over the next 5 years, I envision that trend will only grow, and the medical field will need tools like electronic health records and registries and possibly even artificial intelligence to help improve patient care.



Dr. Kim with coach Mike Krzyzewski of the Duke men's basketball team

6. WKMJ has readers from over 10 countries globally, including current students who are pursuing their goals as physicians. Please share your final words with our readers.

- Medicine is a wonderful field that can be extremely gratifying as a career. However, the path to becoming a physician is not an easy one and will demand a lot of your time and effort. In pursuing this path, my strong advice is to try your best to maintain a work-life balance, which includes your family life as well as your personal hobbies. I have 2 passionate hobbies, which include music and sports, which have interestingly evolved into related activities throughout my career. My musical interests started with studying classical piano for 15 years as a child and then somehow transitioned into DJing during high school. As an ophthalmologist, I resurrected this hobby in 2010, which has now grown into a major social event for both the annual AAO and ASCRS meetings. During these events, I (a.k.a. DJ Special K) spin to a crowd of about 2000 eye care providers that attend these meetings at major entertainment venues like the House of Blues. It has provided a refreshing way to diversify what I do at these busy conferences, and it also helps me connect with my colleagues in ophthalmology in a very fun and different way. My interests in sports started with a black belt in Tae Kwon Do and playing high school basketball and tennis. I quickly became an avid Duke basketball fan during my undergraduate years. When I came back on the Duke Eye Center faculty in 1997, I reconnected with the Duke basketball program by providing the eye care and an annual eye screening for the players and coaches. Though this initiative, I became the Consultant Ophthalmologist for the Duke Men's Basketball Team and formed a close relationship with Coach K and his players and staff. It has been such a special treat to give back to the school that gave me so much, and also to bond with my older daughter Ashley, who is currently a sophomore at Duke. My wife Ellie is Associate Professor of Radiology at UNC and definitely deserves a lot of the credit for raising Ashley and my younger daughter Kayley, who plays on her high school varsity women's golf team as an 8th grader. These are the kinds of accomplishments that you will really cherish and remember during and after your career in medicine. W

Dr. Kim with his family at Juneau, Alaska

Terry Kim, MD

Vice President and President-Elect, American Society of Cataract and Refractive Surgery (ASCRS)

Professor of Ophthalmology, Chief of the Cornea and External Disease Service at Duke University Eye Center

Terry Kim, MD, is Professor of Ophthalmology at Duke University School of Medicine and serves as Chief of the Cornea and External Disease Division and Director of the Refractive Surgery Service at Duke University Eye Center. Dr. Kim's clinical and surgical expertise has resulted in continual annual listings by *Best Doctors in America®, Best Doctors in North Carolina®, and America's Top Ophthalmologists®* since 2003 as well as featured stories on the Discovery Channel and The Wall Street Journal. Dr. Kim's academic accomplishments include over 300 peer-reviewed journal articles, textbook chapters, and scientific abstracts as well as 4 well-respected textbooks on corneal diseases, corneal transplantation, and cataract surgery. His clinical and research work has earned him honors and grants from the AAO, ASCRS, National Institutes of Health, the Fight for Sight/Research to Prevent Blindness Foundation, and the Heed Ophthalmic Foundation. Dr. Kim serves on the Executive Committee of ASCRS, the Annual Program Committee of the AAO, and the Board of Directors of the Cornea Society. He also sits on the Editorial Board for several peer-reviewed journals and trade publications, including *Cornea, Journal of Cataract and Refractive Surgery, Ocular Surgery News, Eyeworld, Cataract & Refractive Surgery Today*. Dr. Kim serves as Consultant to the Ophthalmic Devices Panel of the FDA, Consultant Ophthalmologist for the Duke Men's Basketball Team, and Consultant to numerous ophthalmic companies.

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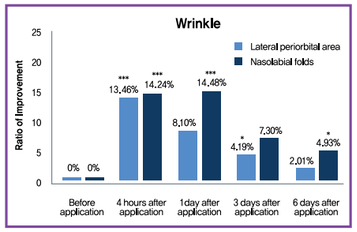
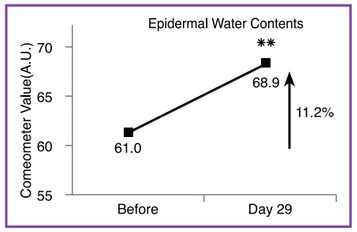
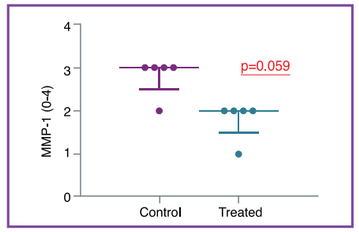


[Fig.1] Improvement of Wrinkle Indentation Index

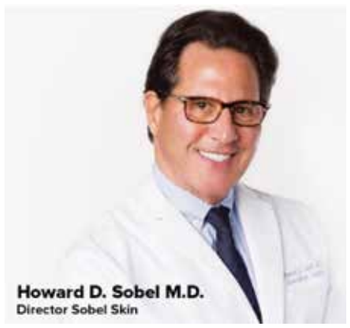


[Fig.2] Increase of Water Contents Level



[Fig.3] Inhibition of Collagenase(MMP-1)

* Excerpted from each clinical study report (Fig.1 - Korea Dermatology Research Institute, Fig. 2 - CHA University School of Medicine, Fig. 3 - Seoul National University Hospital)



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SPECIAL REPORT

New York Health Forum at a Glance

With the 11th New York Health Forum (NYHF) coming December at the Yale Club of New York, with the theme "Healthcare and Life Sciences Industry: Preparing for 2019," here is the breakdown on everything you should know about the event.

About New York Health Forum

The New York Health Forum is a quarter-yearly, one-day event that attracts innovators from all areas of the global medical and life sciences industry, including prominent physicians, researchers, policymakers and financial investors. This winter, the 11th NYHF will be taking place on December 18 with a panelist lineup of various experts, from the founder of the first health records blockchain in the U.S. to the business development executive of a major South Korean drug development company.

Four times a year, the NYHF organizes discussions that examine the most pressing issues and concerns facing the healthcare industry, gathering guest speakers, executives, legislators, scientists and medical practitioners in New York City to share their ideas, expertise and knowledge.

The event—which first launched in 2014—is organized by the forum's chairman, Dr. DoHyun Cho. Dr. Cho is also the President and CEO of the W Medical Strategy Group, a pharmaceutical and biotechnology industry consulting firm focused on providing solutions for the entire healthcare value chain.

NYHF Mission

The NYHF's mission is to actively present significant agendas to the broader healthcare industry, contributing to better public health by illuminating public concerns and pushing for innovation in industry development, technology and management.

The forum, aims to be a "foundation of communication among all areas of healthcare industry," ultimately leading to the discovery and creation of solutions that combine "the ideas of science, industry, and policy for a healthier society." With clear slogans, discussion topics and influential attendees, the NYHF hopes that dialogue can strengthen and form healthcare partnerships while promoting the sharing of knowledge at all levels and within all areas of the healthcare landscape. Every meeting has brought together individuals from an assortment of backgrounds such as business, academia, research facilities and medical service providers.

For the final meeting of 2018, the 11th Forum has been given the theme of "Healthcare and Life Sciences Industry: Preparing for 2019." Celebrating its continuous efforts to build on its programs and platform, the NYHF plans to provide "the setting for stimulating and informative discussions on [current] investment trends, landscapes, risks, and more," with an expected audience of more than one hundred investors, health science professionals and representatives from biopharmaceutical and medical technology companies.

The Purpose of NYHF

NYHF was established in response to the recognition of a need; with the increasing growth and globalization of the healthcare industry, Dr. Cho believed that a platform to foster mutual collaboration and multilateral connections would be both necessary and beneficial to the greater community.

Accordingly, each meeting presents a particular theme, or slogan, under which the discourse and partnerships begin. The past two forums have focused on the following subjects: "Collaboration for Success: Multi-Regional Clinical Development" and "Creating Corporate Shared Value with Society: Supporting Water, Bee and Cancer Research."

The upcoming 11th forum will focus on identifying and forecasting current and future healthcare and life science trends. The NYHF plans to highlight the utilization of licensing in therapeutic companies and mergers and acquisitions in the pharmaceutical and biotechnology industry as key growth strategies. The "transformational role" of new digital health solutions in both patient care and clinical development will also be examined.

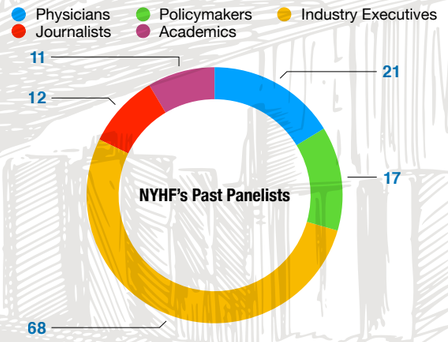
With a number of high-profile sponsors—Hanaro Medical Foundation, Holy Name Medical Center, Enzychem Lifesciences, the Center for Viral Hepatitis and Gilead, among others—supporting its initiatives and work, the NYHF promises to continue to deliver on its belief that the sharing of expert knowledge and ideas can fuel greater growth and empower health industry stakeholders in the midst of rapid change.

NYHF in Numbers

Now looking to hold its 11th conference, the NYHF attracts an increasing number of influential individuals in all fields related to healthcare; what began as an audience of 50 has quickly grown to about 200. Subsequently, the NYHF expects at least a hundred participants for its upcoming December meeting, all from diverse—and very global—backgrounds.

With a regular group of prominent attendees, the NYHF places special emphasis on the quality of its panel discussions, carefully assembling its programs of guest speakers. Some more information about the forum's past 129 panelists is gathered as shown in the infographic below.

Moreover, at each conference, a select few individuals are honored with awards. The New York Health Forum Award recognizes "exemplary and innovative efforts in improving the human condition," seeking to reward "those who have served humanity at large." The event also presents the WMSG Distinguished Contribution Award to individuals or organizations who have "contributed to the advancement of the healthcare industry or the W Medical Strategy Group."



Initiation Ceremony: "Navigating Total Healthcare" | **February 11th, 2014**

The 2014 Special Forum marked the launch of the NYHF as a major initiative to facilitate the advancement of medical research, products and services in the healthcare community. The sessions discussed how the industry can generate greater value and synergies through integration, collaboration and crossovers.

A Timeline of NEW YORK HEALTH FORUM

2014

1st NYHF: "Forecasting Healthcare in 2015 & Trans-Cultural Healthcare"
December 18th, 2014

The 1st NYHF focused on strategies for building international connections among healthcare leaders and business developers to meet growing patient needs. The first panel covered challenges and opportunities for pharma, devices and healthcare providers. The second panel had an active discussion about the trans-cultural healthcare and the establishment of the Center for Viral Hepatitis.

2nd NYHF: "The Pacific Connection: US-East Asia Pharma Collaboration"
February 11th, 2015

The 2nd NYHF was co-hosted with the New York Pharma Forum. The meeting highlighted growing U.S. opportunities for pharmaceutical and biotechnology companies in Asia, especially China, Korea and Japan. Current trends in digital health were also covered, as panelists discussed how mobile devices are expected to change the clinical research landscape.

3rd NYHF: "Future is Now: The Era of Mobile Health"
May 21st, 2015

Experts in the mobile health space were invited to the 3rd NYHF to share insights on the newest technologies, such as remote biometric monitoring and built-in heart rate sensors, in addition to discussing the future of such technologies in a healthcare environment sensitive to privacy issues and the legitimacy of clinical data.

4th NYHF: Co-Hosting "Furthering Global Biopharma: Opportunities for Development with East Asia"
November 12th, 2015

The 4th NYHF exchanged views on the positive and promising aspects of the rapidly growing East Asian life sciences industries. In particular, panelists discussed the nature of clinical trials performed in East Asia, myriad of opportunities for collaboration between Japan's public and academic sectors and drug discovery and development processes in South Korea.

5th NYHF: "Key Trends in US Biopharma/MedTech Investing"
March 31st, 2016

The 5th NYHF was held to dicuss the changing financing environment for biopharmaceutical and medical technology companies, specifically reviewing alternative finance trends in a capital-intensive market. The conference explored new additions to the spectrum of healthcare financing as companies adapt to support their financial needs for new drug development.

6th NYHF: "Korea Rise: New Strategies Transforming Korean Biopharma and Unparalleled Opportunities for Collaboration"
September 27th, 2016

The 6th NYHF put the spotlight on the South Korean healthcare industry, delving into popular growth strategies of Korean firms and their major multinational partnerships. The country's Chungbuk Province was also introduced as a rising hub for internationally competitive biopharmaceutical firms; this growth was connected to other key trends in the global biopharma space.

7th NYHF: "Special KOL Discussion: Strengthening World Korean Medical Journal (WKMJ)"
June 21st, 2017

As an affiliated organization, the NYHF gathered Key Opinion Leaders to discuss how to strengthen the position of the World Korean Medical Journal (WKMJ) for its seventh meeting. Looking at the Journal's past editions and major milestones, the Forum deliberated the paths available to WKMJ to grow as an important publication for healthcare industry insiders.

8th NYHF: "Powerful Transformers of Beauty Industry"
December 4th, 2017

With an audience of around one hundred beauty industry regulators, entrepreneurs, investors, consultants, power bloggers and other stakeholders, the 8th NYHF explored today's demand-driven beauty industry. Invited panelists discussed the trend of eco-innovation in the beauty business, in addition to popular legal issues and online marketing and social media strategies.

9th NYHF: "Collaboration for Success: Multi-Regional Clinical Development"
May 25th, 2018

The ninth meeting of the NYHF focused on biopharmaceutical collaborations established to fuel clinical development processes. The investment trends of contract research organizations (CRO), including mergers and acquisitions, as well as the specifications and popular technologies for successful multi-regional clinical trials were covered by three panels.

10th NYHF: "Special KOL Discussion: Creating Corporate Shared Value with Society"
September 28, 2018

As its slogan suggests, the 10th NYHF focused on the creation of shared corporate value in the context of healthcare, particularly examining water, bee and cancer research. The 10th Forum also introduced the Green Alley Foundation founded by Green Alley, a beauty platform and distributor for cruelty-free K-beauty products that utilize natural ingredients.

1st 2nd 3rd 4th 5th 6th 7th 8th 9th 10th

2018

Benefit of NYHF

By design, the NYHF is a platform through which solutions to practical needs of the healthcare industry are delivered. The event has primarily served Asian companies looking to enter or advance its position within the U.S., connecting them with investment partners, strategic consultants, potential markets and other significant resources necessary for sustained success. Unlike other healthcare industry forums, the NYHF differentiates itself by bringing together a wide spectrum of participants from different parts of the globe and the healthcare value chain. These attendees are then strongly encouraged to initiate an in-depth conversations that have often resulted in long-term collaborations. Accordingly, the NYHF has held eleven Forums in the span of four years, evidence of its continued success in forging such partnerships.

Future of NYHF

Looking to the future, the New York Health Forum aspires to accomplish three objectives. The first is to be a vital channel of communication that mobilizes the global healthcare industry's Key Opinion Leaders (KOL) to come together to discuss major therapeutic trends, topics and dilemmas. On the same vein, the event also desires to become the gateway to address such issues and agendas, eventually helping to deliver much-needed solutions to policymakers and end users, who are usually physicians and patients. Finally, the NYHF aims to become a stage for meaningful cross-border exchange. Recognizing the lack of conferences that focus on cross-border transactions within the healthcare space, the organization distinctly offers a stage for international discussion and reflection on specific issues regarding cross-border activities. And with its forward-looking 11th Forum set for December, it appears to be on the right track. W

Yisun Yuk
Director, Business Operations
W Medical Strategy Group

Yisun is director of business operations at W Medical Strategy Group. She also is an editorial staff of WKMJ and organizing executive of New York Health Forum.

Yeereum Chung, RN, BSN
Manager, Project Management
W Medical Strategy Group

Yeereum is manager of project management at W Medical Strategy Group. She also is an editorial staff of WKMJ and organizing executive of New York Health Forum.

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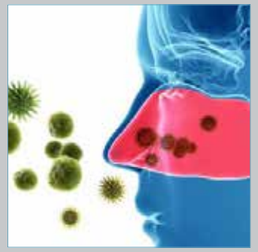


BIOPHARMACEUTICAL REPORT I

ALDEYRA'S REPROXALAP HAS EXPERTS MIXED ON SEASONAL ALLERGIC CONJUNCTIVITIS FOCUS IN PHASE III

BIOPHARMACEUTICAL REPORT II

ACLARIS' PHASE II RESULTS FOR ATI-502 AND ATI- 501 IN ALOPECIA MAY LACK COSMETIC SIGNIFICANCE

Aldeyra's Reproxalap has Experts Mixed on Seasonal Allergic Conjunctivitis Focus in Phase III

Aldeyra Therapeutics' (NASDAQ:ALDX) focus on seasonal allergies in its Phase III study of reproxalap in allergic conjunctivitis has three experts unsure on renewed success prospects given its Phase IIb primary endpoint miss in perennial and seasonal allergy. They noted the Phase IIb data did not give sufficient information on why the perennial allergy group performed poorer than the seasonal group or by how much, while a general lack of studies in literature about this novel mechanism prompts caution.

However, an expert who had been an investigator in reproxalap's trials in other indications said that success in those trials, along with the understanding that seasonal allergies are less likely to be at risk of a placebo effect, could tip reproxalap over into a successful Phase III.

Reproxalap is in a 300-patient Phase III trial, ALLEVIATE (NCT03494504), with results expected in 2H18, according to the company.

Reproxalap had positive Phase IIb data in dry eye (NCT03404115) released on 26 September, and is in an ongoing Phase III trial for noninfectious uveitis (NCT03131154).

That said, experts agreed reproxalap has shown to be well-tolerated in the Phase IIb data and in other indications. However, some experts inquired about its long-term rebound safety, which will require longer follow-up data.

Analysts say despite the Phase II miss, reproxalap provided evidence of effectiveness in allergic conjunctivitis and, pending success in pivotal trials, could be approved before other indications under investigation. They said a successful Phase III could prompt a second Phase III trial for a possible 2020 NDA filing. Analysts noted there is an unmet need for durable treatment options in allergic conjunctivitis, and as reproxalap has shown signs of better durability than current options, it could achieve USD 1bn in sales by 2030. Aldeyra has a market cap of USD 288m.

Aldeyra did not respond for comment.

Mixed opinions on Phase III success

While it would seem that excluding the perennial allergic conjunctivitis group from the Phase III study could tip the results toward success, the failed Phase IIb release provides insufficient subgroup data to rule on success in the seasonal allergic group, Dr John Dart, consultant ophthalmologist, Moorfields Eye Hospital, London and Dr Stephen Foster, president of Massachusetts Eye Research and Surgery Institution said.

The Phase IIb (NCT03012165) data, announced in a June 2017 press release, saw that in 154 patients with allergic conjunctivitis, reproxalap did not meet the primary endpoint of having a statistically significant difference in patients with a one-point improvement in the allergen challenge at one hour versus placebo. However, the difference in improvement it did achieve was statistically significant ($p<0.03$), and in the seasonal allergy subgroup, the improvement was 0.8 ($p=0.02$).

> "There is a general lack of clinical studies beyond Aldeyra's trials to prove the trap theory, and the Phase IIb data did not seem to offer a definitive proof of concept"

As the seasonal allergy group already missed its primary endpoint in Phase IIb, it would require some close reexamination of trial design to gear reproxalap for success in a modified Phase III, Foster said.

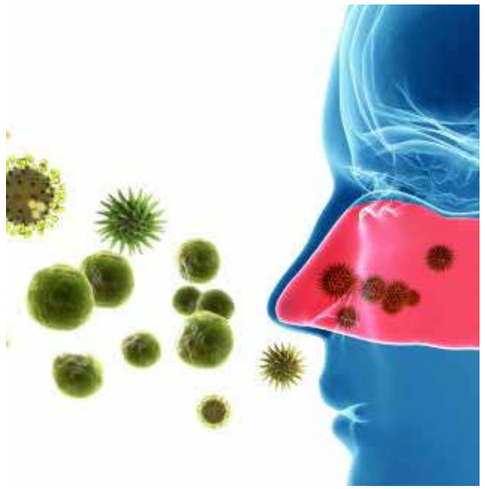
The Phase III primary endpoint is ocular itching using the same scale as in the Phase IIb, but the efficacy assessment period is day -21 through day 1, while the Phase IIb assessed days 3 through 15. Experts said it was not clear what the changing of the timeframe could mean for the Phase III outcome, but noted the drug has shown a rapid onset of action, one hour post treatment.

The June release also stated patients with seasonal allergies demonstrated a 37% improvement in ocular itching at 20 minutes post-treatment, which would have corresponded with a one-point improvement. Those patients also exhibited 55% and 65% itching improvement at 30 and 60 minutes post treatment, respectively.

The seasonal allergy group data indeed looks promising, and the >37% improvements are clinically significant, said Dr John Sheppard, professor of ophthalmology, Eastern Virginia Medical School, Norfolk and Dr Neel Desai, ophthalmologist, Eye Institute of West Florida.

Yet, Foster said the magnitude of benefit was welcome but not overwhelmingly good, and a 50% improvement might have been more encouraging.

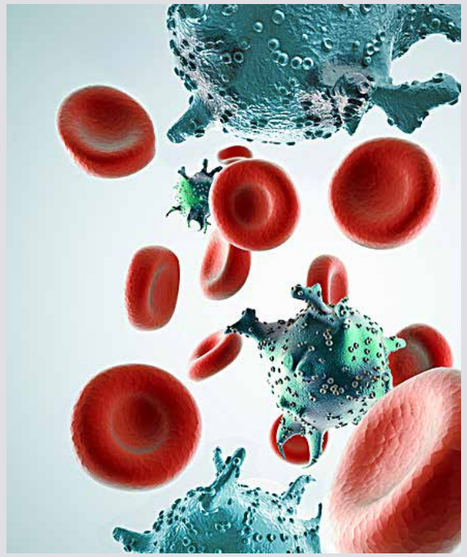
There is a general lack of clinical studies beyond Aldeyra's trials to prove the trap theory, and the Phase IIb data did not seem to offer a definitive proof of concept (POC) of its benefit in seasonal allergic conjunctivitis—since it was designed to look at both seasonal and perennial—thus making Phase III predictions difficult, Dart said.



He noted preclinical studies linking aldehydes to ocular inflammation, but aldehydes have been more extensively studied in autoimmune disease.

Sheppard agreed that understanding of reproxalap's MOA—trapping aldehydes thought to mediate downstream inflammatory processes—is nascent, but consecutive successful trials where lowered aldehyde levels have led to improved inflammatory symptoms lend optimism for allergic conjunctivitis, even if Phase IIb was a miss, he said.

As an investigator in the dry eye and uveitis trials, Sheppard said he has seen a clear benefit between the reduction of aldehyde levels and improvement of inflammatory symptoms. He acknowledged that the etiologies of allergic conjunctivitis might differ from dry eye syndrome or uveitis, but noted the obtained POC in the other indications as promising for ALLEVIATE's success.



It could be possible that focusing only on seasonal allergy patients could prompt better success versus placebo, as seasonal allergy symptoms tend to be more intense and less likely improved with placebo vs perennial allergy patients with lower intensity symptoms, Sheppard said. Desai and Foster said there is no clear-cut difference in symptom severity and it varies greatly.

Robust safety signals, but rebound effect unclear

The Phase IIb data showed reproxalap to be well-tolerated, with no concerning adverse events, according to the June 2017 release.

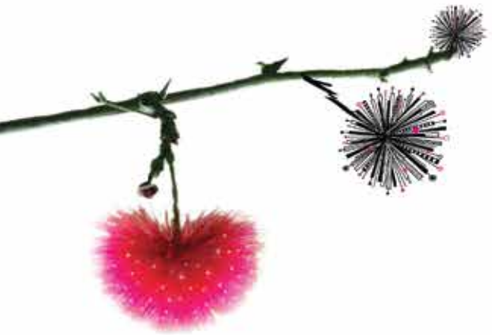
Reproxalap was also shown to be well-tolerated in the Phase IIb (NCT03404115) dry eye trial, with adverse events mostly mild, and this is encouraging for its safety in the allergic conjunctivitis trial, Sheppard said. He noted that side effects were mostly eye irritation, and agreed that reproxalap stings more than saline, but is of low concern.

However, the Phase IIb data is unable to show longer-term and chronic-use safety, especially with regards to a rebound effect, Desai said. Some of the current drugs used for allergic conjunctivitis, including ocular vasoconstrictors, carry the risk of a rebound effect when used chronically, he said. If such a risk was present, it would mean an increasing amount of agent would be needed to be effective, and physicians might advise for cautious use when prescribing to avoid triggering the rebound effect, Foster and Desai said.

Dart said as reproxalap is targeting the aldehydes itself rather than receptors, rebound might be less of a concern, but noted the impact of long-term aldehyde trapping is not yet known. W

Shuan Sim
Reporter, New York

Shuan has a Bachelors degree in linguistics and journalism from New York University. He had previously worked in various trade publications covering technology, precious metals and diamond trade and more. Shuan has worked as a breaking news reporter covering Asia and an international reporter in the Czech Republic. He's also fluent in Mandarin and proficient in Japanese.



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

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BIOPHARMA REPORT II

Aclaris' Phase II Results for ATI-502 and ATI- 501 in Alopecia May Lack Cosmetic Significance

Aclaris Therapeutics' (NASDAQ:ACRS) Phase II ATI-502 for alopecia areata (AA) and Phase II for ATI-501 for AA, alopecia universalis (AU) and alopecia totalis (AT) may lack cosmetic significance due to their primary endpoints, experts said.

The primary endpoint of the topical ATI-502 study measures the amount of hair regrowth by the severity of the alopecia tool, as cited by ClinicalTrials.gov. Aclaris also notes the trial has pharmacokinetic (PK) and pharmacodynamic (PD) endpoints in a June press release. The Severity of Alopecia Tool (SALT) is the primary endpoint of the oral ATI-501 study, according to ClinicalTrials.gov.

The trials' primary endpoints are inadequate to gauge cosmetic significance, said three experts. SALT measures hair loss in different areas rather than the amount of hair regrowth, the latter of which is more relevant for cosmetic value, experts noted. Photographic images should be used to assess cosmetic significance, another expert said.

Experts also noted mixed views on whether the SALT primary endpoint in AT-501 will allow for clinical relevance considering the wider breath of skin area covered in the trial. Still, overall experts expect a positive reduction in hair loss for both topical ATI-502 and oral ATI-501 due to the clinical and real-world results from other JAK inhibitors, which is the class of both Aclaris therapies, and the preliminary positive Phase II biomarker results for ATI-502.

Despite high efficacy expectations, experts also said the primary endpoint durations, at 12 weeks for topical ATI-502 (NCT03354637) and 24 weeks for oral ATI-501 (NCT03594227), are not long enough to assess long-term safety. An open-label extension (OLE) study of at least two years should be performed for both trials to assess safety, as opposed to the company's six-month OLE plan for ATI-502, said experts. In particular, concerns about the potential development of squamous cell carcinoma remain due to the mechanism of action (MOA), said experts.

The full Phase II trial readout for ATI-502 is expected in 1H19 and in 2H19 for ATI-501, according to an Aclaris 2Q18 financial report.

Analysts predict positive results for both Phase II studies, with predicted combined peak sales of USD 1bn, with no peak year indicated. Aclaris' market cap is USD 407m.

Aclaris declined to comment.

> "Both the Phase II trials for ATI-502 and ATI-501 have elicited concerns on cosmetic significance"

Cosmetic significance ultimately most desirable

Both the Phase II trials for ATI-502 and ATI-501 have elicited concerns on cosmetic significance. Despite the SALT's clinical relevance in alopecia, the studies' primary endpoints should have considered the amount of hair regrowth, said three experts. The alopecia tool score measures hair loss with a specific value before and after treatment, whereas determining the hair regrowth by counting hairs in a specific area pre- and post-therapy is closer to achieving cosmetic significance, three experts said.

Photographic imaging and patient satisfaction surveys should also have been co-primary endpoints in both studies to gauge cosmetic significance, said Dr Paul McAndrews, clinical professor, Department of Dermatology, University of Southern California School of Medicine, Pasadena.

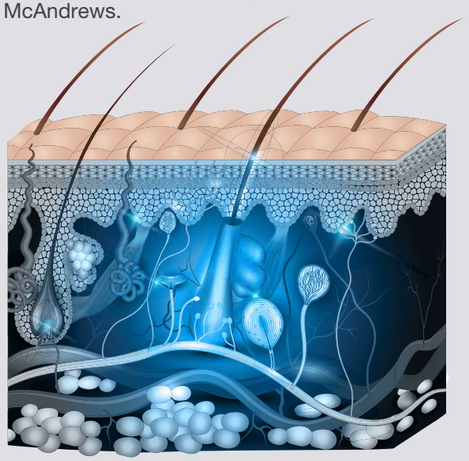
Although the alopecia tool measurement determines clinical significance, cosmetic significance is more important for the patient as it is pertains to patient satisfaction about their treatment and any improvement in hair growth, said Dr Jason Reichenberg, clinical director of dermatology, University of Texas Southwestern, Austin and McAndrews. Even if there is 80% hair regrowth, this may not be cosmetically significant as it could mean only a few more strands of hair, said Reichenberg and McAndrews.

Experts declined or did not comment on the specific percentages and results expected for the SALT for both the ATI-502 and ATI-501 studies.

For ATI-501, which has a target population of AA, AU and AT, the SALT score, which measures the hair regrowth on the scalp, does not accurately measure the efficacy of the treatment on the back and the legs, said Dr David Perez-Meza, medical

“Although the alopecia tool measurement determines clinical significance, cosmetic significance is more important for the patient”

director, Perez-Meza Hair Institute, Malaga, Spain. Even a trial secondary endpoint, the Alopecia Density and Extent Score (ALODEX), measures hair regrowth in the scalp as well, said Perez-Meza. However, Yanling Liao, PhD, clinical assistant professor, Department of Pediatrics, New York Medical College, said it is a sufficient measure of hair regrowth even elsewhere in the body. Even though the primary endpoint is just measuring hair on the scalp, patients are more concerned about hair on their scalp than underarms or pubic regions, making SALT an adequate clinical measure, said Reichenberg and McAndrews.



Positive previous JAK, Phase II data bodes well

Earlier data on JAK inhibitors indicates they are clinically significant in treating AA, said Liao and Perez-Meza. They pointed to a pilot study with Incyte’s (NASDAQ:INCY) Jakafi (ruxolitinib), which showed that nine out of 12 patients (75%) treated with Jakafi had significant scalp hair regrowth and improvement of AA (Mackay-Wiggan et al. JCI Insight. 2016 Sep 22;1(15)).

Pfizer’s (NYSE:PFE) Xeljanz (tofacitinib), a JAK inhibitor approved for rheumatic arthritis and psoriatic arthritis, is being used off-label for AA treatment, said Reichenberg and McAndrews. Xeljanz has shown clinically significant results for patients, therefore ATI-502 and ATI-502 should have similar positive results, said McAndrews.

In addition, in interim Phase II data for ATI-502 in June, two of six patients had marked elevation of interferon gamma (IFN-γ) and cytotoxic T-cell (CTL) gene expression at baseline. After 28 days, the patient with the active treatment showed reduction in the two biomarkers, whilst the patient on vehicle did not demonstrate a positive change.
This data suggests that the MOA of ATI-502 works well in dampening the increase in the IFN-γ and CTL immune response, said Liao, Perez-Meza, Reichenberg and McAndrews. The results gives confidence for further positive outcomes from both Phase II trials, as the MOA reduces the immune response, which is the cause of AA, they said.

However, although there was a reduction in the biomarkers on the patient treated with ATI-502, it is unclear whether the samples were taken from the blood or skin, said Dr Natasha Mesinkova, assistant professor, Department of Dermatology, UC Irvine School of Medicine, California. Reduction in the skin biomarkers would be needed to show ATI-502’s clinical significance, said Mesinkova,

Safety concerns need long-term assessment

Safety concerns linger about the prolonged effects of using JAK inhibitors, said Liao, Perez-Meza, Reichenberg, McAndrews and Dr Brett King, assistant professor of dermatology, Yale School of Medicine, New Haven, Connecticut. In particular, concerns on the risk of squamous cell carcinoma persist due its MOA, as JAK inhibitors can have severe systemic involvement in inhibiting immune signalling, resulting in cancer, said Liao, Reichenberg and McAndrews.

The most common adverse events associated with JAK inhibitors such as Jakafi are anaemia and thrombocytopenia, including the appearance of squamous cell carcinoma, said Liao, Reichenberg and McAndrews (Aboul-Fettouh et al. JAAD Case Rep. 2018 Jun; 4(5): 455–457).

Therefore, the safety assessment should be longer than 12 weeks and 24 weeks for the primary endpoint time frame for ATI-502 and ATI-501, respectively, said Liao, Reichenberg and McAndrews. The current OLE of six months should be up to two years to assess the long-term concerns, they said.

Topical ATI-502 will have fewer side effects compared to oral ATI-501, as it is less systemic, said Liao, Perez-Meza, Reichenberg and McAndrews. Interim Phase II ATI-502 data also suggested there is no systemic involvement, as indicated by plasma drug levels that were below the limits of quantification (1ng/ml) in all subjects at Day 28, said Liao, Perez-Meza, Reichenberg and McAndrews.

Arafa Salam, PhD
Reporter, London

Arafa has completed a PhD in Clinical Immunology and a BSc in Biomedical Sciences from St. George’s University of London. Arafa’s PhD focussed on investigating the effects of an immune inhibitory receptor on Hepatitis C infected patients and on healthy controls. Prior to joining GlobalData, Arafa worked at a Clinical Trials Administrator at St. George’s Hospital.

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FOLLOW THE JOURNEY OF VIREAD

COMPLETE RESPONSE RESULTS AT YEAR 1...

#1 **Prescribed oral antiviral** according to US prescription data for treatment of CHB[1a]

AT YEAR 1

The primary endpoint—complete response*—was evaluated in Studies 102 and 103[2]

THROUGH YEAR 8

Resistance was evaluated as a secondary endpoint[2,3]

In Study 102 (HBeAg–, n=375) and Study 103 (HBeAg+, n=266), a combined total of 641 adult patients with chronic hepatitis B (CHB) and compensated liver disease who were primarily nucleoside treatment naïve entered a 48-week, randomized, double-blind, active-controlled treatment period comparing VIREAD 300 mg to adefovir dipivoxil 10 mg. Subjects who completed double-blind treatment at Week 48 were eligible to roll over with no interruption in treatment to open-label VIREAD. Of 641 patients enrolled in the initial trials, 412 (64%) completed 384 weeks of treatment.[2]

***The primary endpoint in Studies 102 and 103 was complete response to treatment at 48 weeks as defined by HBV DNA <400 copies/mL (69 IU/mL) + histological response (Knodell necroinflammatory score improvement of ≥2 points without worsening in Knodell fibrosis score). Annual evaluation of resistance was a prespecified secondary endpoint. Cumulative VIREAD genotypic resistance was evaluated annually for up to 384 weeks in Studies 102, 103, 106, 108, and 121.[2,3]**

71% of HBeAg– VIREAD patients vs **49%** of adefovir dipivoxil patients.[2-4]

67% of HBeAg+ VIREAD patients vs **12%** of adefovir dipivoxil patients.[2,3,5]

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**

[a]Healthcare Analytics Monthly data, August 2014-June 2015.

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

GILEAD IS COMMITTED TO THE EDUCATION AND TREATMENT OF CHRONIC HEPATITIS B.

Viread® 300 mg tablets
tenofovir disoproxil fumarate

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

...AT 8 YEARS: NO RESISTANCE WAS

Annual evaluation of resistance was a prespecified secondary endpoint for Studies 102 and 103 in HBeAg- and HBeAg+ chronic hepatitis B patients[3]; no evidence of resistance was found. Cumulative VIREAD genotypic resistance was evaluated annually for up to 384 weeks in Studies 102, 103, 106, 108, and 121.[2,4,5]

- In the nucleotide-naïve population from Studies 102 and 103, HBeAg+ subjects had a higher baseline viral load than HBeAg– subjects and a significantly higher proportion of the subjects remained viremic at their last time point on VIREAD monotherapy (15% vs 5%, respectively)[2]
- HBV isolates from these subjects who remained viremic showed treatment-emergent substitutions; however, no specific substitutions occurred at a sufficient frequency to be associated with resistance to VIREAD (genotypic and phenotypic analyses)[2]

IMPORTANT SAFETY INFORMATION (cont'd)

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
- **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

DETECTED AT YEAR 1 THROUGH YEAR 8

NO HBV RESISTANCE DEVELOPED YEAR 1 through YEAR 8

in clinical trials (Studies 102 and 103)[2,3]*

*Data for Years 2 through 8 are from the open-label phase.[6]

- There was a 64% (412/641) retention rate at Year 8: 266/426 patients given VIREAD→VIREAD; 146/215 patients given adefovir dipivoxil→VIREAD[2,6]

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS (cont'd)

- **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 following pages.

References: 1. Data on file, Gilead Sciences, Inc. Healthcare Analytics. **2.** VIREAD [package insert]. Foster City, CA: Gilead Sciences, Inc.; May 2015. **3.** Marcellin P, Heathcote EJ, Buti M, et al. Tenofovir disoproxil fumarate versus adefovir dipivoxil for chronic hepatitis B. *N Engl J Med.* 2008;359(23):2442-2455. **4.** Data on file, Gilead Sciences, Inc. Study 102 CSR. **5.** Data on file, Gilead Sciences, Inc. Study 103 CSR. **6.** Marcellin P, Gane EJ, Flisiak R, et al. Long term treatment with tenofovir disoproxil fumarate for chronic hepatitis B infection is safe and well tolerated and associated with durable virologic response with no detectable resistance: 8 year results from two phase 3 trials [AASLD abstract 229]. *Hepatology.* 2014;60(4)(suppl):313A-314A.

For more information, visit www.viread.com/hcp

300 mg 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 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 calculated 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

Brief Summary (Cont'd)

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 384 weeks.

Laboratory Abnormalities: in Studies 0102 and 0103 (0–48 Weeks) laboratory 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 384 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 coadministered 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 breastfeed 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 breastfeed 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.

CVH

Center for Viral Hepatitis

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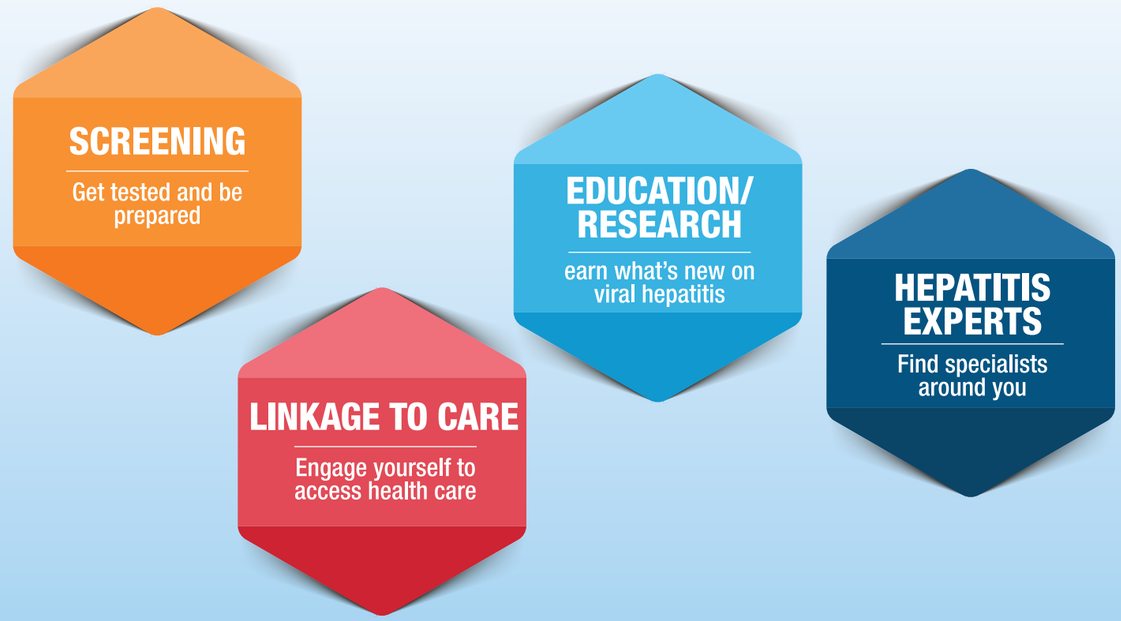

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The conference expect more than 400 companies, both public and private, to deliver presentations to more than 8,000 attendees. The conference provides a unique opportunity for investors to visit with so many inter-related industry leaders in one setting.

Precision Medicine World Conference 2019

January 20-21, 2019 | Silicon Valley, California, USA

Website: https://www.pmwcintl.com/2019sv/
Contact: team@pmwcintl.com

The Precision Medicine World Conference (PMWC) is an independent and established conference series considered to be the preeminent precision medicine conference that attracts recognized leaders, top global researchers and medical professionals, and innovators across healthcare and biotechnology sectors. PMWC provides an exceptional forum for the exchange of information about the latest advances in technology (e.g. DNA sequencing technology), in clinical implementation (e.g. cancer and beyond), research, and in all aspects related to the regulatory and reimbursement sectors.

International Meeting on Simulation in Healthcare (IMSH 2019)

January 26-30, 2019 | San Antonio, Texas, USA

Website: http://imsh2019.com/
Contact: admin@ssih.org

The International Meeting on Simulation in Healthcare (IMSH) is a scientific conference that explores the latest innovations and best practices in healthcare simulation. IMSH provides the tools and resources healthcare professionals need to advance their skills, impact change in delivery systems and practice, and, ultimately, to improve patient safety.

HIMSS Global Conference & Exhibition

February 11-19, 2018 | Orlando, Florida, USA

Website: https://www.himssconference.org/
Contact: himss@compusystems.com

The 2019 HIMSS Global Conference & Exhibition is a leading health information and technology conference held by the Healthcare Information and Management Systems Society (HIMSS), a global non-profit that supports the transformation of health through information and technology. The event will bring together more than 45,000 professionals from over 90 countries to educate, innovate, and collaborate in order to accomplish this mission. Attendees can choose from around 300 education sessions, 1,300 vendors, and hundreds of special programs and networking events.

19th Annual Minimally Invasive Surgery Symposium (MISS)

February 25-28, 2019 | Las Vegas, Nevada, USA

Website: https://www.globalacademycme.com/conferences/miss/minimally-invasive-surgery-symposium-miss-overview
Contact: m.palermo.globalacademycme@gmail.com

The 19th Annual Minimally Invasive Surgery Symposium (MISS) will offer compelling lectures, surgical video presentations, and lively discussion and debate by world-renowned experts. Topics to be discussed include colon, hernia, foregut, enhanced recovery after surgery and metabolic/bariatric surgery.

10th Annual CUGH Conference: Translation and Implementation for Impact in Global Health

March 8-10, 2019 | Chicago, Illinois, USA

Website: https://www.cugh2019.org/
Contact: info@cugh.org

The theme of the 10th Annual Consortium of Universities for Global Health (CUGH) Conference is “Translation and Implementation for Impact in Global Health.” As a leading academic global health conference, the event will bring together leaders from a broad range of areas to share how to overcome the knowledge-needs gap, scale up evidence-based solutions and impact public policies to effectively address pressing global challenges. Attendees will have many opportunities to engage, learn, contribute and collaborate with each other in a dynamic, inspiring environment.

2019 Health Datapalooza

March 27-28, 2019 | Washington, D.C., USA

Website: https://www.academyhealth.org/events/site/2019-health-datapalooza
Contact: registrations@academyhealth.org

Since its inception, the Health Datapalooza has become the gathering place for people and organizations creating knowledge from data and pioneering innovations that drive health policy and practice. Sitting at the nexus of ideas, evidence, and execution, Health Datapalooza is where federal policymakers and regulatory leads take their seats beside the health system’s chief officers (information, medical, innovation), Silicon Valley startups, data gladiators, and patients.

GHIC 2019: Global Health & Innovation Conference

April 13-19, 2019 | New Haven, Connecticut, USA

Website: https://www.uniteforsight.org/conference/
Contact: ufs@uniteforsight.org

The Global Health & Innovation Conference (GHIC) is the world’s leading and largest global health conference as well as the largest social entrepreneurship conference, with nearly 2,000 professionals and students from all 50 states and more than 55 countries. This must-attend, thought-leading conference convenes leaders, change makers, and participants from all sectors of global health, international development, and social entrepreneurship.

Society for Healthcare Epidemiology of America (SHEA) Spring 2019

April 24-26, 2019 | Boston, Massachusetts, USA

Website: http://sheaspring.org/attendees/registration/

Contact: http://sheaspring.org/contact-us

The SHEA 2019 Program Committee combines the expertise of SHEA members who have served on SHEA meeting planning committees for many years and active leaders from the SHEA Education Committee. It also includes broad subject matter expertise in healthcare epidemiology, antibiotic stewardship, long-term care, research methods, clinical microbiology, patient safety and quality, implementation science, and a wide range of opportunities for networking and communication with peers and experts in the field.

WHCC19- The World Health Care Congress 2019

April 28-May 1, 2019 | Washington, D.C., USA

Website: https://www.worldhealthcarecongress.com/

Contact: wcreg@worldcongress.com

WHCC19 brings together global thought leaders and key decision-makers from all sectors of the healthcare. The WHCC19 agenda keeps care delivery and payment transformation front and center by sharing strategic initiatives, results, and steps to overcome access and affordability issues while delivering high-value care. The congress consists of 4 days of C-Level keynote discussions with over 15 distinct, tactical streams of content where the most knowledgeable people in the field convene to learn about industry best practices and exchange ideas.

2019 ASCO Annual Meeting

May 31-June 4, 2019 | Chicago, Illinois, USA

Website: https://meetings.asco.org/am/register-submit

Contact: customerservice@asco.org

The American Society of Clinical Oncologists (ASCO) Annual Meeting offers premier scientific events for oncology professionals, patient advocates, industry representatives, and major media outlets worldwide. As a renowned conference, the meeting offers a variety of options to access the latest discoveries in science as well as educational opportunities.

Europe

IMCAS World Congress 2019 - International Master Course on Aging Science

January 31-February 2, 2010 | Paris, France

Website: https://www.imcas.com/en/attend/imcas-world-congress-2019

Contact: contact@imcas.com

IMCAS (International Master Course on Aging Science) started in 1994 as a congress dedicated to plastic surgeons and dermatologists. Since its conception, IMCAS has sought to bridge the knowledge vacuum between plastic and reconstructive surgery and dermatology, thereby generating a synergetic and mutually reinforcing interface among these two fields. The 2019 World Congress is expected to attract 10,000 dermatologists and plastic surgeons and more than 230 international exhibiting companies for a fully packed 3-day weekend with 310 teaching hours and over 700 key speakers.

14th International Conference on Alzheimer's & Parkinson's Diseases

March 26-31, 2019 | Lisbon, Portugal

Website: https://adpd.kenes.com/2019

Contact: https://adpd.kenes.com/2019/general-information-(2)/contact-us#.W_ISc3pKjOQ

The 14th International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders, also known as AD/PDTM 2019, will build on the well-earned reputation of previous AD/PDTM conferences. The groundbreaking series of Alzheimer's and Parkinson's Diseases Conferences attract international medical and scientific professionals worldwide to offer high-quality scientific programs covering the most recent research, clinical trials, developments, and treatments.

EuroGUCH 2019

April 5-6, 2019 | Zagreb, Croatia

Website: http://wp1.euroguch.com/

Contact: GTito@paragong.com

The 10th European Meeting on Adult Congenital Heart Disease is the most prestigious conference on adult congenital heart disease in Europe, organized under the working group on Grown-Up Congenital Heart Disease of European Society of Cardiology. With adults with congenital heart disease constituting a rapidly growing cohort of cardiology patients with lifelong and unique requirements, the GUCH believes knowledge in adult congenital heart disease is increasingly important not only for adult congenital cardiologists, but also for trainees and general cardiologists.

Pharma CI Conference & Exhibition

March 5-6, 2019 | Basel, Switzerland

Website: http://europe.pharmaciconference.com

Contact: info@pharmaciconference.com

The Pharma CI Conference & Exhibition is the largest assembly of pharmaceutical competitive intelligence executives, which include senior-level pharma, biotech, and medical device professionals seeking the latest news and the rare chance to network with all the industry's luminaries. The gathering offers opportunities to network with key decision makers and learn about the most pressing and relevant issues facing the competitive intelligence community today. The event also features a lineup of speakers and panelists offering unique insights and expertise.

32nd International Conference on Vaccines and Immunization

March 21-22, 2019 | Aurelia Rome, Italy

Website: https://vaccines-immunization.insightconferences.com

Vaccines Summit 2019 conference features highly enlightening and interactive sessions to encourage the exchange of ideas across a wide range of disciplines in the field of vaccination, Immunization and therapeutics. The conference includes explicit keynote talks from distinguished scientists, plenary sessions, Poster competition, Young Researcher sessions, Symposiums, Workshop and Exhibitions. There will be opportunities for those chosen to present at the meeting to publish a manuscript based on their presentation in the Journal of Vaccines & Immunization or its sister publication, Journal of Clinical & Cellular Immunology and Immunome Research.

Asia

9th Emirates Otorhinolaryngology Audiology and Communication Disorders Congress

January 16-19, 2019 | Dubai, United Arab Emirates

Website: http://www.emiratesrhinologyandotology.ae/

Contact: eroc@mci-group.com

The 9th Emirates Otorhinolaryngology Audiology and Communication Disorders Congress joins forces with the German ENT Society to present an international congress covering all aspects of otorhinolaryngology, audiology, and communication disorders. The 2019 conference includes keynote lectures, round table discussions, instructional courses, video sessions and abstract sessions covering a wide array of topics, including the latest technologies and techniques in the field of ENT. The 2019 congress will also have several live surgical pre-congress workshops on state-of-the-art anatomical specimens.

PHAR-EAST Asia's Pharma & Biotech Festival

March 19-20, 2019 | Singapore, Singapore

Website: https://www.terrapinn.com/exhibition/phar-east/index.stm

Contact: sheena.tan@terrapinn.com

Phar-East is the premier meeting place for senior executives from Asia's pharma and biotech industry. Returning in 2019 after a successful 2018 debut, Phar-East will once again bring together experts from Asian pharma & biotechs, big pharma, regulators, payers, technology innovators and more to share their expertise and chart Asia's path forward.

12th Asia Pacific Pediatrics Congress

May 1-2, 2019 | Seoul, South Korea

Website: pediatrics.pediatricsconferences.com

Asian Pediatrics 2019 will be an innovative and informative International conference reflecting the direction of Pediatrics in the 21st century and offers a wide range of diversions to participants of all backgrounds. This Pediatric conference provides an excellent opportunity to discuss the latest developments within the field. The conference runs with the theme "Recent Advances and Future Directions in Pediatrics"

18th Global Ophthalmology Optometry and Glaucoma Conference

February 14-15, 2019 | Dubai, UAE

Website: https://glaucoma.conferenceseries.com

This Ophthalmology Conference depends on the theme "Experiences of Revolutionary Therapeutic Advancements for Profound Vision and Glaucoma". This Glaucoma 2019 expects to bring every one of the specialists around the world working in the part of Ophthalmology, Optometry, Vision Science, Optics and other related controls with a plan to share on going headways in Ophthalmology, set up a system and advance collective research Glaucoma 2019 will highlight two days of logical and research sessions comprising of Plenary addresses, Keynote Presentations, Oral Presentations, welcomed talks, Industrial talks, Poster introductions, Symposiums/workshops, Young Researcher Forum (YRF), Best publication grants, e-Poster Presentations, Debates, Case Studies in Ophthalmology, and Exhibitions and so on.

1. Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs

In a speech at the U.S. Department of Health and Human Services on October 25, President Trump proposed that the prices Medicare pays for certain prescription drugs be based on prices in other industrial countries. If carried out, the proposal would be phased in under the Center for Medicare and Medicaid Innovation created by the Affordable Care Act, from 2020 to 2025. The new drug-pricing plan comes after the recent release of a government study arguing that Medicare pays 80 percent more than other advanced industrial countries for 27 of the most expensive, physician-administered medicines. With growing expenditure costs under Part B of Medicare, the administration projects savings of $17.2 billion for American taxpayers and patients over the five years. The demonstration project would cover half the country, and marks a shift from Trump's campaign promise of the federal negotiation of drug prices to basing prices on negotiations in other countries.

https://nyti.ms/2JfXjXn

2. F.D.A. Approves Powerful New Opioid Despite Warnings of Likely Abuse

AcelRx Pharmaceuticals drug Dsuvia, the tablet form of sufentanil, received FDA approval on November 2. Sufentanil is a synthetic opioid utilized intravenously and in epidurals; it is also 10 times more potent than fentanyl, a parent drug that has caused tens of thousands of overdose deaths in the past few years. Dsuvia's approval comes weeks after Dr. Raeford Brown—the chairman of the advisory committee tasked with reviewing the drug—publicly implored the agency to reject it as it is likely to be abused. The advisory committee ultimately recommended the drug in a 10-3 vote last month, without Dr. Brown's attendance. After final approval, FDA commissioner Dr. Scott Gottlieb stated that Dsuvia will only be available in "prefilled, single-dose applicators" and not for home use or at retail pharmacies. AcelRX plans to follow the risk evaluation and mitigation strategy approved for the drug, which will likely hit the market in early 2019.

https://nyti.ms/2CXfVu2

3. FDA unveils sweeping anti-tobacco effort to reduce underage vaping and smoking

On November 15, the U.S. Food and Drug Administration announced that it will limit sales of flavored e-cigarettes and plans to ban menthol cigarettes and flavored cigars. The affected e-cigarette flavors are those in fruity, sweet and creamy flavors that appeal to or are marketed to underage users, and intentionally exclude mint, menthol and tobacco. Under the new plan, these flavored products will only be available in stores with age-restricted entry or areas that are inaccessible to consumers under 18. The agency will also require stricter methods of age verification online, reflecting concerns that increased adolescent e-cigarette use could lead to surges in early nicotine addiction and subsequent use of regular cigarettes. The FDA's proposal to ban menthol and flavored cigars is more significant, and will require new regulations that could take years to enact if not overturned by the cigarette industry.

https://www.washingtonpost.com/health/2018/11/15/fda-unveils-sweeping-anti-tobacco-effort-reduce-underage-vaping-smoking/?tid=ss_mail&utm_term=.f0734fc6fc46

4. Amgen Slashes the Price of a Promising Cholesterol Drug

In hopes of increasing sales, Amgen lowered the list price of its anti-cholesterol drug Repatha from $14,000 a year to $5,850 a year on October 25. Repatha is one of two PCSK9 inhibitors that came to market in 2015 but has been reluctantly covered by insurers in favor of cheaper statins. Its competitor Praluent—sold by Regeneron and Sanofi—lowered its net price in May to revive sales, and although Amgen has been offering deeper insurer discounts, these discounts have been largely unavailable for Medicare beneficiaries, who account for about 40 percent of Repatha prescriptions. Amgen will continue to offer Repatha under the higher list price to insurers who prefer such rebates until 2020. The price cut comes during a time when the Trump administration has aggressively focused on lowering drug costs, but it remains unclear whether Amgen's decision signals a major shift in the industry.

https://nyti.ms/2ArIyho

5. Cancer Society Executive Resigns Amid Upset Over Corporate Partnerships

The American Cancer Society's Executive Vice President and Chief Medical and Scientific Officer Dr. Otis W. Brawley resigned in early November after 11 years at his post. Although Dr. Brawley stated he was unable to disclose the terms of his departure, his resignation is largely attributed to concern over the organization's commercial partnerships. The 105-year-old organization has recently been subject to increased criticism regarding its fundraising partnerships, which include supplements company Herbalife International and Long John Silver's, a fast food chain known for fried fish. Due to changing donation patterns and decreasing fundraising income, the cancer society has been working to diversify its revenue portfolio, which historically relied on walks such as Relay for Life. Dr. Brawley's leave comes during a time when patient advocacy and other health groups are increasingly sourcing funding from businesses with questionable health credentials and even colliding interests .

https://nyti.ms/2yOCxdm

6. Alphabet stops its project to create a glucose-measuring contact lens for diabetes patients

On November 16, Alphabet Inc.'s life sciences organization Verily—previously known as Google Life Sciences—announced that it will be shelving its program on glucose-sensing contact lens in favor of other eye-related projects. First introduced in 2014, the "smart lens" project partnered with Novartis' eye-care arm Alcon to measure blood sugar levels in tears through sensors on contact lenses, in efforts to create a less invasive method for diabetics to track glucose levels. Verily stated that due to insufficiently consistent data to support its proposed medical device, it will be moving on to lenses for age-related farsightedness and improving sight after cataract surgery. The research arm also emphasized its continued commitment to projects in the diabetes space, noting its ongoing partnerships with Dexcom and Onduo, its joint venture with Sanofi.

https://www.cnbc.com/2018/11/16/alphabet-verily-stops-smart-lens-glucose-measuring-contact-lens.html

7. Obamacare early enrollment rate drops in first sign-up season since GOP changes

According to the U.S. Centers for Medicare and Medicaid Services, sign-ups for Obamacare on HealthCare.gov decreased by 20.4 percent in the first two weeks of the 2018 enrollment season compared to last year. Enrollment has been receiving increased attention as 2019 will be the first year since 2013 in which the Affordable Care Act's individual mandate tax penalty—which was repealed by Congress in December 2017—will not be imposed. The Trump administration's decision to increase the terms of short-term health plans from three months to up to 12 months, in addition to allowing for two renewals, is also expected to depress enrollment for 2019. The first two weeks of open enrollment saw more than 901,300 existing Obamacare customers renewing their coverage and 274,913 new consumers for a total of 1,176,232 insured.

https://www.cnbc.com/2018/11/14/obamacare-early-enrollment-rate-drops-in-first-season-since-gop-changes.html

8. U.K. to Allow Prescriptions for Medicinal Cannabis

U.K. Home Secretary Sajid Javid announced on October 11 that doctors in England, Wales, and Scotland will be permitted to legally prescribe medicinal cannabis starting on November 1. The new policy allows senior clinicians and specialist doctors, but not general practice doctors, to prescribe marijuana-based treatments to patients on a case-by-case basis, or "when the patient has an unmet special clinical need that cannot be met by licensed products." The Home Office's decision follows the cases of two children with epilepsy treatments dependent on cannabis-based medicine that were highly publicized in the British media. The subsequent public pressure led to a review of marijuana-based medicinal products that began in July. The legalization of cannabis for medical use does not indicate a shift toward legalizing recreational cannabis-derived products.
https://nyti.ms/2A5IDHw

9. CVS Health and Aetna $69 Billion Merger Is Approved With Conditions

On October 10, the U.S. Justice Department granted preliminary approval for the $69 billion merger between CVS Health and Aetna, weeks after Aetna's conditional selling of its private Medicare Part D drug plan business to WellCare Health Plans to address federal concerns about market share. The CVS-Aetna deal marks a shift toward the integration of pharmacy benefit managers with the rest of the drug prescription pipeline, and is expected to help tighten cost controls. The merger, which combines CVS's 10,000 pharmacies and 1,100 retail clinics with Aetna's 22 million customers, continues to elicit concerns over the potential control of consumer choice and increases in the cost of drugs that are likely to occur as an insurer gains control over the retail component to delivering care. The combined companies will keep CVS Health's Larry J. Merlo as chief executive, while Aetna's CEO Mark T. Bertolini will step down to join the new board.
https://nyti.ms/2A2QsNX

10. Pfizer to Raise Prices on 41 Drugs in January

On November 16, Pfizer Inc. announced plans to raise list prices for 41 of its prescription drugs early next year. The price increases will affect 10% of the drugmaker's portfolio and accompanies price increases by other pharmaceutical companies such as Bristol-Myers Squibb Co. and Allergan PLC. Although Pfizer has regularly increased prices over the years to help boost revenues, the latest announcement follows increasing scrutiny of drug pricing and pressure to lower costs by both the public and the Trump administration, which heavily criticized the decision. In July, Pfizer temporarily reversed more than 40 price increases of 9.4% after presidential rebuke. The new changes, which do not affect recently approved drugs and sterile injectables, will mostly be of 5%. Pfizer also plans to increase discounts and rebates accordingly, and does not expect the price adjustments to lead to additional revenue growth.
https://www.wsj.com/articles/pfizer-to-raise-prices-on-41-drugs-1542398034

11. 2018 Nobel Prize in Medicine Awarded to 2 Cancer Immunotherapy Researchers

The 2018 Nobel Prize in Physiology or Medicine was awarded to Dr. James P. Allison of the United States and Dr. Tasuku Honjo of Japan for their work on immunotherapy, or utilizing the body's immune system to recognize and attack cancer cells. Working separately in the 1990s, Dr. Allison and Dr. Honjo demonstrated that certain proteins—checkpoints—could shut down T-cells and thus limit the immune system's ability to fight cancer. Dr. Allison identified a checkpoint called CTLA-4, and Dr. Honjo found PD-1. The resulting class of new drugs known as checkpoint inhibitors provided treatment options for patients who had run out of conventional possibilities, and checkpoint inhibitors are now used for a number of cancers, including of the lung, kidney, bladder, head and neck, aggressive skin cancer melanoma, and Hodgkin lymphoma. In the future, Dr. Allison and Dr. Honjo plan to continue to search for ways to best combine checkpoint inhibitors and integrate them into other treatments to fight cancer.
https://nyti.ms/2Ol0mTd

13. Shingles Vaccine Shortages Result From High Demand

GlaxoSmithKline's Shingrix—a shingles vaccine approved last year—has experienced uptake so strong that increased demand has led to production shortages. The vaccine is recommended for most adults over the age of 50, when the illness is most likely to develop, and two Shingrix injections, two to six months apart, have been shown to be about 90 percent effective at preventing shingles and the nerve complications that may follow the viral infection. The popularity of the vaccine was unanticipated, and GlaxoSmithKline has announced its increase and expedition of shipments. With many patients unable to receive their second shot within the recommended six-month time frame, after which overall immune response varies individually, the Centers for Disease Control and Prevention has advised providers to give preference to patient seeking their second dose.
https://nyti.ms/2N1PViB

14. Syphilis Rises Sharply Among Newborns

According to the U.S. Centers for Disease Control and Prevention, the rate of infants born with syphilis has more than doubled in the past four years to reach a 20-year high. The recent rise in congenital syphilis, passed from the mother to the baby through the placenta, accompanies a significant increase in adult infections. Syphilis can lead to miscarriage and stillbirth, in addition to a variety of infant health problems such as deformities, seizures, anemia and jaundice. The disease, which was reported to be on the brink of elimination in 2000, has experienced a resurgence in the past few years, with the number of adult cases growing every year since 2013. Although congenital syphilis can be inexpensively treated with penicillin, rates of the disease remain high, especially in communities in Louisiana, Nevada, California, Texas and Florida.
https://www.nytimes.com/2018/09/28/science/congenital-syphilis-infants.html?rref=collection%2Fsectioncollection%2Fhealth

15. Venezuela's Health Crisis Is Crossing the Border

The ongoing five-year-old meltdown of Venezuela's economy has led to the swift collapse of its health system, forcing millions out of the country in search of medical assistance in addition to financial and political stability. Venezuelan refugees have carried, and continue to carry, disease into neighboring countries such as Brazil, Colombia, Peru, and even Argentina. Once Latin America's richest country and leader in disease prevention, Venezuela has transformed into an incubator for measles, malaria, yellow fever, diphtheria, dengue, tuberculosis, and the virus that causes AIDS. With the government's insistence that the deterioration of public health care—hospitals are unable to provide basic services or medicine—is simply a conspiracy theory, doctors who have spoken out have been fired or threatened with arrest. As the Venezuelan government continues to ignore the state of public health care, neighboring countries project increases in both refugees and disease.
https://www.wsj.com/articles/venezuelas-latest-export-infectious-diseases-1540997657

16. Sloan Kettering Researchers Correct the Record by Revealing Company Ties

Following the September resignation of Dr. José Baselga, the Memorial Sloan Kettering Cancer Center's chief medical officer, senior researchers at the center have filed corrections with medical journals that illuminate undisclosed financial relationships with healthcare companies. Dr. Baselga was heavily criticized after failing to report his corporate ties and stakes—including payments amounting to millions of dollars—in a number of medical journal articles. In October, the hospital's chief executive Dr. Craig B. Thompson resigned from the boards of Merck and Charles River Laboratories after disclosing his various company relationships. Other researchers who have newly listed affiliations include Drs. Jedd Wolchok, Matthew D. Hellmann, Taha Merghoub, Michael A. Postow, and Michelle Bradbury. Public scrutiny of the nonprofit cancer center continues as it instructs its researchers to review and revise conflict-of-interest disclosures, undertakes a review of staff and industry interactions and policies, and hires a law firm to investigate specific allegations.
https://www.nytimes.com/2018/10/12/health/memorial-sloan-kettering-cancer-disclosure.html

17. F.D.A. Approves New Drug for Flu

Antiviral Xofluza (baloxavir marboxil) received U.S. FDA approval on October 24, becoming the first new flu drug to win FDA approval in 20 years. The new drug is a $150 single dose treatment developed and discovered by Shionogi & Co., Ltd. and sold by Genentech in the U.S., who will offer coupons to lower the price to $30 for patients with health insurance and $90 for the uninsured. After two clinical trials, Xofluza received approval for patients aged 12 or more, and introduces a new way to combat flu strains through the inhibition of cap-dependent endonuclease, an enzyme necessary for viral replication. The drug is expected to work as well as popular anti-flu drug Tamiflu (oseltamivir), which is sold by Genentech's parent company Roche, and against resistant strains such as the A strains of H5N1 and A H7N9.

https://www.nytimes.com/2018/10/24/health/flu-pill-xofluza.html?rref=collection%2Fsectioncollection%2Fhealth

18. Australia's Sonic Healthcare to Buy U.S.-Based Aurora Diagnostics for $540 Million

Australian pathology and radiology group Sonic Healthcare Ltd (SHL.AX) said on Wednesday it had agreed to buy Florida-based Aurora Diagnostics LLC ADI.UL for $540 million. The acquisition of Aurora is expected to be about three percent EPS accretive post-placement on a pro-forma FY2019 basis before expected revenue and cost synergies, Sonic said in a statement. The acquisition, Sonic said, would help it "substantially grow" its operations in the United States. Sonic also announced a fully underwritten institutional placement to raise A$600 million ($431.88 million) and a non-underwritten share purchase plan to retail shareholders in Australia and New Zealand to raise up to A$100 million.

https://www.reuters.com/article/us-aurora-m-a-sonic-healthcare/australias-sonic-healthcare-to-buy-u-s-based-aurora-diagnostics-for-540-million-idUSKBN1OA2JG

19. Scientists to Test Tailor-Made Vaccine Tech to Fight Epidemics

A global coalition set up to fight disease epidemics is investing up to $8.4 million to develop a synthetic vaccine system that could be tailor-made to fight multiple pathogens such as flu, Ebola, Marburg and Rabies. The deal, between the Coalition for Epidemic Preparedness Innovations (CEPI) and a team of scientists at Britain's Imperial College London is aimed at progressing a "vaccine platform" which uses synthetic self-amplifying RNA (saRNA). A vaccine platform is a system that uses the same basic components as a backbone or framework, and can be adapted to immunise against different diseases by inserting new genetic sequences from, for example, the flu or Marburg or rabies virus.

https://www.reuters.com/article/us-health-vaccines-epidemics/scientists-to-test-tailor-made-vaccine-tech-to-fight-epidemics-idUSKBN1O9008

20. Roche's Lung Cancer Combo Treatment Wins FDA Approval

Swiss drug maker Roche Holding AG said on Thursday that its Tecentriq immunotherapy in combination with Avastin and chemotherapy won U.S. Food and Drug Administration approval as a first-line treatment for a type of lung cancer. The drug on Wednesday had also won priority review from the U.S. regulator for treating patients with untreated extensive-stage small cell lung cancer. Tecentriq is already approved in the United States to treat certain types of lung cancers, as well as a type of bladder and urinary tract cancer.

https://www.reuters.com/article/us-roche-hldg-fda/roches-lung-cancer-combo-treatment-wins-fda-approval-idUSKBN1O52KP

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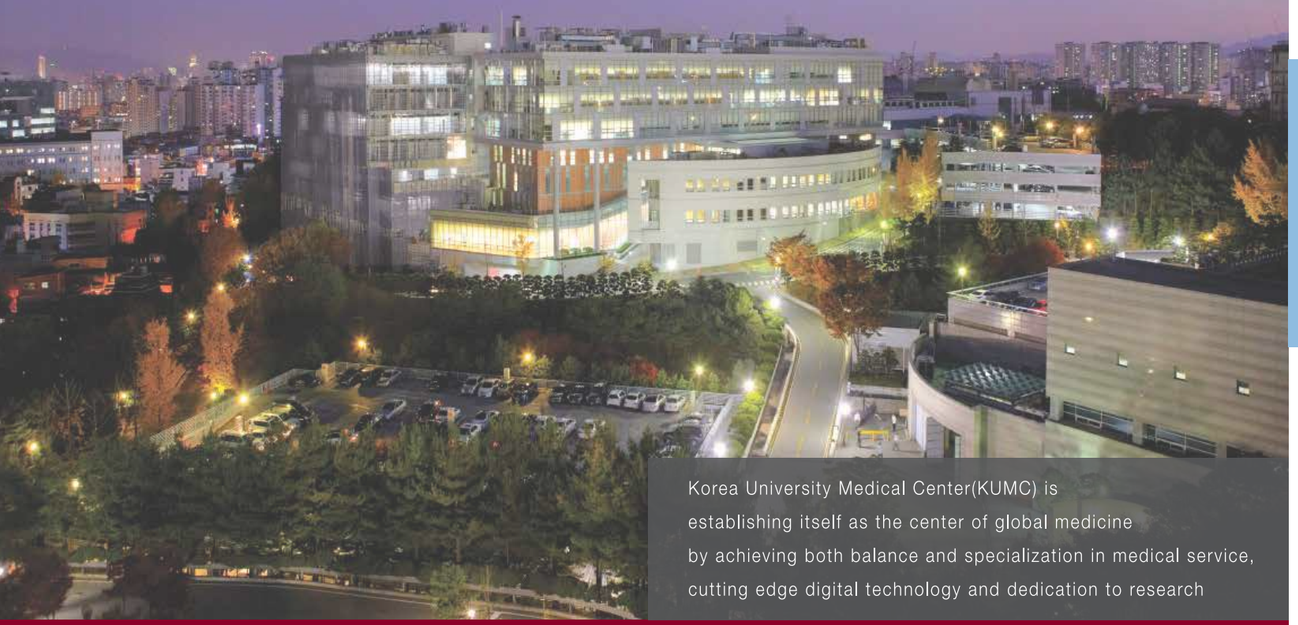

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