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WKMJ

World Korean Medical Journal

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Myung-Hwan Kim, MD, PhD, President of the Asian-Oceanic Pancreatic Association

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Powerful Transformers of the Beauty Industry

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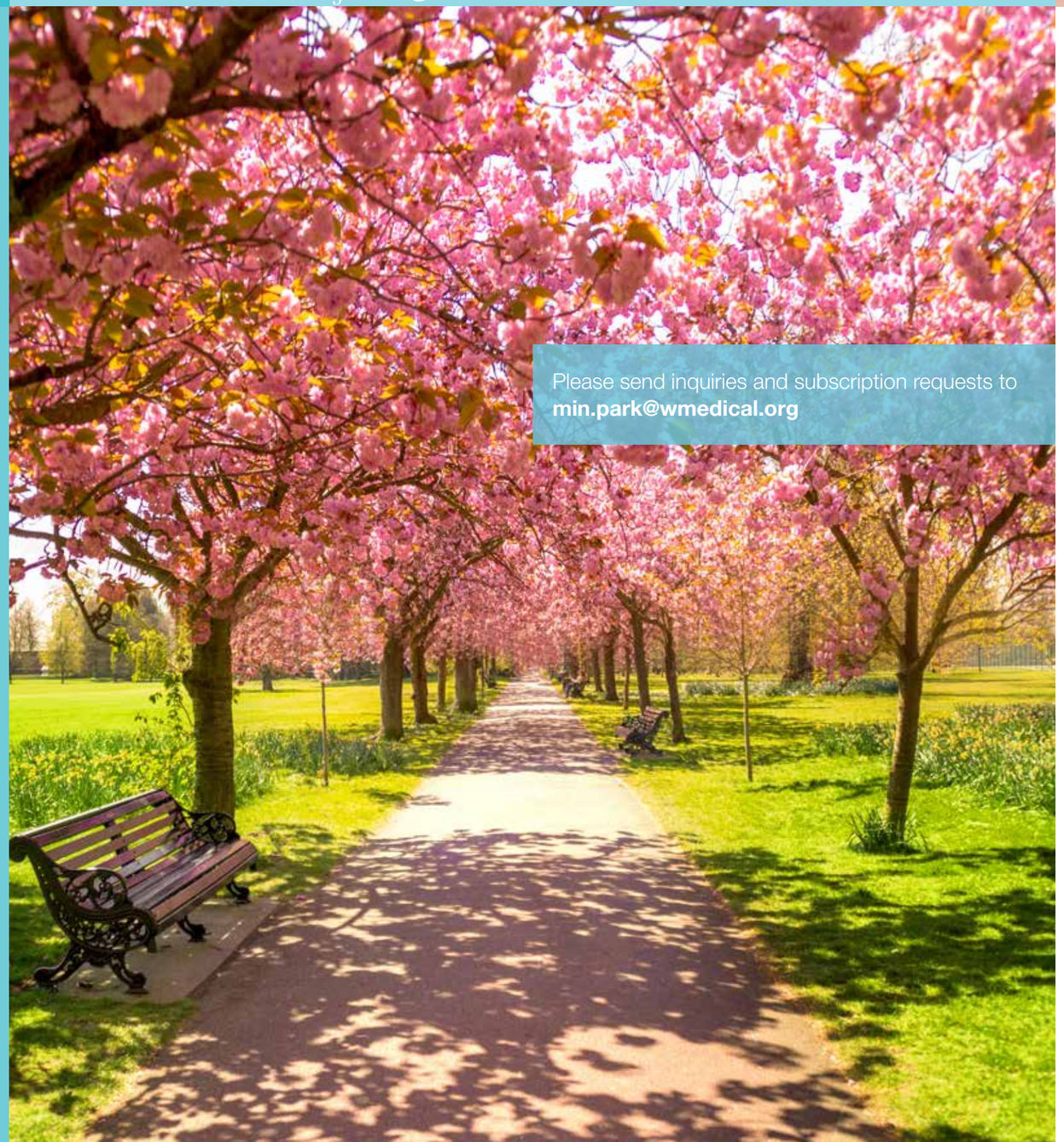

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FROM THE PUBLISHER

Greetings! 2018 has already been a remarkable year. South Korea hosted an exciting Winter Olympics which has increased the dialogue between the two Koreas as they marched together and competed as a unified team in hockey. The heat of the Winter Olympics thawed the cold relations between the two Koreas as well as between the US and North Korea. Like the Olympic sport of curling, there seems to be a smoothing path at play as the top leaders plan to meet in order to clear out the past obscurity.

While the Olympic Games in South Korea has come to an end, the progression of Korean medicine and healthcare still marches on. In the cover story of this edition, we featured Dr. Myung-Hwan Kim of Asan Medical Center. Dr. Kim is a world-renowned gastroenterologist with subspecialty in pancreatic and biliary disease. Pancreatic cancer is known to have high mortality rate, as we have witnessed one of the most influential icons, Steve Jobs, struggled even with access to the best medical care. Any medical progress in the pancreatic cancer research is commendable due to the level of difficulty in treating the disease. In this respect, Dr. Kim's practice and pancreatic cancer research in this field are important contributions and achieved high honor in receiving the prestigious Dr. Wunsch Medical Award. As a clinician, educator and researcher, Dr.Kim is a true mentor for those who want to pursue in the medical field.

In the special report, we featured recent New York Health Forum where experts gathered to discuss about the development of Korean skincare industry. As featured previously in the last edition, skin health is very important across all ages and genders, and therefore, there has been a greater focus on the research and science involved in the skincare and cosmetic industry. With the growing trend in avoiding harmful chemicals and using natural ingredients, both the US and South Korea should actively develop regulations and technologies to improve overall skin health.

The modern world is moving at a faster pace than ever before. However, there is still a struggle in moving forward with medical cooperation with North Korea due to the political unrest that scaled back the humanitarian and educational medical efforts. Due to these political sanctions, North Korea's medical needs are still unmet, but as physicians who honor the Hippocratic Oath and like the Médecins Sans Frontières/Doctors Without Borders (MSF) Organization, we must tend to patients' needs. Hopefully with the political turnaround of North Korea, there would be an opportunity for medical improvements and increased humanitarian efforts in the near future. I hope that 2018 may become the pivotal year in the Korean peninsula.

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

FROM THE EDITOR-IN-CHIEF

Over the last decade in the healthcare industry, there has been a growing importance for clinicians to lead their practice with greater sense of accountability. Clinicians should be attentive to patient care visibility in order to make appropriate decisions when facing complex situations. In this edition of our cover story, we interviewed a well-known clinical physician, Dr. Myung-Hwan Kim, who believes that the best clinical treatments develop from both patients' and clinicians' efforts in raising the bar of the healthcare landscape.

"There are doctors who may advise that medical adverse events or errors occur in every 10,000 patients with approximately 0.01% possibility. Despite the approximated statistics, from a patient's perspective, the possibility of the event happening is 100%." The quote from Dr. Kim emphasizes the responsibility that clinicians must have every day when seeing patients. Dr. Kim is a distinguished clinical physician in pancreatology and gastroenterology who always practices patient care with precision and meticulousness with accountability at heart. He is a true pursuer of perfecting clinical performance and puts his best efforts in treating every patient.

Dr. Myung-Hwan Kim is newly elected as the president of the Asian-Oceanic Pancreatic Association, a leading international organization of clinicians who focus their study on various medical and surgical areas of pancreatology. He is also the director of Center for Pancreatobiliary Diseases at Asan Medical Center, the largest medical institute in South Korea. Dr. Kim has a background in both clinical medicine and therapeutic research and has actively participated in numerous academic researches and clinical developments. Dr. Myung-Hwan Kim is undoubtedly one of the most highly respected physicians and a strong expert in gastroenterology in the global community. I met Dr. Kim for the first time several years ago and I was impressed the most by his humility, thoughtfulness and depth in vision of patient care and quality of life. I hope our readers find great delight and enlightenment in reading his story and his philosophy in life.

For the special report, we summarized the 8th New York Health Forum (NYHF) which was held at the Yale Club of New York on December 6th, 2017. Focused on the theme of "Powerful Transformers of the Beauty Industry," the forum created a platform to stimulate a conversation among multiple top consultants, entrepreneurs, investors, government officials as well as digital influencers to network and share recent trends and dynamics of the beauty industry.

In addition to these two major articles, we have a rich selection of articles and reports which will bring excitement to our readers.

Hope you enjoy reading this edition. Thank you.

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 Global Healthcare Leader "Dr. Henry W. Lim, President of the American Academy of Dermatology"

Dr. Henry Lim is the president of the American Academy of Dermatology, the world's largest dermatologic society. He was also the chair emeritus of the Department of Dermatology and senior vice president for Academic Affairs at Henry Ford Hospital in Detroit, Michigan, USA. Dr. Henry Lim is a world-renowned specialist in photodermatology and achieved high honor in receiving the Fred W. Whitehouse, MD, Distinguish Career Award of the Henry Ford medial Group. Prior to joining the Henry Ford Hospital, he was a professor of dermatology at NYU School of Medicine. He also has published more than 400 articles, and edited 7 textbooks. To learn more about Dr. Lim, please read issue 15 of WKMJ.

Entrepreneur Interview
Jinmin Lee, Chief Executive Officer and Founder of isoi

Jinmin Lee is the founder and current Chief Executive Officer of isoi, the first Korean brand to receive top scores from the EWG for providing skincare products with natural ingredients and without harmful chemicals. isoi is rapidly gaining a reputation in the US as a leading Korean natural skincare brand. With a special interest in women's health and rights, she is an active member of the Board of Directors at the Hope Institute as well as an Advisory Board Member at the Seoul Culture Forum. She was also the youngest Creative Director at Cheil, a marketing company under the Samsung Group. To learn more about her philosophy and brand story, please refer to issue 15 of WKMJ.

Biopharmaceutical Report I
Corbus' Phase II Anabusum in Dermatomyositis Garner Mixed Expert Expectations

Experts have divided views on the Corbus Pharmaceuticals Phase II study of anabasum. The contrast of opinions on anabasum comes from the suspicion of the drug's efficacy in its co-primary endpoint. Anabasum is used to treat dermatomyositis, a rare inflammatory disease with variable symptoms, including skin rash, muscle weakness and muscle inflammation. Despite the studies on the reporting by some experts who believe that the drug is based on small sample size and therefore might miss the co-primary endpoint also due to disease's heterogeneous nature, others are optimistic in that it may still show a good-side effect profile and tolerability data. To read more on this reporting please refer to issue 15 of WKMJ.

Biopharmaceutical Report II
BeiGene's Phase III BGB-3111 in WM Has Unclear Efficacy Advantage over Imbruvica

According to the recent research on BeiGene's BGB-3111 for Waldenstrom's macroglobulinemia (WM), analysts said that it will take another two or three years before fully assessing then confirming the superiority of efficacy of BGB-3111 over Imbruvica. Despite the previous data that revealed the potential difference between Imbruvica and BGB-3111, experts said that for now they appear comparable to each other in terms of efficacy. While the efficacy data for the moment appears comparable to Imbruvica, BGB-3111 does not have sufficient follow- up to get a firm sense of the capacity to produce a significant effect. For more details on the findings of the research on BGB-3111, please refer to issue 15 of WKMJ.

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INSPIRATIONAL KOREAN HEALTHCARE LEADER

Myung-Hwan Kim, MD, PhD
President of the Asian-Oceanic Pancreatic Association
Director of Center for Pancreatobiliary Diseases at Asan Medical Center

AOPA

ASAN

1. Dr. Kim, you are a world-renowned gastroenterologist and a respected member of the medical community. What was your reason for attending medical school? Can you please share with us what motivated you to become a physician?

- Frankly speaking, I originally applied to the medical school because of my parent's recommendation rather than of my own decision because back in the 70's, medical doctors had a stable occupational status and received high respect from the community. Although I entered medical school upon my parent's recommendation, I now value my work as both a clinician and a clinical researcher, specializing in gastroenterology with sub-specialties in pancreatobiliary diseases and cancers. Both pancreatic and biliary cancers are notorious for high mortality rates even with the most up-to-date treatments. As a clinician who works with patients with such high mortality rate, I sometimes feel pressured being on the front line of saving their lives, but I feel a stronger motivation to fight for my patients under the gravity of it all.

Dr. Kim receiving the Dr. Wunsch Medical Award

2. As a successful physician with nearly 40 years of experience, can you share with our readers some of the major achievements and outcomes you have accomplished during your professional life? Also, were there any difficult moments you had to overcome during the path of your career?

- I truly enjoyed and had a great privilege to work as a clinician for many years. I have to admit that it wasn't always an easy road but with the great Asan Medical team, we made a progress in researching and developing many pancreatobiliary related studies. One of our achievements was establishing the Kim Diagnostic Criteria for diagnosing autoimmune pancreatitis (AIP) that led to further development of the international consensus diagnostic criteria for AIP. Throughout my career, I have been very fortunate to make small contributions in advancing the field of pancreatology in Korea. With great appreciation, my contribution was recognized, and I received Dr. Wunsch Medical Award from the Korean Academy of Medical Sciences in 2008.[1]
As a clinical doctor who works directly with patients every day, I felt honored to be acknowledged for my clinical practice. Receiving such a reputable award, I find greater responsibility and opportunity to develop Korea as a global leader in the field of clinical medicine.

> "We, as clinicians, should persevere in advancing medicine to improve patient outcome"

Not all significant achievements come with ease, and there were various obstacles that I had to overcome throughout my career as a physician. Encountering adverse events during my medical practice was one of the most challenging moments in my career. Although I am a veteran clinician with many years of experience, adverse events are sometimes unavoidable even with the foremost caution. There are doctors who may advise that such events occur in every 10,000 patients with approximately 0.01% possibility. Despite the approximated statistics, from a patient's perspective, the possibility of the event happening is 100%. Being mindful of patients' feelings and emotional stress, I am always meticulous with treatments and procedures in an effort to minimize any negative outcomes. I can't emphasize enough that no matter how skillful or attentive a clinician may be, these events are inevitable. Even with these unavoidable obstacles, We, as clinicians, should persevere and continue advancing medicine to improve patient outcome.

[1] Dr. Wunsch Medical Award is established by The Korean Academy of Medical Sciences and Boehringer Ingelheim Korea in 1990, naming it after Richard Wunsch, the first German physician in Korea. The Dr. Wunsch Medical Award is also called "Korea's Nobel Prize in Medicine," and has maintained its top reputation through a strict screening process.

“We must constantly train ourselves in preparation to deliver the evidence-based, up-to-date diagnostic and therapeutic modalities”

3. Dr. Kim, you have been a professor of gastroenterology at University of Ulsan College of Medicine and a director of Center for Pancreatobiliary Diseases at Asan Medical Center. How do you view yourself as an educator? What are your principles or philosophies as a teacher?

- I always emphasize to my colleagues and young faculty members that modern medicine needs to take a multidisciplinary approach. A clinician should always consider all areas of medicine when treating his or her patients. Young clinicians make a common mistake in limiting their scope of specialties. It is important for clinicians to broaden their abilities to collaborate with different specialties in treating their patients. Modern medicine is evolving fast. Having an open minded view and working with various experts from different medical fields are necessary to provide effective treatments to patients.

My second philosophy in medical education is that doctors must be ready to provide the best diagnostic and therapeutic options for patients. From a patient’s perspective, it is not only very disappointing but also frustrating when one receives an outdated and suboptimal treatment while a better treatment method exists in the field. I believe that all patients are entitled to receive the most effective and the most recent treatments and as healthcare professionals, we must constantly train ourselves in preparation to deliver the evidence-based, up-to-date diagnostic and therapeutic modalities.

As a senior faculty member in a university hospital, I have always tried to be a good mentor for training fellows and recently joined young colleagues. My duties as an educator are: to motivate and guide fellows in training to become physician-scientist in the world of academia, to support them in overcoming certain obstacles in the practice and clinical research and to encourage them to achieve their individual success in their field of study.

Dr.Kim performing endoscopic surgery at Asan Medical Center (photo credit: Munhwa Ilbo)

ASAN FOUNDATION 아산재단

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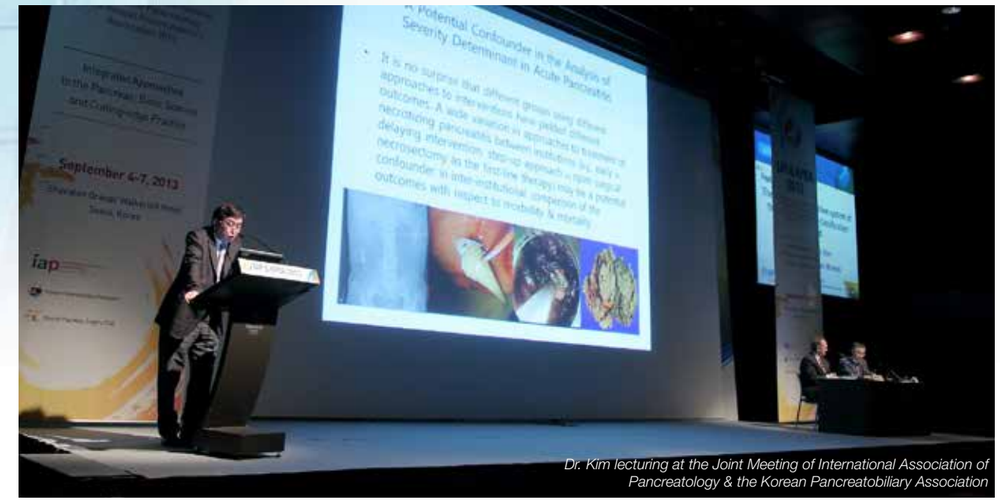
Asan Medical Center (AMC) is Korea’s largest general tertiary-care hospital. It is one of the most sophisticated medical facilities in Korea with 2,704 patient beds, serving 11,862 outpatients and 2,557 inpatients on average per day while performing about 63,791 surgeries per year. The medical center encompasses three highly specialized institutes including 27 specialized centers, 44 clinical departments and a research institute for the life sciences. Since its establishment in June, 1989, Asan Medical Center gained a name as the most-visited hospital in Korea and achieved a world-class medical reputation as it has continued to invest in R&D and clinical treatment.



Dr. Kim lecturing at the Joint Meeting of International Association of Pancreatology & the Korean Pancreatobiliary Association

4. You have become the president of Asian-Oceanic Pancreatic Association (AOPA). What are your key roles, responsibilities, and principles of leading the Asia's largest pancreatic society? Can you also share with us the main goal and mission of the AOPA meetings?

- It is my great honor and privilege to serve as president of the Asian-Oceanic Pancreatic Association (AOPA). The AOPA encourages the advancement and sharing of knowledge regarding pancreatic diseases and promotes a public interest in pancreatology. Another important mission of AOPA is to attract and support young researchers in continuing their research and clinical study of pancreatology.

In that respect, my main responsibility as president of AOPA is to promote clinical, translational, and basic research in pancreatology and to organize scientific meetings cooperating with eminent pancreatologists across the world. I also offer opportunities for clinicians and researchers to exchange up-to-date clinical and research study results.

Upcoming 7th biennial AOPA meeting will be held on April 25th thru 27th in Seoul, South Korea. The main theme of AOPA 2018 is "Debates & Challenges in Clinical Pancreatology" with a main goal to disseminate the best clinical practice in the field of pancreatology among hundreds of clinicians and professionals from all over the world.

5. You have conducted hundreds of research and served as an author and co-author in many research papers. As an eminent opinion leader of pancreatobiliary diseases, what are some major changes or trends happening in the area currently? Also what do you forecast the major changes would be in pancreatobiliary gastroenterology in the next five years?

- Recently, there has been a major change in the field of pancreatobiliary diseases, which increased effectiveness of surgery. Pancreatic cancer can be classified as surgically resectable tumor, unresectable tumor, and borderline resectable tumor based on the disease stage. In the past, we took an aggressive approach to undergo surgical resection for borderline resectable tumor. According to the recent clinical studies, however, patients with positive resection margin after surgical resection (R1) have a significantly poor prognosis compared with those with a negative resection margin (R0). With an effort to increase the chance of R0 resection, neoadjuvant treatment (chemotherapy followed by radiation) is performed first before considering surgical treatment in borderline resectable pancreatic cancer. With assessing the response to neoadjuvant therapy, we can select the best candidate for surgery because these patients are at a high risk for harboring occult metastatic disease and vessel encasement and for undergoing a margin-positive resection. This recent change has resulted in an increase in the effectiveness of the surgery and eventually to a prolongation of patient survival.

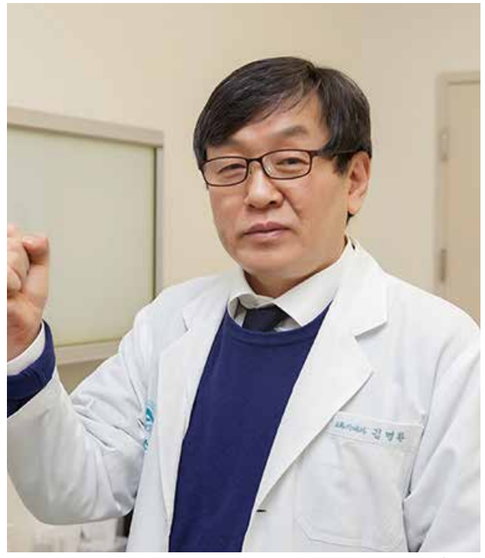

Dr. Kim and his colleague in discussion

"Precision Cancer Medicine" has recently been in the limelight and many researches have been actively conducted on this area. As to pancreatic cancer, this new trend of research will lead to personalized cancer medicine, in which the patient will have his or her own unique cancer treatment plan based on his or her molecular or genetic heterogeneity. This individualized cancer care also focuses on stromal targeting strategies and immunotherapy. There is also a growing need for genomics-driven precision cancer medicine to guide patient selection by predicting treatment response.

In pancreatic cancer, PARP inhibitor and PEG-PH 20 are now studied in patients with pancreatic cancer harboring BRCA mutation and hyaluronic acid overexpression, respectively. These efforts for the application of precision medicine will improve the outcome of patients with pancreatic cancer.

6. We also noted that you serve a role in medical leadership of various clinical studies developing new drugs. Asan Medical Center is also a world-renowned clinical study site. Can you share your experience on how the scientific leadership takes a significant part in new drug development?

- I believe a clinician has a significant role in the development of new drugs by evaluating efficacy and toxicity of new treatment. Clinicians and basic scientists have their own roles to play in the new drug development respectfully. To translate clinical observation into clinical science is a distinct role of


Dr.Kim in his office at Asan Medical Center

Dr. Kim speaking at IAP&KPBA meeting

clinical researcher. The role of clinician is highlighted in the determination of targeting the disease and in the process of study design. Also, in the analysis of the results, even when a study may seem to have no apparent efficacy, a competent clinician can detect a beneficial individual group by undergoing subgroup analysis.

Through this process and co-efforts from the clinicians and the basic scientists, we will be able to find a more effective treatment option for a specific population. I hope more clinicians find interest in new drug development and actively participate in the development of new drugs from the initial step. Asan Medical Center has 2,700 beds for inpatients and are full of faculty members with sufficient clinical experience. These qualifications make Asan Medical Center one of the best clinical study sites for a new drug development.

7. WKMJ has readers from over 10 countries globally. Please share your final words with our readers.

- I hope the readers of WKMJ will look after their health and well-being. I want WKMJ readers to learn the importance of work-life balance to help reduce the mental stress. Maintaining a positive attitude and keeping a proactive mindset are critical in this generation.

Myung-Hwan Kim, MD, PhD

President of the Asian-Oceanic Pancreatic Association

Director of Center for Pancreatobiliary Diseases at Asan Medical Center

Dr. Myung-Hwan Kim is the president of the Asian-Oceanic Pancreatic Association and the director of Center for Pancreatobiliary Diseases at Asan Medical Center, the largest medical institution in South Korea. Dr. Kim is the first in Korea to diagnose and report on Intraductal papillary mucinous neoplasm (IPMN) of the pancreas and autoimmune pancreatitis. He also performed the country's first Extracorporeal Shock Wave Lithotripsy and greatly helped to improve the endoscopic removal rate of pancreatic stones. A leader in domestic research on gallstones, Dr. Kim gained global acclaim for his research on autoimmune pancreatitis, regarding differential diagnosis between autoimmune pancreatitis and pancreatic cancer by using two-week steroid trial. He also developed the 'Kim Diagnostic Criteria' on autoimmune pancreatitis and published related papers in number of influential SCI (Science Citation Index) journals such as "Gastroenterology" and "Gut." Dr. Kim published nearly 200 articles on pancreatobiliary diseases over the past decade and his research work is regarded as having greatly contributed to advancing the level of Korea's clinical medicine.

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SPECIAL REPORT

Powerful Transformers of the Beauty Industry

The 8th New York Health Forum

December 6th, 2017 | The Yale Club of New York City

The 8th New York Health Forum (NYHF) was held at the Yale Club of New York City on December 6, 2017 with close to 100 experts, industry leaders of notable Korean cosmetic companies and executives from national chain platforms. The theme of the 8th NYHF was "Powerful Transformers of the Beauty Industry." DoHyun Cho, the founder of the New York Health Forum and the president and CEO of W Medical Strategy Group, welcomed all the attendees with opening remarks. He emphasized the importance of engaging in a stimulating conversation with the industry's top entrepreneurs, investors, government officials, journalists as well as marketing experts and digital influencers to learn and discuss about today's cosmetics advancements and trends.

There were four sessions, consisting of 16 speakers who shared their insights and expertise on beauty and cosmetics industry. The first session was themed "Shop or Drop: The inevitable path of growth in beauty," which was moderated by Yiqin Shen, the senior reporter at Mergermarket and Dealreporter in New York, with panelists Hana Ben-Shabet, a partner at A.T. Kearney, Marko Horvat, vice president of Financo Investment, and Jaewook Yoo, director of Korea Trade Investment Promotion Agency. The topic highlighted the growing track of the global beauty industry, including a large number of mergers and acquisitions over the years as well as major trends and current landscape of the beauty industry in socioeconomic and cultural aspects.

The second session was titled "Embracing the Era of Natural Ingredients: Eco-innovation in beauty industry." Yisun Yuk, director of business operations at Green Alley, a natural skincare distribution company, moderated the topic on how to transform the beauty community into an environmental friendly industry and the importance of meeting consumer demands for safer and cleaner products in the marketplace. US representative for isoi Cosmetics, Kathleen Broderick also joined in the conversation to discuss about companies' responsibilities on ingredients and consumers' expectations on natural skincare products. Kristin Booker, lifestyle journalist and a beauty influential blogger who was featured in Marie Claire, ELLE, and other prominent publications, gave her professional perspective on creating beauty trends in the eco-friendly scope.

The audience engaging in the first session, "Shop or Drop: The inevitable path of growth in beauty"

The third session was titled "Building a Right Platform: Key legal issues of the US beauty industry." The panel discussion provided important legal issues associated with the US beauty industry. Along with moderator Joe McMenamin, executive vice president and chief legal officer of W Medical Strategy Group, and panelists Tony Handal, a partner at Greenspoon Marder, Ji Soo Yoon, compliance officer at Green Alley and Steven Shapiro, of counsel to Rivikin Radler, addressed the regulatory of cosmetics and personal care products. They also discussed safety and labeling requirements and intellectual property issues, such as patents, brands and trademarks.

The fourth and last session was titled "Powerful Transformers of Beauty Business: Online marketing and social media." It focused on how social media and digital marketing are shaping the cosmetics community, providing an open space for industry leaders to interact and build a diverse platform to expand business. Joseph Nam, senior associate of Madison Bay Capital Partners, moderated the session with the panelists, Laura Carabello, co-founder and principal of CPR Strategic Marketing Communications, Sue Park, branch manager and brand curator at StyleKorean, and Matthew Prepis, director of business development at SmarSites, who shared their expertise on creating business models in the digital marketing landscape.

Third session moderator Joseph P.McMenamin, MD, JD, FCLM, and panelists, Tony Handal, JD, Steven Shapiro, JD and Ji Soo Yoon, JD (left to right)

The 8th New York Health Forum successfully concluded with the announcement of two WMSG Appreciation Award recipients, Chul Kyoon Park, president of It's a Wig, and Joseph H. Carabello, CEO of CPR Strategic Marketing Communications. The awards were given in recognition of their achievements in contributing to the innovation of healthcare and beauty industry. The 8th NYHF generated a significant discussion on all the different areas of the cosmetics and beauty industry. In 2018, the New York Health Forum hopes to expand on addressing other various contemporary issues that are evident in making progress for future healthcare. W

President DoHyun Cho (left) and moderator Dr. Joseph McMenamin (right) with two awardees of the 8th NYHF, CEO Joseph Carabello and President Chul Kyoon Park (center)

Yeereum Chung, RN, BSN

Manager, Project Planning,
W Medical Strategy Group

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

Grace Park

Marketing Specialist, Green Alley

Grace is editorial staff of WKMJ and agenda coordinator of New York Health Forum. She is also a marketing specialist at Green Alley.

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BIOPHARMACEUTICAL REPORT I

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SHOOTING FOR THE UNIVERSE

Alnylam vs Dicerna Trade Secret Litigation May Be Influenced by Emotive Arguments

Alnylam's (NASDAQ:ALNY) trade secrets litigation case against Dicerna (NASDAQ:DRNA) could see the jury influenced by emotive arguments of document theft, as opposed to entertaining the finer details of nuanced trade secret law, lawyers said.

Alnylam acquired Merck's (NYSE:MRK) RNAi subsidiary Sirna for USD 175m in 2014, however 18 months later Alnylam initiated legal proceedings for trade secret misappropriation against Dicerna – a separate RNAi company that also bid for Sirna -- related to GalNAc technology. Dicerna is alleged to have misappropriated trade secrets surrounding Sirna's technology by hiring scientists laid-off by Merck, who took confidential documents with them.

Lawyers noted that even those versed in law may find trade secret law's nuances challenging, and the case's emotive nature could influence a jury of laypeople, favoring Alnylam.

Lawyers noted that a settlement is likely, with the vast majority of trade secrets cases settling before going before juries. Lawyers added that while Dicerna may not have significant grounds in its antitrust case accusing Alnylam of stifling R&D, it could use it as leverage to force an early settlement in the trade secrets case.

A Dicerna 10Q statement notes the court has set a trial date of 23 April 2018 for the trade secret case.

Alnylam noted it believes in the merits of its case but declined to comment on pending litigation. Merck and Dicerna did not respond to requests for comment.

Jury trial clouds potential judgement

A jury trial makes it challenging to say which company will have the upper hand based on legal merit, said Patricia Carson, partner, Kirkland & Ellis, New York. Juries often seek a moral or ethical decision, and if jurors think Dicerna has done something wrong, for example the alleged theft of documents, they may side with Alnylam, said Justin Beyer, partner, Seyfarth Shaw, Chicago, Illinois. The jury may find some of the document theft arguments more compelling – and definitely more intriguing – than the finer details of what is and what isn't a trade secret, said Beyer and Annsley Merelle Ward, senior associate, Bristows, London, UK.

This news service reported on 7 February that Dicerna's key defence may rest upon the idea that the information used to generate its technology was public and thus not a misappropriated trade secret. It also reported that Merck's procedures to protect internal documents could come into question.

Most people, including lawyers, do not understand the nuanced factors of trade secret law, so "buzzwords" used by lawyers on both sides will likely seek an emotive impact on the jurors, said Ward.

> "Most of these trade secret lawsuits end up in a settlement, tipping the odds in this case as well"

Dicerna could well lose the case if it goes to trial, as the American public is generally pro-prosecutor and pro-plaintiff, especially in cases where something is acquired improperly, Beyer said.

Dicerna's lawyers could also appeal to public interest, asserting that Alnylam is trying to monopolize RNAi therapeutics that could help people, said Ward. Dicerna's most advanced candidate is the Phase I DCR-PHXC for primary hyperoxaluria, while Alnylam has seven clinical programs in development ranging from Phase I to FDA registration.

Quantifying actual damages may be challenging as neither company has yet a marketed product from which accounting information can be analysed, said Beyer and Ward. However, damages can also be assessed to compensate for savings in R&D time and money in reaching a specific point and the investment attracted as a result of the misappropriation, although all must be proven, said Ward and Beyer.

While a jury could be susceptible to persuasion by some facts in the case – such as the scientists leaving Merck with documents – the judge will give clear instructions to jurors about what the law is, with both sides offering counterarguments, a biotechnology industry attorney said. Thus, he said, while some facts may sway a jury in theory, that is unlikely as juries frequently do well at weighing evidence.

Settlement possible before the trial

Most of these trade secret lawsuits end up in a settlement, tipping the odds in this case as well, said Beyer. There are many reasons for companies to settle as a trade secrets owner may not want to broadcast its secrets to the other side -- usually their competitor -- and when the trial approaches the judge will increasingly pressure the parties to limit redacted materials or materials only discussed in a closed court room, Ward said. Avoiding negative publicity or any chilling effect on investment opportunity may also motivate the defendant as well as trade secrets owners to settle.

A settlement could involve a structured royalty payment, a lump sum agreement, some sort of licensing deal, periodic accounting or any combination of these, said Ward. The court would likely also order the destruction of any documents that the defendant may still have and may prevent Dicerna from using the confidential information, she noted. In addition to a royalty structure or cross-licensing of technologies of mutual interest, there could also be an agreement between the two companies over what each one could do with the respective products they develop, such as what indications they could pursue, the trade secrets attorney said.

Beyer noted he believed a royalty agreement was most likely for a settlement, wherein Dicerna would pay a percentage of any future sales of the product to Alnylam.

Antitrust case could be settlement tactic

On 9 August 2017, Dicerna filed an antitrust law suit accusing Alnylam of scheming to undermine Dicerna from developing metabolism disorder treatments using RNAi by filing its trade secrets litigation case.

It's possible that the trade secrets litigation could influence the decision of the antitrust suit, as both arise from the same series of events, said Carson. Beyer pointed to the Noerr-Pennington Doctrine, which notes that one cannot be charged or found to be in violation of antitrust law for suing someone in another court. He added for this reason, he questioned the credibility of Dicerna's complaint. Neither of the companies have marketed or competing products, and these are often critical to antitrust cases, he noted. Ward agreed noting that Alnylam cannot be said to have a dominant competitive position, which is key to antitrust law.

Beyer noted that he believed the motive behind Dicerna's antitrust case against Alnylam is to sway the dispute toward an early settlement. Even if Alnylam has a strong case, it will likely want to avoid a lengthy federal antitrust case, which could be costly, he explained. Ward agreed, saying no company wants to be embroiled in an extended antitrust case so it is likely Discerna's strategy will be to help settle.

Alaric DeArment

Reporter, New York

Alaric DeArment covers cancer drug development for BioPharm Insight. He served as associate editor of Drug Store News from 2008 to 2014, covering branded and generic drugs from development to distribution, retail and specialty pharmacy and regulatory affairs. In 2011-2012, he edited the book Contestation and Adaption: The Politics of National Identity in China. A native of Seattle, he graduated with honors with a bachelor degree in journalism from Ball State University and also lived in China from 2001-2004.

Hamish McDougall

Reporter, London

Hamish has a BSc in Neuroscience from the University of Sussex and is primarily covering the neuroscience indications for BioPharm Insight. Prior to joining us he was assistant commissioning editor for a well-known collection of biomedical journals at Expert Reviews, including Expert Review of Gastroenterology & Hepatology, Expert Review of Clinical Pharmacology and Expert Review of Respiratory Medicine.

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

BIOPHARMA REPORT II

Biosimilar Uptake Still Plagued by Interchangeability Hurdles

Biosimilar interchangeability with reference biologics remains a challenge years after product launches, with use depending on physician comfort, experts said. Despite multiple state legislations promoting biosimilar substitution, barriers to uptake remain as use is limited to FDA-approved interchangeable biosimilars, of which there are currently none, they noted.

Lack of interchangeability data and regulatory guidance on using biosimilars in place of originators is a significant barrier to biosimilar uptake. Furthermore, physician and patient education will likely be a growing challenge as more oncology biosimilars get launched. Even though one supportive care oncology biosimilar -- Zarxio (filgrastim-snz) by Novartis' (VTX:NOVN) generics division Sandoz -- was approved in April 2015, upcoming biosimilars used as treatment may face a higher uptake barrier.

A recent Medicare Part B policy change allows for biosimilars to get an individual billing code under the Healthcare Common Procedure Coding System (HCPCS) for reimbursement, which analysts have said would encourage uptake and price competition. While experts agreed this will help promote prescribing, they were more tempered in the policy having a major and immediate impact on biosimilar usage, this news service reported on 27 February.

Lack of interchangeability remains a barrier

The use of biosimilars is still dependent on physician preference, said Michael Hunter, pharmacy management consultant, Milliman, Chicago, Illinois. However, guidance on interchangeability, like clinical evidence or data, would ultimately help the choice for biosimilars over brands, which is still lacking, he added.

Analysts noted that Medicare considered comments from various stakeholders during the comment period before the policy was implemented. The comments showed that grouping biosimilars together led to the impression that the products could be interchangeable. Even thoug h biosimilars may be approved for fewer indications than the reference product or another biosimilar, the grouping could lead to misconceptions on interchangeability without any evidence, analysts added.

The Medicare reimbursement policy change will allow biosimilars to differentiate themselves from each other, which is appropriate for products that are not medically interchangeable, said Richard Manning, partner, Bates White Consulting, Washington DC.

However, experts said interchangeability -- where the biosimilars could be used in place of the reference biologics -- inherently remains a challenge for biosimilar uptake. Despite biosimilars being grouped together under one code in the past, they have largely not been interchangeable, the noted.

Interchangeability is not done at the pharmacist level as a physician's approval is still required for biosimilar use, said Dr Nabhan Chadi, vice president and chief medical officer, Cardinal Health Specialty Solutions, Waukegan, Illinois, adding that at larger institutions, these decisions are made by institutional committees. Physicians have to specifically prescribe the biosimilar, said Hunter, adding that interchangeability remains easier with small molecules and generics, which can be done by a pharmacist. It is difficult to estimate the impact of this recent reimbursement policy change when the long-term interchangeability guidance is not known, said Hunter.

> **"Interchangeability is not done at the pharmacist level as a physician's approval is still required for biosimilar use"**

This news service has previously reported on physician reservations on biosimilar interchangeability, particularly interchangeability of biosimilars of AbbVie's (NYSE:ABBV) Humira (adalimumab). Amgen's (NASDAQ:AMGN) Amjevita and Boehringer Ingelheim's Cyltezo are both approved but not launched. This news service reported 27 February that Amgen would not be conducting interchangeability studies. Coherus Biosciences' (NASDAQ:CHRS) CHS-1420 is in late-stage development, and recently had Phase III equivalency data to Humira announced in August 2017.

Over the last five years, 37 states and Puerto Rico allow biosimilar substitution to be covered under insurance, but it is not clear if that has impacted uptake, said Chadi. While this promotes biosimilar use, other barriers remain, he added. Most states that have enacted legislation on biosimilar substitution require that the prescribing physician be notified or be consulted in some manner about a substitution, said Manning.

It is important to note that while most state laws allow substitution, they do so only of FDA-recognized interchangeable products, he noted. No biosimilars have that designation to date and getting interchangeability on the label seems an unlikely reality in the near term, he added. Until there is more experience with implementing the law in cases with interchangeable biosimilars, it is very hard to say what type of substitutions will be done, he added.

Biosimilar usage will be driven by the collective expertise of the physician and pharmacist, said Steven Lucio, associate vice president, Center for Pharmacy Practice Excellence, Vizient, Irving, Texas. But there is a lack of a reliable source to give guidance on interchangeability of biosimilars

to pharmacists, said Suchira Ghosh, Counsel, Axinn, Veltrop & Harkrider, New York.

Unlike the Orange book -- which is used by pharmacists to make substitution decisions for generics -- the Purple book for biologics and biosimilars does not give adequate information on whether interchangeability is possible, and the decision is left to the clinicians or state, she added. Guidelines by ASCO or NCCN do suggest biosimilar use, but they could add more clarity on substitution to encourage use, said Chadi.

In larger institutions, the use of the biosimilar in place of the originator drug is heavily driven by the payer committees, and some payers have stuck with originator products despite the availability of biosimilars he added.

Oncology uptake faces larger barriers

Favorable reimbursement policies involving separate billing codes such that continued development and therapeutic competition is encouraged are especially important in oncology compared to other conditions like rheumatoid arthritis, said Manning. However, oncologists still need to become more familiar with biosimilars and there is a push for education initiatives aimed at detailing the approval review rigor that biosimilars undergo, said Lucio.

Physician education will be important especially in the next few years as biosimilars for drugs like Roche's (VTX:ROG) Herceptin (trastuzumab) and Avastin (bevacizumab), used directly in treatment, are launched, Lucio noted. There haven't been any major reservations with using Zarxio, a biosimilar for Amgen's Neupogen (filgrastim), for treating neutropenia , mainly because it is supportive care, said Chadi.

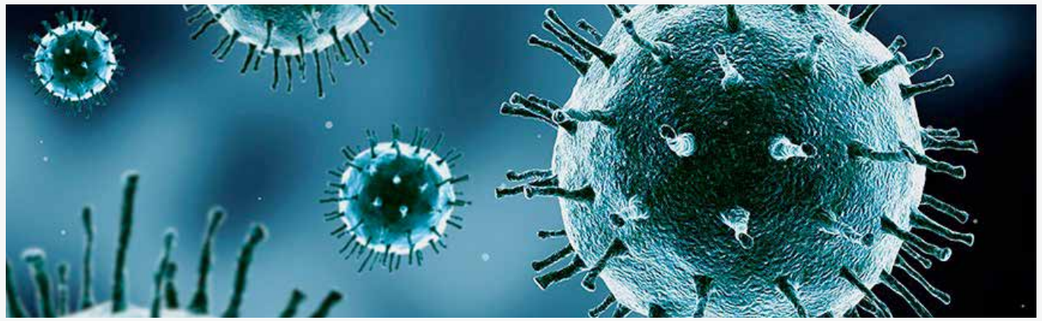
Zarxio has a clear surrogate marker of white blood cell counts to indicate its efficacy in supportive care, but there aren't any similar markers for the Herceptin and Avastin biosimilars, said Lucio. Oncologists would thus have to wait a long time to see if the biosimilar is working, he noted. Mylan's (NASDAQ:MYL) Ogivri, a biosimilar Herceptin and Amgen's Mvasi, a biosimilar for Avastin, were both approved in 2H17 but have not yet been launched.

Patient education is also essential with the use of biosimilars like Zarxio, since patients need explanations of why they are being given a biosimilar substitution of branded product like Neupogen, how the biosimilar has proven safety and efficacy and the rigor of the approval process, said Sandeep Parsad, assistant director of Pharmacy, Cancer and Investigational Drug Services at University of Chicago Medicine. There may be instances where patients would be prescribed the originator but their insurance only covers the biosimilar, she explained.

Manasi Vaidya
Reporter, New York

Manasi Vaidya has a Masters degree in biotechnology. After a stint in a research lab, she spent two years as correspondent in India for BioSpectrum, a publication focused on the Asian biotechnology industry. She then moved to the United States to pursue a Masters degree in Science, Health and Environmental Reporting at New York University. Manasi has reported primarily on topics that combine health and policy, and her work has appeared in Nature Medicine, Nautilus and Scienceline. Her coverage at BioPharm Insight focuses on cancer.

Shooting for the Universe



THINKSTOCK

PRODUCT R&D

SHOOTING FOR THE UNIVERSE

By Michael Leviten, Senior Writer

CureVac AG is bringing a new modality to the race for a universal flu vaccine with an mRNA program backed by a grant from the Bill & Melinda Gates Foundation. While the company believes its approach can yield a product with a cost structure and supply chain relevant for the developing world, it faces a steady pipeline of clinical compounds based on conventional modalities.

Last week, CureVac announced it received backing from Gates for a universal flu vaccine and a vaccine against malaria. The funding comes three years after Gates made a $52 million equity investment in CureVac to support development of the company's RNA platform and construction of an industrial-scale GMP facility.

Daniel Menichella, CBO of CureVac and CEO of its U.S. CureVac Inc. subsidiary, told BioCentury the company expects to select a clinical candidate by the end of 2020, and said Gates' help goes beyond funding and includes coordination with academics that could help selection of an optimal vaccine design.

He would not disclose the amount of either of the new grants, although he told BioCentury the flu vaccine award is "sizable."

The need for a universal flu vaccine has been heightened by this year's harsh flu season. According to the CDC, the current vaccine provides only 36% protection.

A Feb. 15 statement from FDA Commissioner Scott Gottlieb highlighted the challenges of depending on seasonal vaccines, which include prediction of which strain will be dominant, the ability of the virus to mutate as it circulates, and efficacy differences among different manufacturing approaches. For example, for unknown reasons, cell-based vaccines against the H3N2 strain provided better protection than egg-based vaccines this year.

Momentum for moving away from seasonal vaccines is starting to mount. "Ultimately, developing a universal flu vaccine that provides protection against many different strains of flu from year-to-year would be ideal," wrote Gottlieb, although he noted that such a solution is likely "several years away."

On the same day, Sen. Ed Markey (D-Mass.) introduced a bill to make a $1 billion commitment to NIH over five years for research towards a universal influenza vaccine, with the goal of creating lifetime protection from the disease.

NIH's National Institute of Allergy and Infectious Diseases (NIAID) has a universal flu vaccine in Phase I testing, and at least 10 companies and institutions outside of CureVac have universal flu vaccines in preclinical to Phase II testing (see "An Expanding Universe").

NIAID Director Anthony Fauci told BioCentury the key is to create a product that induces an immune response against the conserved region of the virus that isn't subject to season-to-season change.

"A universal vaccine would prevent the need for a new vaccine every year to accommodate genetic drift and protect us from the emergence of a pandemic strain," said Fauci.

While there is no consensus on the best region to target, most approaches leave out or use weakly immunogenic versions of the rapidly mutating head region of influenza HA. The HA head normally dominates the immune response and occludes response to other, more broadly conserved regions of the protein.

The products in development are protein, peptide or synthetic DNA in nature. CureVac believes that its RNA product can have advantages in price and CMC that make it competitive, said Menichella.

Gates did not respond to requests for an interview. On its website it stated that its focus for the CureVac relationship is to "leverage the mRNA platform to significantly reduce timelines and manufacturing cost involved in developing thermostable vaccines against the foundation's target diseases."

Gates has given four other R&D grants that specify universal flu vaccines, and a fifth to form a consortium of funders for advancing development of a universal flu vaccine.

MODALITY MOVE

Menichella said CureVac has produced a lyophilized RNA formulation, paving the way for a heat-resistant vaccine that could avoid the need for cold chain distribution.

He would not comment on the costs of producing other types of vaccines, but said the RNA approach is "extremely cost effective. The vial costs more than the vaccine inside," he told BioCentury.

The terms of the 2015 agreement with Gates require CureVac to make funded products available "at an affordable price in poor countries." The company will be able to market the products in developed countries either by itself or through licensees.

Fauci told BioCentury that the new modality adds to the field. "It's too early to pass any judgment on the best way to make a vaccine but RNA vaccines are a new platform. It's an interesting platform for vaccines and we always welcome new approaches."

Fauci noted RNA vaccines are still an unknown quantity because they are not yet on the market. CureVac has at least 8 RNA-based preventative vaccines in development; the most advanced, CV7201, is in Phase I to prevent rabies.

Still, Fauci thinks there are specific advantages to the modality. "RNA is relatively easy to scale up quickly and there is a degree of precision about it," he told BioCentury.

David Vaughn, director, R&D, GSK vaccines at GlaxoSmithKline plc, agreed that the CMC advantages could make a difference. "In terms of a nucleic acid vaccine approach the huge advantage is speed," said Vaughn.

BIOCENTURY PRODUCT PROFILE

BIOCENTURY PRODUCT PROFILE	
INNOVATION STAGE	
Product	RNA-based universal flu vaccine
Concept	Encodes flu antigens derived from conserved regions of flu proteins
Disease	Influenza
Competition	Seasonal flu vaccine; other universal flu vaccine strategies
Differentiation	Protects against more flu strains; faster and cheaper to produce
Administration	IM
Risks	Allergic response to novel vaccine antigens
Development status	Preclinical
Patents	CureVac AG has two issued patents covering RNA-based flu vaccines
Company; lead investigator	CureVac

He cited a publication that used GSK's self-amplifying mRNA system to take a sequence for an H7N9 strain that produced an outbreak in China in 2013 and create a vaccine that was ready for testing in mice within eight days.

He said GSK is interested in nucleic acid vaccines, which he thinks represent a "true rapid response technology" and could be an intermediate step in the quest for a universal vaccine.

According to Vaughn, the pharma is working on a vaccine that is stable at room temperature, and plans to develop one that can remain active at 30°C for use in African nations.

UNIVERSAL RACE

The search for a universal flu vaccine dates back over a decade, and has been hampered by technical challenges such as production of a recombinant version of the conserved HA stem, and finding other conserved regions to target.

CureVac is not disclosing which antigenic regions it's focusing on or other molecular details of its flu vaccine.

The most advanced compound in development is M-001 from Biondvax Pharmaceuticals Ltd., which is slated to enter Phase III testing this year. M-001 is a fusion protein that strings together triplicates of nine peptides from conserved regions of three flu proteins, HA, M1 and NP, and excludes the HA head

AN EXPANDING UNIVERSE

At least eight companies are developing universal flu vaccines that could pose competition for **CureVac AG**. Additionally, the **Bill & Melinda Gates Foundation** has awarded funds for universal vaccine R&D to research institutes as large as the **National Institute of Allergy and Infectious Diseases** (NIAID) and as small as the U.K.'s **Pirbright Institute**, which focuses on animal health but is working on a vaccine that could be used in both animals and humans. The most advanced program, M-001 from **BiondVax Pharmaceuticals Ltd.** (NASDQ:BVXV) is scheduled to start Phase III trials later this year. Others not shown have made it to the clinic but been discontinued, including a recombinant fusion protein from now defunct VaxInnate Corp., which reached Phase I/II testing. (A) **Imutex Ltd.** is a JV between **Seek Ltd.** and **hVIVO plc** (LSE:HVO); (B) EB66 cell culture technology licensed from **Valneva SE** (Euronext:VLA; VSE:VLA); (C) cell culture technology from **SK Chemicals Co. Ltd.** (KRX:006120); *Source: BCIQ: BioCentury Online Intelligence; ClinicalTrials.gov; Bill & Melinda Gates Foundation website, company and institution websites*

COMPANY OR INSTITUTE	PRODUCT	MODALITY	STATUS
BiondVax Pharmaceuticals Ltd. (NASDAQ:BVXV)	M-001	Peptide	Phase II
Imutex Ltd. (A)	FLU-v	Peptide	Phase II
Vaccitech Ltd.	MVA-NP+M1	Fusion protein	Phase II
FluGen Inc.	RedeeFlu	Viral vaccine (cell culture)	Phase I
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	cH5/1N1 IIV	Viral vaccine (EB66 cell culture (B))	Phase I
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	cH8/1N1 LAIV	Viral vaccine (egg-based)	Phase I
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK)	D-SUIV	Viral vaccine (egg-based)	Phase I
National Institute of Allergy and Infectious Diseases (NIAID)	Universal flu vaccine	DNA vaccine	Phase I
CureVac AG	Universal flu vaccine	mRNA	Preclinical
Inovio Pharmaceuticals Inc. (NASDAQ:INO)	Influenza microconsensus DNA vaccine	DNA vaccine	Preclinical
Johnson & Johnson (NYSE:JNJ)	Universal flu vaccine	Protein	Preclinical
Sanofi (Euronext:SAN; NYSE:SNY)	Universal flu vaccine	Viral vaccine (cell culture (C))	Preclinical
Pirbright Institute	S-FLU	Viral vaccine (cell culture)	Preclinical

region. Within the fusion protein, the peptides are separated by a single amino acid that introduces a kink to promote an immune response to each.

According to Joshua Phillipson, business development manager at BiondVax, the vaccine elicits both cellular and humoral responses and has been tested in almost 700 subjects in trials in Europe and Israel. Phillipson said the company is planning a Phase III trial in Europe and Phase II trial in the U.S. The U.S. study will be conducted in collaboration with NIH.

Two candidates are in Phase II trials: FLU-v from Imutex Ltd. and MVA-NP+M1 from Vaccitech Ltd. Flu-v is a peptide vaccine that targets T cell responses to a trio of influenza proteins — NP, M1 and M2. Vaccitech's candidate is an adenoviral vaccine that includes NP and M1 sequences, and uses a prime boost strategy to stimulate cellular and humoral responses.

NIAID's Phase I candidate is a "headless" HA vaccine that targets the protein's stem region.

According to Fauci, HA's stem has arisen as one of the most promising targets for eliciting a broad immune response. "Over the last decade or so we found there were these cross-reactive stem responses, but, sometimes people didn't pay much attention to them because they weren't very powerful," he said. NIAID's recombinant HA stem is meant to harness that broad response and make it stronger by avoiding exposure to the protein's head.

NIAID researchers have published animal data showing the nanoparticle-loaded stem protein vaccine can induce immune responses, reduce viral titers and protect mice from weight loss and a lethal challenge.

GSK has three potentially universal vaccines in Phase I testing that employ both heads and stems.

The vaccines, which were developed at Icahn School of Medicine at Mount Sinai, use chimeric viruses with "exotic" and poorly immunogenic head regions from rare flu viruses, such as H5, 7 or 8, fused to an H1 stem. The approach involves a heterologous vaccination strategy that alternates the head regions in the vaccine but keeps the stem constant so only the stock response becomes amplified. Each of GSK's Phase I candidates contain a different head region.

Florian Krammer, associate professor of microbiology at Icahn, told BioCentury the strategy protected mice from at least six different HA variant strains.

> "RNA is relatively easy to scale up quickly and there is a degree of precision about it."
>
> Anthony Fauci, NIAID

However, Sanofi SVP of Vaccine R&D John Shiver is skeptical about the preventive potential of vaccines designed for the stem response. "They're more likely to protect from the more severe consequences of flu rather than the less severe ones or blocking infection. That doesn't mean there's no role for those types of antigens but that's not what current flu vaccines are expected to do," he told BioCentury.

Sanofi has a preclinical universal flu vaccine program, and is using computational methods to find conserved regions of flu proteins to target.

Fauci noted that these first wave vaccines are likely to provide broader coverage than the current approach but may not result in full universality. "I look at it as a gradually improving iterative process. So there will be a universal flu vaccine 1.0 which means it won't protect against all influenza but maybe all H3N2s.That's the first goal I'd like to achieve – getting it against all H3N2s – that would be really good," he said.

COMPANIES AND INSTITUTIONS MENTIONED

Bill & Melinda Gates Foundation, Seattle, Wash.
BiondVax Pharmaceuticals Ltd. (NASDAQ:BVXV), Ness Ziona, Israel
CureVac AG, Tübingen, Germany
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.
Icahn School of Medicine at Mount Sinai, New York, N.Y.
National Institute of Allergy and Infectious Diseases (NIAID), Bethesda, Md.
National Institutes of Health (NIH), Bethesda, Md.
Sanofi (Euronext:SAN; NYSE:SNY), Paris, France
Vaccitech Ltd., Oxford, U.K.

TARGETS AND COMPOUNDS

HA - Influenza A virus hemagglutinin
M1 - Influenza A virus matrix protein M1
M2 - Influenza A virus matrix protein M2
NP - Influenza A virus nucleoprotein

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Keynote Speaker:
Ui-Hwa Chung, MD
Speaker, National Assembly

"Symposium on Global Health Disparities"

Rayburn House Office Building
Washington DC

Keynote Speaker:
Congressman Mike Honda
Congressman Charles Rangel

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).*

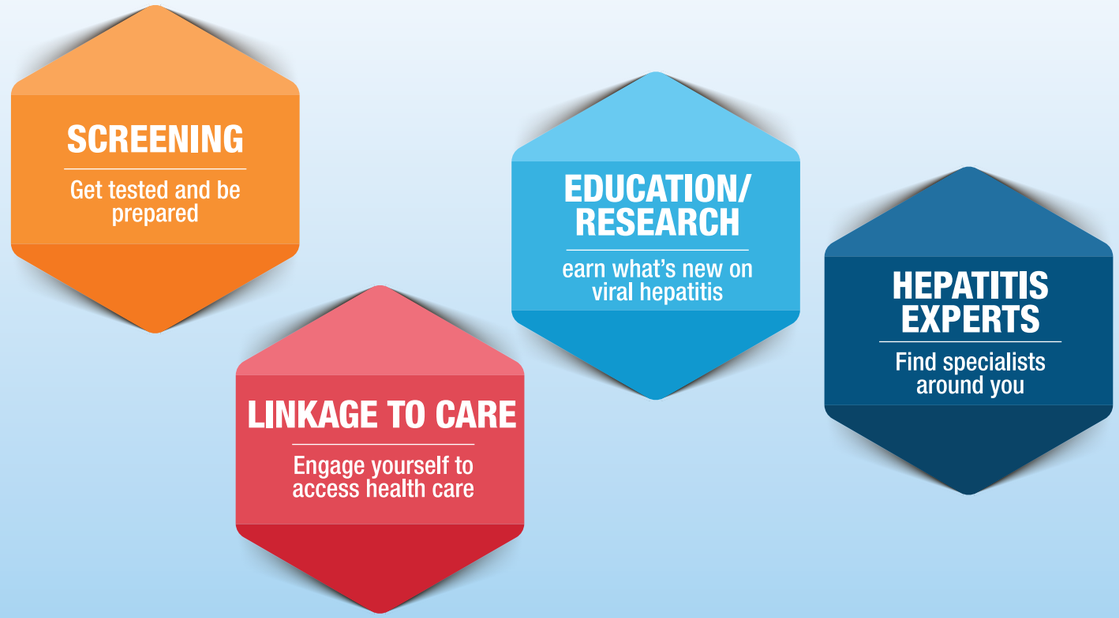
For detailed information, please see full Prescribing Information. To learn more call 1-800-GILEAD-5 (1-800-445-3235) or visit www.VIREAD.com.

CVH

Center for Viral Hepatitis

바이러스간염진료센터

- **To promote the awareness of hepatitis B**
- **To screen in high risk population**
- **To facilitate the linkage to care**



www.cureHep.org

Conference Alerts

North America

2018 Health Datapalooza
April 26 - 27, 2018 | Washington DC, USA

Website: http://www.academyhealth.org/events/site/2018-health-datapalooza
Contact: https://www.academyhealth.org/contact

2018 Health Datapalooza is where Silicon Valley meets healthcare system. This unique gathering of big thinkers who are federal policymakers, regulatory leaders and heads of Silicon Valley startups aims to pioneer and further develop innovations that drive health policy and practice by using data and technology.

The 15th Annual World Health Care Congress
April 29 - May 2, 2018 | Washington DC, USA

Website: http://www.worldcongress.com/events/HR18000/
Contact: wcreg@worldcongress.com

Attendees from more than 1,500 national and global industry leaders will assemble at the 15th Annual World Health Care Congress to discuss current healthcare system. The conference will be concentrating on topics of strategic initiatives and planning that will define advancement of healthcare delivery in creating a healthy population. It is where decision makers ranging from payers, providers as well as pharmaceuticals will share ideas in identifying consumer needs in finding solutions for high-value healthcare.

2018 BIO International Convention
June 4 - 7, 2018 | Boston, Massachusetts, USA

Website: http://convention.bio.org/2018/
Contact: convention@bio.org

Hosted by the Biotechnology Innovation Organization (BIO), The BIO International Convention will be a gathering of more than 1,100 biotechnology companies, academic institutions, and related organizations that are representing states across the US and more than 30 other nations. This is an opportunity for leaders in the biotech and pharma industry to globally network and gain access to over 500 education sessions and networking or partnerships with more than 16,000 attendees from 74 countries.

Academy Health 2018 Annual Research Meeting
June 24 - 26, 2018 | Seattle, Washington, USA

Website: http://www.academyhealth.org/events/site/2018-annual-research-meeting
Contact: http://www.academyhealth.org/contact

Annual Research Meeting (ARM), the premier forum for health services research (HSR), will convene the foremost experts at the intersection of health, healthcare, and policy to share and showcase the latest research on how the health system works, what it costs, and how to improve it. The largest meeting of its kind, the ARM is packed with new research, cutting edge methods, and robust discussions of HSR's impact on health policy and practice. The meeting features compelling sessions, panels on critical and emerging issues in health services research, and presentations of high quality peer-reviewed research.

HLTH - The Future of Healthcare
May 6 - 9, 2018 | Las Vegas, Nevada, USA

Website: https://hlth.co/
Contact: info@hlth.co

HLTH is the leading event covering innovation in healthcare that is driving substantial reduction in costs and dramatic increase in quality. It's an unprecedented, large-scale forum for individuals, companies and policymakers, who are reshaping the healthcare industry to learn, collaborate and evolve. The event is unique in bringing together all key industry stakeholders, ranging from established providers, payers, employers and pharma services to disruptive startups and prolific investors as well as representatives from government, media and analysts.

18th International Biotechnology Symposium and Exhibition
August 12 - 17, 2018 | Montréal, Canada

Website: http://www.ibs2018montreal.org/en/index.html
Contact: info@ibs2018montreal.org

The 18th edition of the International Biotechnology Symposium will be held in Montreal, Canada. The five- day conference will be hosted by the International Union of Pure and Applied Chemistry and co-organized with the National Research of Canada, McGill University, the University of Waterloo and BIOTECanada. The theme of 2018 symposium will be "Supporting a Healthy World." It will provide an international forum on how biotechnology is advancing the development of medicine and diagnostics with the integration of big data and artificial intelligence.

Europe

World Precision Medicine Congress
May 16 - 18, 2018 | London, United Kingdom

Website: http://www.terrapinn.com/conference/world-precision-medicine-congress/index.stm
Contact: issa.mauthoor@terrapinn.com

World Precision Medicine Congress 2018 will be dedicating to the discussion of Artificial Intelligence in Healthcare. This year's conference will highlight the thought-provoking topics on drug discovery and development relevant to genomic medicine, big data and genomics and not limited to rare diseases, precision oncology as well as other therapy areas. There will be a gathering of 80 companies and hundreds of attendees from pharma and biotech companies and academia.

6th Edition of International Conference on Infectious Diseases
June 7 - 8, 2018 | London, United Kingdom

Website: https://infectious-diseases.euroscicon.com/
Contact: info@euroscicon.com

The 6th Edition of International Conference on Infectious Diseases is organized by EuroSciCon. Euroscicon is the longest running independent life science events company with a predominantly academic client base. The Infectious Diseases-2018 conference is a leading forum for virologists, microbiologists, bacteriologists, public health professionals, immunologists and epidemiologists. The main theme of the conference is "Global Impact on the Control, Treatment and Elimination of Infectious Diseases," which will cover a wide range of critically important sessions from basic research to innovations in the area of Infectious Diseases.

Europe

50th Jubilee Meeting of the European Pancreatic Club

June 13 - 16, 2018 | Berlin, Germany

Website: https://epc2018.eu/
Contact: epc2018@interplan.de

The European Pancreatic Club (EPC) is a non-profit, international scientific organization dedicated to the study of the pancreas. EPC was founded in 1965, with the idea to bring together basic scientists and clinicians in an informal atmosphere to promote friendship and research communication. Therefore, EPC has provided a platform for pancreatologists for five decades. EPC has strong connections with various European National Pancreatic Societies (from 22 countries). The EPC meeting 2018 welcomes all attendees to a program ranging from clinical controversies to basic research issues. The EPC meeting 2018 includes the following congress highlights: endoscopic, surgical and medical management of pancreatitis, pancreatic origins of diabetes, molecular diseases markers and cellular mechanisms, neuroendocrine and cystic pancreatic tumors, novel drug treatments and drug-induced injury and more.

SLAS Europe 2018 Annual Conference & Exhibition, Brussels

June 27 - 29, 2018 | Brussels, Belgium

Website: https://www.slaseurope2018.org/
Contact: odupuy@slas.org

The first annual event for the European Life Sciences Discovery and Technology Community (SLAS), the SLAS Europe 2018 Annual Conference and Exhibition will bring together over 1,000 academic and industry scientists and technologists throughout Europe. The program will have 50 scientific presentations, addressing emerging areas in biology, technology and discovery, and it will highlight impact on big data and artificial intelligence on biotechnology advancement of today's world. The conference is also a great opportunity to find out about the latest developments in instrumentations, assays diagnostics, etc.

8th World Congress of Biomechanics

July 8 - 12, 2018 | Dublin, Ireland

Website: http://wcb2018.com/
Contact: expo@wcb2018.com

The World Congress of Biomechanics is held once every four years and is the premier meeting worldwide in its field. It has been running for the past 25 years as the leading international event in this multidisciplinary field. The five- day scientific program at the World Congress of Biomechanics will cover a wide spectrum of the sector. An expected attendance of 4,000 delegates from across the globe in one location will provide an excellent opportunity for knowledge sharing, debate and engagement. Ireland's medical technology sector has evolved into one of the leading clusters globally. 18 of the world's top 25 medical technology companies have a base in Ireland and 50% of the 400 med tech companies based here are indigenous.

17th European Congress of Internal Medicine

August 30 - September 1, 2018 | Wiesbaden, Germany

Website: https://ecim2018.eu/
Contact: info@efim.org

The European Congress of Internal Medicine (ECIM) is a major event where physicians, scientists and other experts in the field of Internal Medicine exchange the latest information on advances in science and clinical practice. In addition to the presentation of the results of clinical and basic research, the ECIM 2018 will focus on innovative and comprehensive overview of the treatment of complex, multi-morbid patients. Therefore, the theme of ECIM 2018 is "The Art of Managing Clinical Complexity: an integrated, patient-centered approach." Particular areas of interest include the prevention, diagnosis and treatment of the principal features of metabolic syndrome and the associated spectrum of cardiovascular disease and other comorbid conditions.

Asia

AOPA & KPBA & KPSC 2018

April 26 - 28, 2018 | Seoul, Republic of Korea

Website: www.aopa2018.org
Contact: aopa2018@conventionpm.com

Asian-Oceanic Pancreatic Association, Korean Pancreatobiliary Association, and the Korean Pancreas Surgery Club 2018 (AOPA & KPBA & KPSC 2018) will be held at the Lotte Hotel in Seoul, Korea under the them of "Debate and Challenges in Clinical Pancreatology". This meeting will bring together clinicians who are engaged in studying pancreatology in various fields of medical and surgical departments to share knowledge and skills on better taking care of the patients with case based discussion.

Singapore Hepatology Conference 2018

June 8 - 9, 2018 | Singapore, Singapore

Website: http://www.shc-sg.com/landingpage/
Contact: info@shc-sg.com

The scientific program of Singapore Hepatology Conference 2018 includes a multi-disciplinary approach to the assessment, diagnosis and treatment strategies to eradicate HBV, HCV, NASH and HCC. With an outstanding success of the 4th Singapore Hepatology Conference and the best of EASL (SHC-EASL) 2017 with over 600 participants from 30 countries, the scientific program encompasses a multi-disciplinary approach to the assessment, diagnosis and treatment strategies to eradicate HBV, HCV, NASH and HCC. The 5th Singapore Hepatology Conference (SHC) 2018 will continue to provide focused updates, advances in the prevention, treatment and management of liver diseases.

BIT's 7th Annual World Congress of Infectious Diseases 2018

July 12 - 14, 2018 | Bangkok, Thailand

Website: http://www.bitcongress.com/wcid2018/default.asp
Contact: zoe@wcidcongress.com

The theme of the 7th Annual World Congress of Infectious Diseases (WCID-2018) is "World Dream of Eradicating Infection." The conference will include 9 research fields in infection diseases and 50 parallel sessions with 500 attendees coming from all over the world. The WCID-2018 program will follow the path of eradicating infectious diseases development and showcase some of the cutting edge technologies, latest developments and efficient methodologies. The WCID is also the place to start find new collaborations between academia, industry and institutes to further develop or apply new antimicrobial drugs' development towards the market.

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8th Forum | December 6, 2017

Special KOL Discussion :
Strengthening World Korean Medical Journal (WKMJ)
7th Forum | June 21, 2017

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

Key Trends in US Biopharma/Medtech Investing
5th Forum | March 31, 2016

Furthering Global Biopharma: Opportunities for Development with East Asia
4th Forum | November 12, 2015

Future is Now: The Era of Mobile Health
3rd Forum | May 21, 2015

The Pacific Connection: US- East Asia Pharma Collaboration
2nd Forum | Feburary 11, 2015

Forecasting Healthcare in 2015 & Trans-Cultural Healthcare
1st Forum | December 18, 2014

For more information

www.newyorkhealthforum.net

min.park@wmedical.org

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1. Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.

The price of Humira, an anti-inflammatory drug dispensed in an injectable pen, has risen from about $19,000 a year in 2012, to more than $38,000 today, per patient, after rebates, according to SSR Health, a research firm. Humira is among a new class of drugs known as biologics, which are made from living cells rather than synthetic chemicals. The industry has argued that high American prices are needed to fund drug development, but a 2016 study published by the Journal of the American Medical Association found "no evidence" of an association between research and development costs and prices; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.

https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html

2. Fed Up With Drug Companies, Hospitals Decide to Start Their Own

For years, hospital executives have expressed frustration when essential drugs like heart medicines have become scarce, or when prices have skyrocketed because investors manipulated the market. Now, some of the country's largest hospital systems are taking an aggressive step to combat the problem: they plan to go into the drug business themselves, in a move that appears to be the first on this scale. The idea is to directly challenge the host of industry players who have capitalized on certain markets, buying up monopolies of old, off-patent drugs and then sharply raising prices. Several major hospital systems, including Ascension, a Catholic system that is the nation's largest nonprofit hospital group, plan to form a new nonprofit company that will provide a number of generic drugs to the hospitals.

https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html

3. Celgene Confirms $9B Juno Buyout, Sees $3B Sales for JCAR017

Celgene has agreed to buy CAR-T specialist Juno Therapeutics for around $9 billion in a deal that instantly makes it a big cheese in this emerging therapeutic category. The definitive terms of the deal—rumors of which hit the headlines —were laid out and revealed Celgene's lofty ambitions for Juno's pipeline, including what it expects could become $3 billion in sales for lead CAR-T JCAR017, assuming it gets FDA approval next year. Celgene already owns a little under 10% of Juno and has collaborated with the CAR-T specialist since 2015, when they signed a 10-year collaboration to develop treatments for cancer and immune diseases, but will now take complete control of JCAR017—in phase 1 for non-Hodgkin's lymphoma—as well as eight additional clinical and preclinical projects.

https://www.fiercebiotech.com/biotech/celgene-confirms-9bn-juno-buyout-sees-3bn-sales-for-jcar017

4. Sanofi, Facing Threat From Generics, Moves to Buy Hemophilia Drug Maker

The French drug maker Sanofi stated that it had agreed to acquire Bioverativ, a biopharmaceutical company focused on treatments for hemophilia and other rare blood disorders, for $11.6 billion in cash. Sanofi has sought use acquisitions to bolster its portfolio of drugs, particularly because it faces declining sales for its diabetes drug, Lantus, which has lost its patent protection. The Bioverativ deal would enhance Sanofi's presence in specialty care and leadership in rare diseases and creates a platform for growth in other rare blood disorders.

https://www.nytimes.com/2018/01/22/business/dealbook/sanofi-hemophilia-bioverativ.html

5. New Index Rates Drug Companies in Fight against 'Superbugs'

GlaxoSmithKline and Johnson & Johnson are the best of the big pharmaceutical companies at tackling the growing "superbug" threat, according to an index released at the World Economic Forum in Davos, Switzerland. The index, which rates companies on their contributions in preventing the spread of bacteria that are resistant to antibiotics, found Mylan to be the best of the generic drug makers and rated a little-known company, Entasis, as top among biotechnology companies. Growing numbers of people are dying from "flesh-eating" microbes; from infections picked up in hospital and nursing homes; and from strains of pneumonia, tuberculosis, gonorrhea and other diseases that are impervious to most drugs. The Centers for Disease Control and Prevention estimates such infections kill about 23,000 Americans a year.

https://www.nytimes.com/2018/01/23/health/antibiotic-resistence-glaxo-johnson.html

6. Big Data Methods Applied to the Fitness Landscape of the HIV Envelope Protein

There is still no effective vaccine for the human immunodeficiency virus (HIV), although recent hope has emerged through the discovery of antibodies capable of neutralizing diverse HIV strains. However, HIV can sometimes evade known broadly neutralizing antibody responses via mutational pathways, which makes it all the more difficult to design an effective solution. An ideal vaccine would elicit broadly neutralizing antibodies that target parts of the virus's spike proteins where mutations severely compromise viral fitness or the ability to replicate. To achieve this goal, data scientists from the HKUST and their collaborators from MIT have employed a computational approach to estimate the fitness landscape of gp160, the polyprotein that comprises HIV's spike.

https://medicalxpress.com/news/2018-02-big-methods-landscape-hiv-envelope.html

7. From Clinics to Child Insurance, Budget Deal Affects Health Care

The budget deal in Congress is billed as a measure to grant stability to a government funding process that has lurched from crisis to crisis — but it is also stuffed with provisions that will broadly affect the nation's health care system, like repealing an advisory board to curb Medicare spending and funding community health centers. Among the more significant provisions is one that would eliminate a powerful 15-member panel, known as the Independent Payment Advisory Board, created by the Affordable Care Act to control the rising costs of Medicare. Now, under the budget deal, it would be eliminated. The Congressional Budget Office estimated that killing the panel would increase federal spending by $17.5 billion over 10 years.

https://www.nytimes.com/2018/02/08/us/politics/budget-deal-health-care.html

8. FDA Clears Insulin Dose Calculator that's Connected to a Smartphone App

The US Food and Drug Administration has cleared a mobile system that could simplify diabetes management for some patients. Glooko's Mobile Insulin Dosing System allows doctors to set a dosage and pulls data from the patient's glucose monitor to recalculate levels based on the reading. It's integrated into Glooko's existing mobile app and sends reminders to patients' cellphones when it's time to take another dose. Now that the system is approved, Glooko will start commercializing it and work through reimbursement.Glooko already has a partnership with Novo Nordisk, which produces Levemir and Tresiba.

https://www.cnbc.com/2018/02/14/fda-approves-insulin-dose-calculator-thats-connected-to-a-smartphone-app.html

9. How Dental Inequality Hurts Americans

Not being able to see a dentist is related to a range of health problems. Periodontal disease (gum infection) is associated with an increased risk of cancer and cardiovascular diseases. In part, this reflects how people with oral health problems tend to be less healthy in other ways; diabetes and smoking, for instance, increase the chances of cardiovascular problems and endanger mouth health. But the problems go beyond health. People with bad teeth can be stigmatized, both in social settings and in finding employment. Studies document that we make judgments about one another — including about intelligence — according to the aesthetics of teeth and mouth.

https://www.nytimes.com/2018/02/19/upshot/how-dental-inequality-hurts-americans.html

10. Deal Making Just Got Tougher for Struggling Generic Drugmaker

Generic drugmakers are being squeezed from both sides. Prices are falling because the companies that buy the drugs have consolidated, putting the relatively fragmented drugmakers at a disadvantage. And, the Food and Drug Administration has sped up approvals for new generic drugs, adding new competition to the market. Mergers among manufacturers would, in theory, help the industry get its bargaining power back, and there are some small deals awaiting regulatory approval. Teva Pharmaceutical Industries told that it is considering additional asset sales as a way to help reduce its high debt burden.

https://www.wsj.com/articles/deal-making-just-got-tougher-for-struggling-generic-drugmakers-1519209002?mod=searchresults&page=1&pos=7

11. How Amazon, JPMorgan, Berkshire Could Transform American Health Care

With the world's three richest people leading the charge – Amazon CEO Jeff Bezos and Berkshire CEO Warren Buffett – as well as JPMorgan Chase CEO Jamie Dimon, the newly minted coalition is hoping to lower health care costs for the companies' employees and deliver significant advancements for all patients. One sign the new alliance is building momentum is that more companies are interested in joining them. Perhaps the biggest key to the coalition leaders' strategy is their disavowal of profit motives. The new company they plan to establish will not seek to profit off of health care, unlike the industry's leading for-profit insurers, drug makers and many health care providers.

https://www.usatoday.com/story/money/2018/02/25/amazon-jpmorgan-berkshire-health-care

12. Discovery Reveals Way to Stop Inflammation in Alzheimer's, Arthritis, More

A new discovery about the immune system may allow doctors to treat harmful inflammation that damages the brain in neurodegenerative diseases such as Alzheimer's. It might also let doctors save patients from the potentially deadly inflammation of sepsis, a full-body infection that kills a quarter-million Americans every year. UVA's Carter Immunology Center's new finding, involving important immune cells known as macrophages, could offer a way around that. The center have identified a specific electrical switch, known as an ion channel, within macrophages that controls the flow of calcium into the cells. By targeting this switch with tiny molecules, researchers could deny the macrophages calcium and prevent inflammation - even in the brain.

https://www.sciencedaily.com/releases/2018/02/180226122511.htm

13. States Consider Bringing Prescription Drugs from Canada to US as Costs Soar

In the face of surging prescription drug prices, some US states are proposing to import medicines in bulk from Canada, where many drugs are cheaper thanks to government price controls. Vermont lawmakers are considering legislation to create an agency which would buy popular prescription medicines in bulk from Canada, and then distribute to pharmacies in the state. Utah, Oklahoma and West Virginia have proposed similar measures. The desperate move comes as the cost of pharmaceuticals is expected to grow faster than other US healthcare spending in the next decade.

https://www.theguardian.com/us-news/2018/mar/01/prescription-drugs-costs-us-import-canada

14. Opioid Maker Insys Still Has Fans on Wall Street

Insys Therapeutics has lost its former CEO and co-founder, John Kapoor, and several top executives, all charged with conspiracy to illegally distribute an addictive prescription painkiller. The company has lost more than 80% of its market cap since its peak price in 2015 amid declining sales and multiple lawsuits from states over how it marketed Subsys, a mouth-spray version of the potent opioid painkiller fentanyl that is approved by the Food and Drug Administration to treat cancer-related pain. But Insys hasn't lost all of its following on Wall Street. Four of the six analysts who cover Insys still recommend buying the stock. Despite the threat of looming litigation, they note the possibilities in the company's pipeline and the potential stabilization of Subsys sales, among other things.

https://www.wsj.com/articles/opioid-maker-insys-still-has-fans-on-wall-street-1520286053?mod=searchresults&page=1&pos=3

15. United Healthcare Says It Will Pass on Rebates from Drug Companies to Consumers

In response to growing consumer frustration over drug prices, United Healthcare, one of the nation's largest health insurers, said that it would stop keeping millions of dollars in discounts it gets from drug companies and share them with its customers. Dan Schumacher, the president of United Healthcare, said the new policy will apply to more than seven million people who are enrolled in the company's fully insured plans, beginning 2019. Insurers like United Healthcare, whose parent company also owns a large pharmacy benefit manager, OptumRx, have come under increasing public pressure as drug prices — especially for brand-name drugs — continue to rise, angering consumers and lawmakers.

https://www.nytimes.com/2018/03/06/health/unitedhealth-drug-prices.html

16. Healthcare M&A Outlook Bright for 2018: Analysts

After a subdued 2017, analysts and industry experts predict 2018 to be a robust year for healthcare M&A. Separate reports by EY and Baker & McKenzie predict a significant rise in M&A's this year. Aligning with the forecasts, healthcare companies have started the year on a positive note, announcing deals worth over $30bn already. Giving the biotech sector a flying start, Sanofi announced two major acquisitions- Bioverativ for $11.6bn and Albynx for $4.8bn. Marking Korea's first pharma investment in Ireland, the country's SK Biotek a global life sciences company announced the acquisition of the former Bristol-Myers Squibb API facility. This recent flurry of M&A activity in pharmaceuticals and biotech has prompted industry experts to predict a robust year for M&A across life sciences.

https://www.biospectrumasia.com/analysis/25/10447/healthcare-ma-outlook-bright-for-2018-analysts.html

17. Cigna to Buy Express Scripts for $67 Billion

Cigna has announced plans to buy Express Scripts pharmacy management organization in a deal valued north of $60 billion. The deal will bring pharmaceutical and medical claims branches of the health care business under one roof and represents the latest example of industry consolidation, following the nearly $70 billion CVS-Aetna union announced late last year. In total, the deal is expected to be valued at $67 billion, including Cigna's acceptance of $15 billion of debt held by Express Scripts. It is expected to allow Cigna to have a hand in negotiating lower prescription drug prices, potentially cutting costs for the company during a time of health care volatility.

https://www.usnews.com/news/economy/articles/2018-03-08/cigna-to-buy-express-scripts-for-67-billion

18. World Health Organization Gets Ready for 'Disease X'

The World Health Organization included "Disease X" in its most recent global plan for accelerating research and development during health emergencies like the Ebola, SARS or Zika epidemics. The strategy and preparedness plan, known as the 2018 R&D Blueprint, was published last month. Essentially, scientists develop customizable recipes for creating vaccines. Then, when an outbreak happens, they can sequence the unique genetics of the virus causing the disease and plug the correct sequence into the already-developed platform to create a new vaccine.

https://www.cnn.com/2018/03/12/health/disease-x-blueprint-who/index.html

19. Trump Promising Consumers Digital-Age Healthcare Approach

The Trump administration is taking a pragmatic new tack on health care, with officials promising consumer friendly changes and savings in areas from computerized medical records to prescription drugs. New Health and Human Services Secretary Alex Azar has been rolling out the agenda, saying it has the full backing of President Donald Trump. With Azar installed as Trump's second health secretary, the administration is shifting to issues of broader concern for people with Medicare and employer-provided coverage. Many of the ideas have bipartisan support and can be advanced without legislation from Congress.

https://www.washingtonpost.com/politics/health_care/trump-promising-consumers-digital-age-health-care-approach/2018/03/12/

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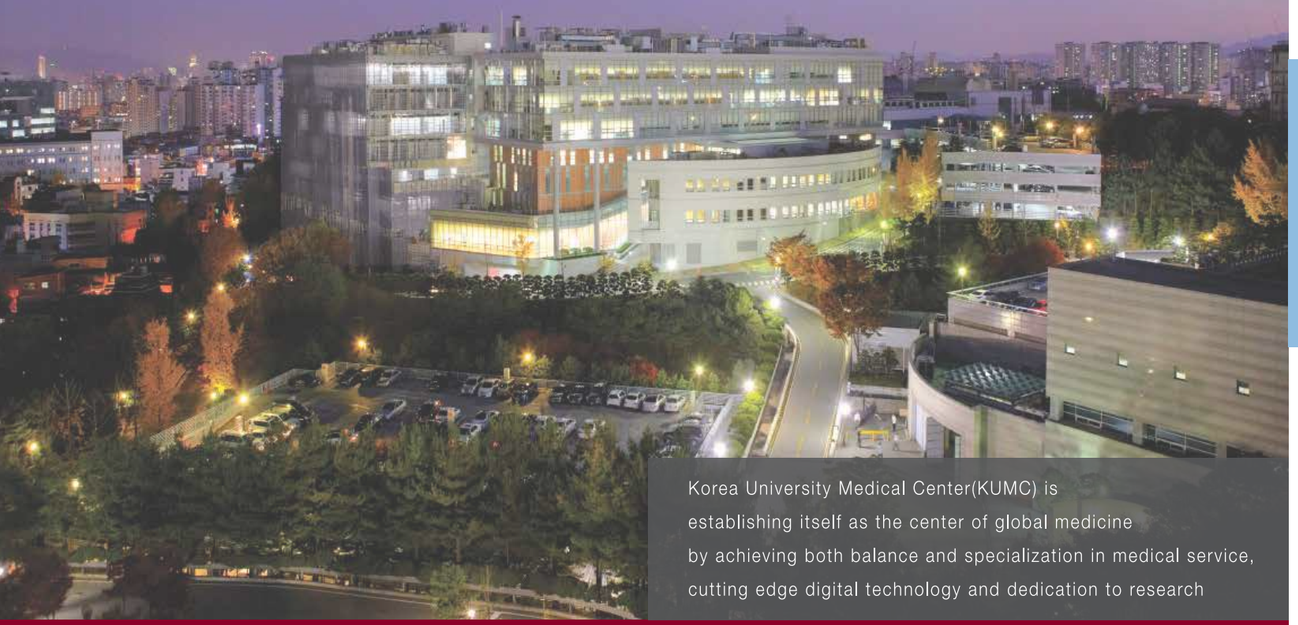

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