July 2018 - ISSUE 17

WKMJ

World Korean Medical Journal

Cover Story

Inspirational Korean Healthcare Leader

Eun Sook Lee, MD, PhD
President of the Korean National Cancer Center

Special Report

The Benefits of Pharmacogenomics

Ductal Carcinoma in Situ: Current Status and Future Perspectives

Biopharmaceutical Report

Immunomedics' Sacituzumab Has Insufficient Dataset to Pursue Accelerated Approval

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

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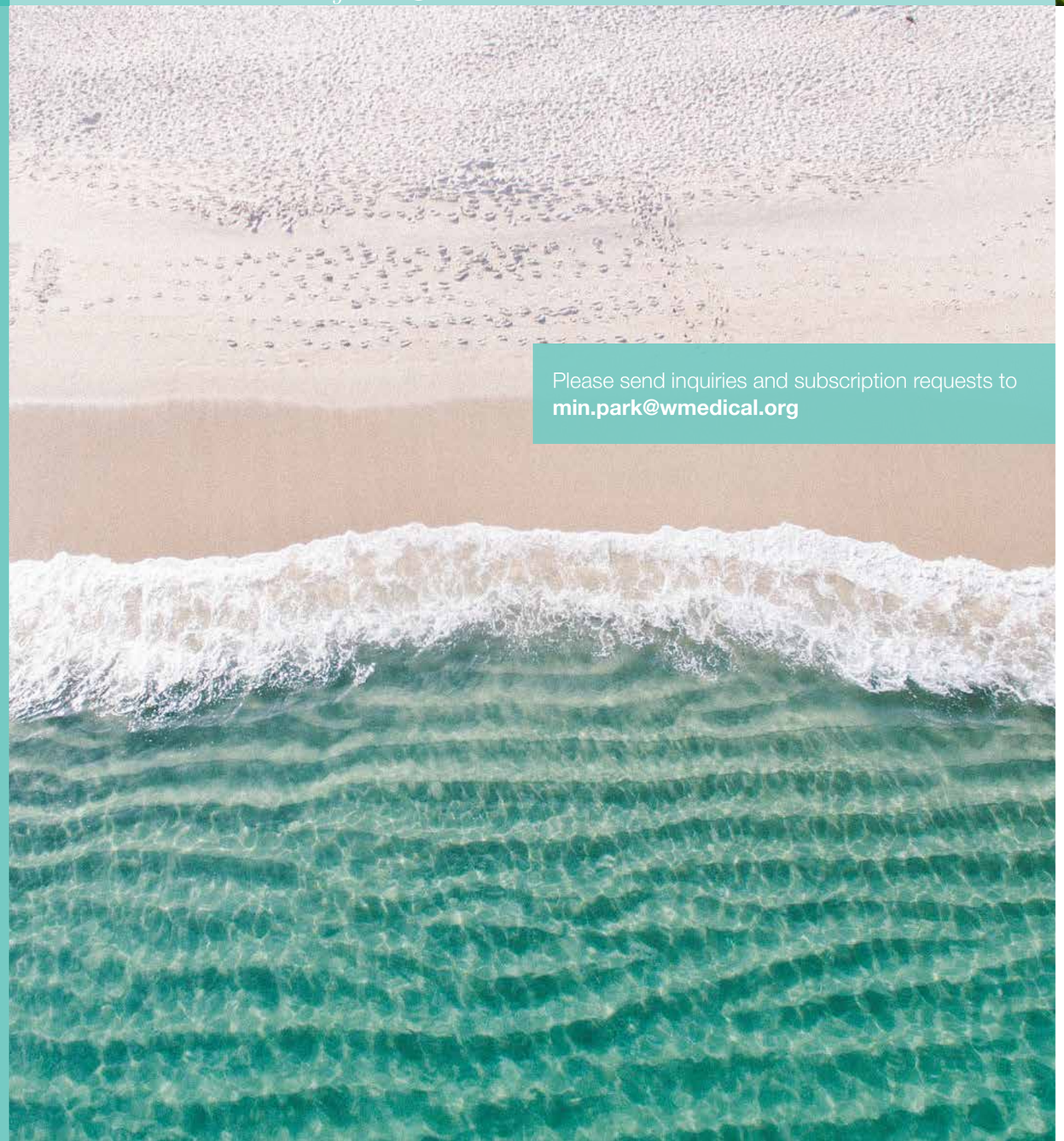

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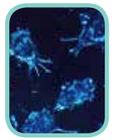
Cover Story

Eun Sook Lee, MD, PhD,
President of the Korean National Cancer Center

SPECIAL REPORT

The Benefits of Pharmacogenomics

Ductal Carcinoma in Situ: Current Status and Future Perspectives



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FROM THE PUBLISHER

Many events have happened around the globe in a relatively short time frame. Just last month, we saw a historic moment where President Donald Trump and North Korean leader Kim Jong Un met face-to-face for a summit in Singapore. It was the first time we witnessed the sitting leaders of United States and North Korea meet to conduct diplomatic negotiations and ease international tensions between the two countries. June also marked the beginning of a long anticipated 2018 World Cup in Russia. Although South Korea was unsuccessful in advancing to Round 16, they stunned the nation and the world by defeating the defending champion Germany.

In this issue we feature a prominent physician Dr. Eun Sook Lee who is at the forefront of war on cancer. The interview of Dr. Lee is meaningful as she is the first female physician to be featured on WKMJ's cover story. She has dedicated herself to breast cancer treatment where the somber diagnosis may be tendered more sensibly by a female doctor. Cancer outcome depends on the staging and this is where screening is important to pick up in the early phase. And her positive attitude is one of the most important therapeutic interventions that sets the tone. Dr. Lee clearly personifies the 'tip of the spear' as a first female in many regards, and she has been a leader in her field for the past 30 years. And today she carries the spear forward as the president of Korean National Cancer Center which is the leading cancer research center in the country. Bringing Proton Therapy, which is as effective as X-ray therapy while causing less collateral damage on healthy tissue, to NCC in 2007 was a major advancement. Dr. Lee is comprehensive in her outlook on cancer, and the most beneficial and broad application of her endeavors is in cancer prevention through healthy lifestyle. In Loma Linda CA, or other parts of the world known as Blue Zones, healthy lifestyle has shown to lead to longevity. Dr. Lee has been a pioneer, and hopefully through her continued efforts future Blue Zones will emerge in Korea. The story of her career is a model for those aspiring future physicians, both men and women, who will advance the medical field as Dr. Lee has done.

Many changes are happening in the world and with a political shift, there seem to be emerging signs of nationalism with less globalization and cooperation between the nations; Britain left EU, US closed its borders, and Russia tried to expand its borders. Despite this shift toward nationalism, I believe there is still hope for more medical cooperation among the nations.

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

FROM THE EDITOR-IN-CHIEF

The National Cancer Center (NCC) is the Korean government's principal agency for cancer research, cancer patient treatment and cancer specialists training. NCC leads, conducts, and supports cancer research across the nation to advance scientific knowledge and to help all people live cancer-free lives. The battle to conquer cancer through prevention, diagnosis, treatment, and research is being fought on both national and international levels, and the NCC has persevered to be the leader in these battles for the Koreans. For the Cover Story, WKMJ interviewed Eun Sook Lee, MD, PhD who is currently the president of the National Cancer Center (NCC).

As the editor-in-chief, I have two reasons to introduce Dr. Eun Sook Lee and the NCC to our readers. First reason is my keen affection for the NCC. In the late 2000s, when I was serving as the secretariat for Korea Health Forum for two years, I worked closely with Dr. Keun-Young Yoo, the president of NCC at the time, as one of the board members, and I had the chance to learn much about the roles and the responsibilities of the NCC from him. Ever since, I tried to become a conduit for the agency whenever I had the chance to introduce the NCC to the outer world, and now I have the chance to introduce the agency to our WKMJ readers worldwide. Second reason is the specialty of Dr. Eun Sook Lee. Dr. Lee is a world-renowned breast cancer surgeon, and WKMJ aims to feature breast cancer leaders in our consecutive editions to enhance the awareness of breast cancer, one of the most common threats to women's health. As a physician, her achievements in the area of cancer treatment have been significant. As a healthcare leader and a female role model, her visions on human health has become an inspiration for the young generation.

New trends and issues of the bio-health industry were featured in the articles. In the Special Report, we also introduced current findings in breast cancer clinical studies.

World Korean Medical Journal was founded and published to feature the most relevant issues on the global healthcare arena while introducing the most influential and inspirational healthcare leaders.

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

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 Korean Healthcare Leader "Dr. Myung-Hwan Kim, President of the Asian-Oceanic Pancreatic Association"

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. He is a world-renowned gastroenterologist and a leader in domestic research on gallstones. Dr. Kim performed the country's first Extracorporeal Shock Wave Lithotripsy and developed the 'Kim Diagnostic Criteria' on autoimmune pancreatitis. He published nearly 200 articles on pancreatobiliary diseases, and his research work is regarded as a great contribution to advancement of Korea's clinical medicine. To learn more about Dr. Kim, please refer to Issue 16 of WKMJ.

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

According to the lawyers, Alnylam's trade secrets litigation case against Dicerna could be influenced by emotive arguments of document theft rather than entertaining the details of nuanced trade secret law. 18 months after Alnylam acquired Merck's RNAi subsidiary Sirna, Alnylam initiated litigation against Dicerna, a separate RNAi company that also bid for Sirna. Dicerna has misappropriated trade secrets about Sirna's technology by hiring Merck's laid-off scientists who took confidential documents with them. Lawyers have noted that the case's emotive nature could affect the jury, favoring Alnylam. However, it is also noted that there could be a settlement before the trial. To read more, please refer to Issue 16 of WKMJ.

Biopharmaceutical Report II
Biosimilar Uptake Still Plagued by Interchangeability Hurdles

Despite multiple state legislations promoting biosimilar substitution, the lack of interchangeability data and regulatory guidance on using biosimilars remains as a barrier to biosimilar uptake due to the limitation to FDA-approved interchangeable biosimilars. As the experts said, interchangeability, where the biosimilars could be used as replacement of the reference biologics, is still a challenge for biosimilar uptake. Interchangeability still requires a physician's approval for biosimilar use rather than being done at the pharmacist level due to the lack of reliable sources to give guidance to pharmacists. For more information about biosimilar interchangeability, please refer to Issue 16 of WKMJ.

Biopharmaceutical Report III
Shooting for the Universe

CureVac AG is bringing a new modality for a universal flu vaccine and a vaccine against malaria with an mRNA program supported by the Bill & Melinda Gates Foundation. The need for a universal flu vaccine has increased due to this year's harsh flu season, and the current vaccine provides only 36% protection, according to the CDC. The company believes that its approach can yield a product with a cost structure and supply chain relevant for the world. CureVac is currently in progress of developing the company's RNA platform and constructing an industrial-scale GMP facility. To learn more about CureVac's new modality, please refer to Issue 16 of WKMJ.

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INSPIRATIONAL KOREAN HEALTHCARE LEADER

Eun Sook Lee, MD, PhD
President of the Korean National Cancer Center

1. Dr. Lee, you are a world-renowned surgical oncologist and a respected member of the medical community. What was your reason for choosing specialty in breast cancer? Can you please share with us what keeps you motivated throughout your career?

- On average, during the 1970s and '80s in Korea, there were only about 10 females among 100 students in the medical school. When I entered medical school in 1980, there were about 25 females admitted to the school, which was considerably high. However, the number of female students was still too low compared to males due to the fact that it was a predominantly male profession. Despite the fact that there was no precedent for a woman to become a surgeon at that time, I wanted to challenge myself and pursue a career in medicine. Fortunately, because of my academic performance in high school, I was able to study in the field of my choice.

I originally hoped to study internal medicine because I wanted to study the body in a broader spectrum rather than to become a specialist in a certain field. During my 4th year in internal medicine, I learned that although internal medicine is a rewarding field, it generally requires long-term treatments. Instead, I wanted to take a more immediate approach to help patients. During this time, my senior colleague suggested me to go into general surgery, and I decided then to divert my career path to become a surgeon.

Throughout my career, I always strived to be the best and first in my field, which has led me to become the first female surgeon from my medical school, the Korea University Medical College. Ever since I studied at the MD Anderson Cancer Center in the U.S. during the mid-1990s, I've focused my skills on improving the areas of breast cancer research. I always wanted to be a fully dedicated breast cancer specialist who always prioritizes patient care, and I am fortunate enough to be recognized as one of the best in my field. When it comes to patient care, I try to allow my patients to feel comfortable as if they are casually conversing with their friends or family. Creating a friendly environment for patients is an important responsibility for physicians. I believe that fundamentals of supporting patients fight cancer lie not only giving them healthy lifestyle recommendations but also providing good energy and positivity.

> "I always wanted to be a fully dedicated breast cancer specialist who always prioritizes patient care"

2. As a successful physician with more than 30 years of experience, you may have gone through various obstacles. Can you share some of the most difficult moments in your career?

- I started at the department of surgery, but soon I realized how hard it was for a woman to work in this field. Unlike today, I was the only woman staff in the department, so they did not have a proper women's locker room. There were even times when I was being acknowledged differently from other male colleagues, and occasionally, my competency was undermined when working along with them. Every day was nerve-racking and I cried in the restroom in solitude, but I managed to endure for a year. However, it was not long before I encountered another obstacle. I wanted to be a professor, but despite my high GPA and scores, no one dared to hire a female professor because it was a very rare case to have a female faculty in their institution.

After thinking long and hard, I decided to study abroad in the States. This was when my first child was four and my second was only six months old. Despite my internal conflicts and others' attempts to dissuade me, my mind was set on going to the U.S. to continue my studies. As in any field of medicine, the competition intensifies as you move

Dr. Lee in her office at National Cancer Center

Dr. Lee consulting with a patient

up in your career, and there are far more obstacles along the way for a female surgeon. Every time I faced hardships, I thought of the future of female surgeons. I wanted to pave the way for them, and such determination helped me to overcome these obstacles.

3. You have become the president of the National Cancer Center (NCC). What are your principles and philosophies in leading one of the world's largest cancer center? How would you distinguish NCC from other institutions?

- When I gave my inauguration speech, I promised my colleagues at National Cancer Center (NCC) Korea that I will make positive changes for our organization, our government, and eventually the global public health.

The National Cancer Center Hospital recognizes the importance of prevention and early detection for cancer and provides specialized cancer check-ups through its Cancer Prevention and Early Detection Center. Equipped with the state-of-the-art technologies such as colonoscopy, endoscopy, 64 channel CT, PET/CT and 3T MRI, the cancer specialists at NCC Hospital strive to satisfy the patients' various needs through preemptive strategies.

We also provide quality patient care services at our modern facilities, using cutting edge equipments such as proton beam therapy, PET/CT, IMRT, tomotherapy, etc. After six years of preparation, we have successfully installed a proton beam therapy system in 2007. This technology radiates a higher dose of beam directly to tumor sites without causing harm to surrounding normal tissues and organs. The proton radiation therapy uses x-rays or electron beams to destroy cancer cells, but unlike X-rays, proton beams release most of their energy when they reach the tumor cells. The patient does not feel any pain during the therapy, and there are minimal side effects. Thus, it allows the patient to quickly return to normal, daily life after treatment compared to those treated with conventional X-rays.

Dr. Lee giving a speech at the Korean National Cancer Center

In addition, as a leading center for developing and disseminating evidence-based, standard cancer-care guidelines, the NCC Hospital plays a coordinating role in Korea. The NCC Hospital has established a new system that enables 60 clinical staff from the hospital to engage in rapid translational research discoveries at the NCC Research Institute and bring about promising clinical interventions.

At the NCC Hospital, I believe that it does not take one but our whole staff to bring our hospital to where it is today. I am truly grateful for the hard work of those who take initiatives toward innovation. Our employees are dedicated to prepare for the future with a youthful spirit, constantly learning and facing challenges without fear of failure. We will open new roads in scientific innovation through our continuing collaborative efforts. We still have more to accomplish along the road, but I am confident that the goals of the National Cancer Center will soon be achieved in the future.

Dr. Lee receiving the certificate of appointment as the president of the National Cancer Center from the Ministry of Health and Welfare

4. You have conducted hundreds of research and served as an author and co-author in many research papers. As an eminent opinion leader, what are some of the major contributions you have made for breast cancer surgery?

- I am a general surgeon who specializes in breast cancer and breast reconstruction surgeries. I am currently involved in 500 surgeries every year. I have also written 128 research papers, hold 5 patents and contributed in the technology transfer for one of those patents. I have been very fortunate to make contributions toward breast cancer surgery in Korea by implementing breast conserving surgery (BCS) and sentinel lymph node biopsy that minimize surgical morbidity. In the past, aggressive surgical treatments were heavily focused on the survival rate of breast cancer patients without much aesthetic consideration for patients' self-esteem after their surgery. However, as a woman, I believe preserving as much healthy tissue is important for postoperative self-esteem and minimizing the psychological impact of breast cancer patients. Thus, I focused on the surveillance of lymph node dissection to minimize the surgical site.

> **"To become a good leader, some sacrifices have to be made in order to enhance the organization"**

5. Dr. Lee, you are the first surgeon among the female graduates of the Korea University Medical School, the first female director in the 60-year history of the Korean Surgical Society, and the first female president of the National Cancer Center Korea (NCC) since its opening. Do you have any words of advice to share with other female colleagues?

- To become a good leader, some sacrifices have to be made in order to enhance the organization. I encourage more women to take leadership because I believe that women have the ability to understand individuals' needs, and direct and harmonize different interests of others. Leadership should be established at home, and it is important to teach and make aware of gender equality to our children. There are many women who have inspired me to become who I am today in many different aspects. I am greatly thankful for my mother-in-law, who helped me in child-raising and supporting my family while I was working towards my career.

Dr. Lee with members of the 2nd Joint International Symposium of National Center Center

I am also inspired by Dr. Monica Morrow, who is a breast cancer surgeon at Memorial Sloan Kettering Cancer Center. Moreover, I admire all the artists in the areas of literature and arts who constantly challenge the social norms. We must educate our children and ourselves to set goals in moving forward when faced with challenges and never let societal standards ruin our passion for success.

I want to tell my female colleagues that they should never give up on their dreams even if the challenges facing them may seem unfair right now. If they continue to make efforts and take incremental steps toward achieving their dreams, a moment of opportunity will come someday. I do not want to force my female colleagues to follow my path or try to imitate what I have done so far. Instead, I suggest that they walk shoulder-to-shoulder, and I offer to be right beside them when they need me.

Dr. Lee in discussion with her patient about breast cancer-related topics

6. What are some of the major issues or trends happening in the field? Under your leadership, what is the NCC doing to address these issues and how will this impact the future of public health in Korea?

- The National Cancer Center is currently focused on the impact of big data on public health. We are currently working to establish an open platform where we can share and route cancer-related big data. The application of this big data will allow us to accurately examine patients and will eventually reduce medical expenses.

In addition, sharing this big data with other medical institutions will create an efficient network and a hub for connecting the three essential elements for scientific progress: research, treatment and policies. In recent years, I have been conducting research through big data analysis that will establish a basis for national policies. Such policies will grant patients with a life-long plan for cancer prevention, screening, and treatment as well as cancer survivor management.

We will ensure that our center becomes a testing site for new treatment technologies. We have research resources such as the NCC Biobank, the Animal Sciences Branch, the Omics Core Lab, and the GMP pharmaceutical laboratories that are accessible to any researchers.

At NCC, we recently completed our own data warehouse and search portal for clinical research in order to systematically combine and manage data. Currently, we have 490,000 patient information in our database that has been categorized. Although the access to data from other institutions is prohibited due to privacy-related issues, the National Assembly is currently in discussion for an amendment to the Cancer Control Act. If this amendment passes, the big data will be available to be shared among different institutions, and I believe it will significantly enhance public health and cancer research in Korea.

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

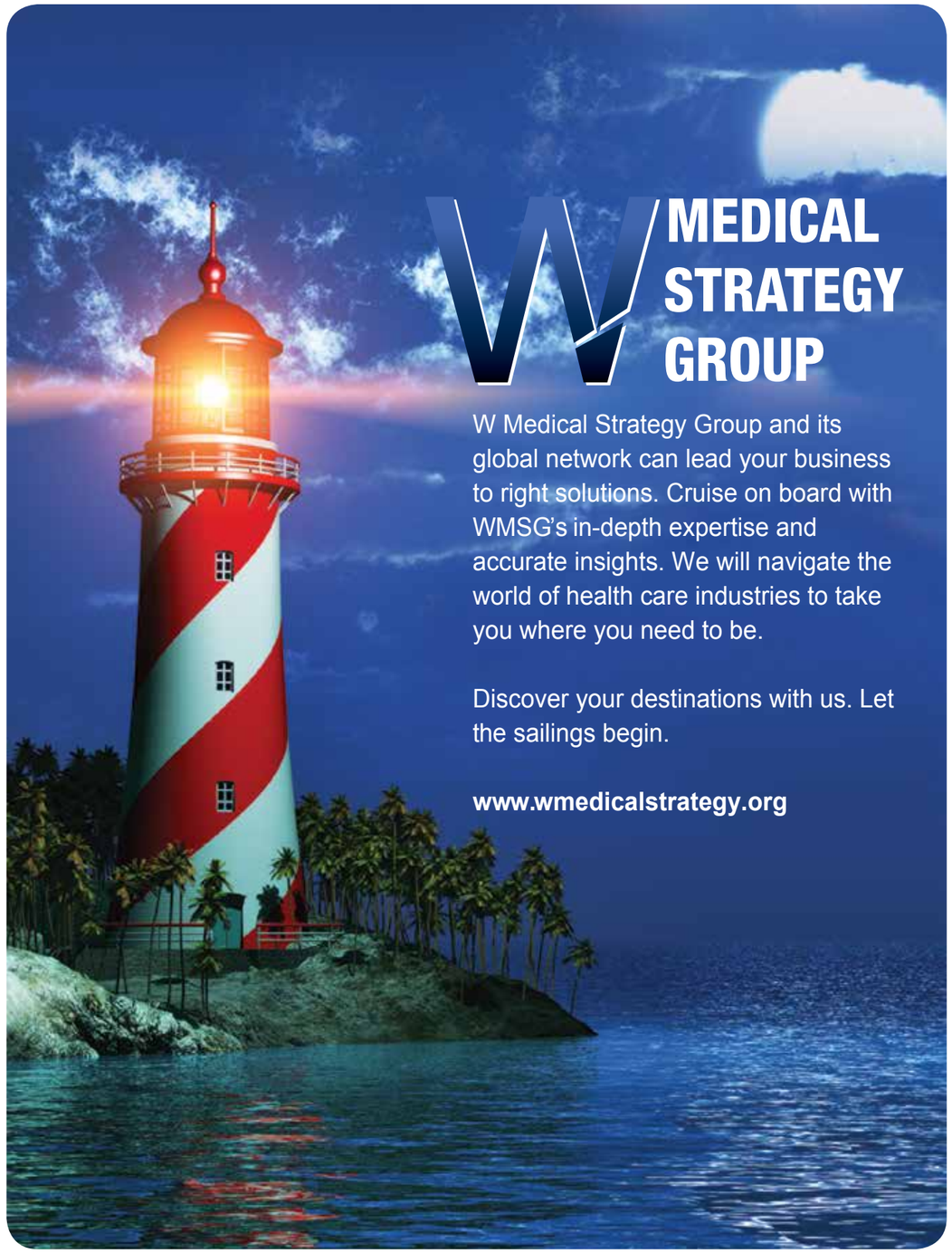
- If there are those who are currently struggling in difficult environments, I hope that my story would reassure them in their endeavors. I strongly believe that perseverance and positive attitude will eventually win the day, and that those small battles of each day will eventually make a difference in the world.

Also, for medical professionals, I would like to emphasize the importance of relationships. It is important for both the patients and their families to remain strong during treatment. Therefore, I hope that all medical professionals will strive to support their patients and their families, not only with medical support, but also with encouragement and positive attitude so that unbearable illnesses can be endured and overcome with confidence. W

Eun Sook Lee, MD, PhD

President of the Korean National Cancer Center

Dr. Eun Sook Lee has devoted herself to the diagnosis and treatment of breast cancer for more than 30 years as a surgical oncologist. She has also performed translational research to provide a guideline on high quality diagnosis and the selection of the appropriate local therapy to be used in cancer treatment that varies with the individual cancer type and the site of involvement. Dr. Lee obtained necessary knowledge and laboratory experience from her postdoctoral fellowship in MD Anderson Cancer Center in 1994 and as visiting assistant professor in Northwestern University from 1998 to 2000. Dr. Lee returned to Korea in order to concentrate on the treatment of breast cancer and was Head of the Breast Cancer Center at the National Cancer Center Korea from 2000 to 2008. In 2017, Dr. Lee became the president of Korean National Cancer Center. She has published almost hundred clinical and basic research papers relating development of therapeutics and optimization of clinical diagnosis.



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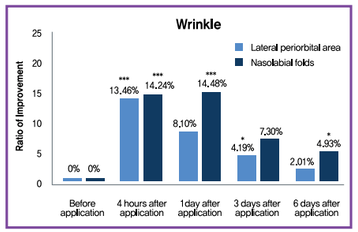
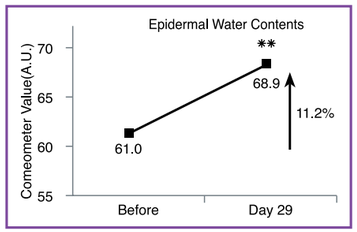
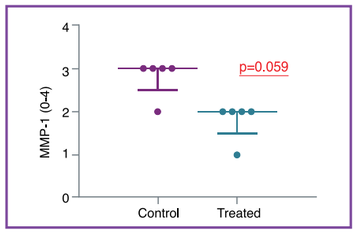


[Fig.1] Improvement of Wrinkle Indentation Index



[Fig.2] Increase of Water Contents Level



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

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

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Special Report

TENET Diagnostics

SPECIAL REPORT I

THE BENEFITS OF
PHARMACOGENOMICS

SPECIAL REPORT II

DUCTAL CARCINOMA IN SITU: CURRENT
STATUS AND FUTURE PERSPECTIVES

SR

SPECIAL REPORT I

The Benefits of Pharmacogenomics

As more physicians gain a better understanding of the role that genes play in individual drug response, there's been a steady increase in the number of clinical pharmacogenetic (PGx) tests performed.

Because people metabolize drugs differently, finding the most appropriate medication and dosage based on genetic profile is critical for better patient outcomes. PGx testing uses an individual's personalized genetic makeup to help make these determinations and identify response to specific drugs.

What's more, PGx testing is lowering medication costs and overall healthcare expenditures by avoiding drug-drug interactions, medication allergies, and trial-and-error medications that contribute to increased healthcare costs.

PGx testing:

- Determines individual responses to specific drugs
- Identifies drug-drug interactions, medication allergies, and trial-and-error medications
- Reduces the risk for adverse drug reactions and ineffective prescribing
- Makes medication treatment safer and at lower cost.

Industry leaders report that PGx testing for potential adverse drug events (ADEs) or ineffective drug responses may reduce healthcare costs over the long term by diminishing the duration and severity of illness and the costs associated with ineffective treatment and avoidable ADEs.

The U.S. Food and Drug Administration (FDA) maintains a list of FDA-approved drugs and genes (currently 164 drug–gene pairs) with PGx information in their labeling, including psychotropic, cardiovascular and gastrointestinal drugs. The FDA also notes that PGx can play an important role in avoiding adverse events, identifying responders and non-responders to medications, and optimizing drug dosage.

Through its collaboration with MedTek21, a comprehensive medication risk management platform that delivers the benefits of continuous genomics-based medication monitoring to every patient, Tenet's PGx testing can identify potential adverse drug events (ADEs) or ineffective drug responses. This helps self-insured companies and plan sponsors reduce healthcare costs over the long term by diminishing the duration and severity of illness and the costs associated with ineffective treatment and avoidable ADEs.

Scott Howell, MD, MPH&TM, CPE

Chief Medical Officer, Tenet Diagnostics

Dr. Scott Howell is the Chief Medical Officer for Tenet Diagnostic, a comprehensive full service laboratory with concentration on clinical quality, population health and next generation genetic tests. He also is board certified in Family Practice, Preventative Medicine and Public Health and Addiction Medicine and has been in medicine for over 25 years. He is certified by the American College of Physician Executives as a Certified Physician Executive (CPE) and has served the military for 25 years. His current reserve assignment is with the Office of Secretary of Defense (OSD) at the Department of Defense Inspector General (DoDIG) concentrating on the Wounded Warrior Program, BioAssurity, and Ebola Outbreak Assessment.

TENET Diagnostics

About Tenet Diagnostics

Tenet Diagnostics offers fast, accurate, high-quality laboratory and genomic testing to hospitals, clinics and physicians' offices to help them provide the best patient care. As collaborators with employers, payers and clinicians, we offer an extensive range of testing services, including specialized diagnosis, screening and evaluation for a host of conditions and diseases related to orthopedics, pain management, primary care and oncology. Tenet Diagnostics has been accredited by the College of American Pathologists (CAP) to ensure the highest standard of care for patients.

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SPECIAL REPORT II

Ductal Carcinoma in Situ: Current Status and Future Perspectives

In 1976, mammography (MMG) became a standard cancer screening strategy to detect breast cancer at an earlier stage in hopes of reducing mortality. Unsurprisingly, the incidence of ductal carcinoma in situ (DCIS), an early form of breast cancer, increased markedly from 7 cases per 100,000 women before the implementation of screening MMG to 56 per 100,000 women three decades afterwards in the late 2000s. Now, DCIS accounts for 20-25% of newly diagnosed breast cancers, more commonly detected on MMG as microcalcifications before presenting as a palpable mass. In 2015 alone, there were roughly 50,000 new DCIS diagnoses in the United States. The increased incidence of DCIS, however, has only been coupled with a marginal reduction in women presenting advanced breast cancer, raising concern for overdiagnosis of breast cancer.

(photo credit: ScienceDaily)

(photo credit: The ASCO Post)

DCIS is a type of non-invasive cancer contained within the basement membrane of the mammary ducts. An estimated 20-30% of DCIS cases progress to invasive carcinoma, meaning 70-80% of cases do not. A number of predictive radiological and biologic markers have been explored for prognostication, such as nuclear grade, histologic type, size, and estrogen receptor (ER) status and more recently, molecular markers progesterone receptor, HER2, Ki67, and p16 expression. However, further research is needed to better understand the difference between DCIS that will progress to invasive disease in a clinically relevant timespan and those that will not.

Due to the concern of disease progression, the conventional treatment has been surgical removal of breast tissue with or without adjuvant radiation therapy and systemic therapy. With the current treatment strategy, prognosis for DCIS is extremely favorable with 10-year cumulative breast cancer death rate of 1.4-2.8%. Unfortunately, surgical treatment is not without risks. Even with the improvement in surgical techniques, like breast conserving partial mastectomies as opposed to mastectomies for certain surgical candidates, surgical treatment of DCIS is associated with potential

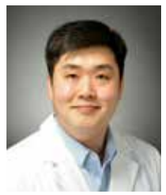
complications, such as chronic incisional pain, breast fibrosis, breast lymphedema, chronic breast cellulitis, and poor patient reported outcomes (PRO) (i.e. negative body image). Treatment is also associated with depression and does not necessarily resolve patients' fears of recurrence. Favorable prognosis for low grade DCIS raises concerns for overtreatment with potentially unnecessary surgical and radiation treatment, thus much interest has been generated in improving treatment strategies. How can the extremely favorable prognosis of current treatment strategies for DCIS be maintained, while reducing the number of patients receiving surgical treatments and associated morbidity?

At the American Society of Clinical Oncology (ASCO) Conference Annual Meeting on June 1-5, 2018 in Chicago, IL, landmark TAILORx results, a clinical trial assigning individualized options for treatment (Rx), were presented. The result demonstrates the Oncotype DX Breast Recurrence Score® test definitively identifies the 70% of women with early-stage breast cancer who receive no benefit from chemotherapy, and the 30% of women for whom chemotherapy benefit can be life-saving result of the TAILORx.

Dr. Hwang is a world-renowned expert in early-stage breast cancer and participated on DCIS studies, and currently the chief of breast surgical oncology at Duke Cancer Institute. Her extensive work includes basic science research to identify biological markers for better prognostication, clinical trials of less invasive systemic treatments, patient-centered research around their perceptions and experiences, and collaborative work on diagnostic imaging. Recently, she completed the CALGB40903 trial that looked at endocrine therapy with letrozole alone, as opposed to surgery for ER-positive DCIS. The primary outcomes of interest were changes in total MRI volume at 3 months and 6 months, which showed statistically significant reduction in volume. Further reports should follow regarding radiographic-pathologic correlation

and reduction in Ki67 expression to help identify potential non-operative candidates who could be treated with endocrine therapy alone.

Currently, she is the principal investigator for an exciting and potentially groundbreaking COMET study. This is a prospective randomized trial powered for non-inferiority comparing conventional therapy to active surveillance (AS) consisting of biannual MMG and endocrine therapy for low-risk, ER-positive DCIS patients. The primary outcome is the rate of ipsilateral invasive cancer in 2 years. The secondary outcomes include quality of life outcomes, such as anxiety, depression, decisional regret, and body image. Two other prospective randomized trials, LORIS trial and LORD trial, also look at active surveillance as a non-inferior strategy for low-risk DCIS. Between the three trials, we should expect to be introduced to innovative ways we treat DCIS.

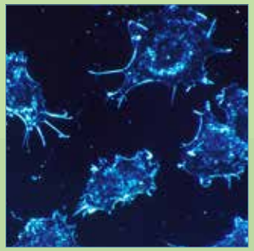


Andrew Siyeon Seong, MD, ME
Resident Physician, University of
Washington Medical Center Department of Surgery

Dr. Seong is a resident physician at the University of Washington Medical Center Department of Surgery. He graduated from the Robert Larner College of Medicine at the University of Vermont and studied mechanical engineering at Cornell University for his Bachelor's and Master's degree.

SR

Biopharma Report



BIOPHARMACEUTICAL REPORT I

IMMUNOMEDICS' SACITUZUMAB HAS INSUFFICIENT DATASET TO PURSUE ACCELERATED APPROVAL

BIOPHARMACEUTICAL REPORT II

EISAI'S LENVIMA FOR FIRST-LINE HCC IS APPROVABLE BUT NONINFERIORITY DATA TO SOC MAY SLOW UPTAKE

Immunomedics' Sacituzumab Has Insufficient Dataset to Pursue Accelerated Approval

Immunomedics' (NASDAQ:IMMU) Phase I/II sacituzumab govitecan hormone receptor positive (HR+) Her2-negative breast cancer data may not be enough for an accelerated approval despite showing clinically significant responses in a heavily pretreated population and a similar path adopted in triple-negative breast cancer (TNBC), experts said.

On the sidelines of the ASCO meeting last week, the company's chief business officer, Usama Malik, said that due to the compelling activity seen in Phase I/II (NCT01631552) data, the company will consider their registrational approach in HR+ Her2-negative after discussions with key opinion leaders and regulatory authorities. Immunomedics is considering a number of options like using the Phase I/II data to support a filing or converting the single-arm study to a randomized one, said Malik, but did not comment on specific timelines.

Analysts thought the Phase I/II data established proof-of-concept, and they compared sacituzumab to other CDK4/6 inhibitors like Eli Lilly's (NYSE:LLY) Verzenio (abemaciclib) -- whose initial approval was based on a single-arm study -- and suggested a similar path for approval. One analyst said the overall response rate (ORR) and median duration of response is in line with data used to file for an accelerated approval in metastatic TNBC (mTNBC), while others expect the Phase II data to support a breakthrough designation and potential fast-to-market path for that indication.

However, experts told this news service that while impressive in a heavily pretreated population, the data would unlikely be adequate for an accelerated approval. They said a direct randomized comparison with a chemotherapy like Roche's (VTX:ROG) Xeloda (capecitabine) was required to provide further evidence of efficacy, since the HR+ Her2-negative breast cancer space has more options and a higher expectation of efficacy than TNBC.

Not all patients in the dataset were previously treated with CDK4/6 inhibitors in combination hormone therapies -- a key issue since the drug class is now a part of the standard-of-care (SOC) -- which reduced the data's relevance, as CDK4/6 inhibitor use could impact responses to subsequent sacituzumab treatment, experts added.

Sacituzumab is an antibody drug conjugate (ADC) consisting of an anti-TROP2 antibody linked to SN-38, the active metabolite of irinotecan. While HR+ Her2-negative sales estimates are not available, those in TNBC are expected to be USD 1bn by 2025. The relapsed/refractory (r/r) HR+ Her2-negative subset is expected to be two-three times the number of patients with r/r mTNBC.

Accelerated approval needs more data

The early Phase I/II data has given a good signal, since chemotherapies like taxol or docetaxel are associated with response rates of approximately 20% and 25% respectively, and a therapy with an ORR of 31% is significant, said Dr Awada Ahmad, head, Medical Oncology Clinic, Jules Bordet Cancer Institute, Brussels, Belgium. Among the 54 patients with HR+ Her2-negative metastatic breast cancer in the Phase I/II basket study, the ORR was 31% and 24% among the 37 patients who received prior CDK4/6 inhibitors, as per the ASCO 2018 abstract (no. 1004).

> "An improved toxicity profile could give sacituzumab leverage for an approval if further validated in more patients"

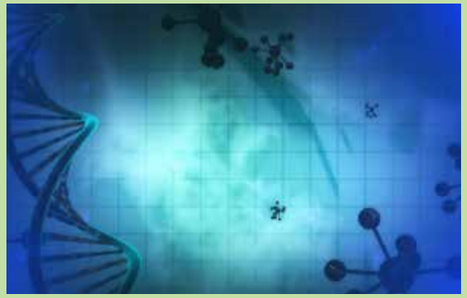
However, while the Phase I/II data could support a breakthrough status for the drug, it would likely be insufficient for an approval as a single-arm study, said Dr Hatem Soliman, associate member, Moffitt Cancer Center, Tampa, Florida. Dr Katherine Tkaczuk, director, Breast Evaluation and Treatment Program, University of Maryland School of Medicine, Baltimore, agreed adding that there is a need for a direct comparison with SOC chemotherapy. But if efficacy was confirmed in a larger trial with a chemotherapy comparison, sacituzumab could get an approval, said Ahmad.

It is not clear if the dataset is adequate for an approval, but it would be surprising if development does not include a randomized study comparing sacituzumab to Xeloda or physician's choice of chemotherapy, said Dr Linda Vahdat, chief, Cancer Services at Memorial Sloan Kettering Cancer Center Norwalk Hospital Partnership, New York. A comparison is necessary since chemotherapy is still active in HR+ patients in later lines, said Ahmad. Soliman expressed caution on relying too much on early datasets due to registrational trial failures in breast cancer after early signs of efficacy.

A trial needs to show that sacituzumab is superior to anthracycline chemotherapy or other endocrine therapies used in later lines, added Dr Lajos Pusztai, director, Breast Cancer Translational Research, Yale Cancer Center, New Haven, Connecticut. Non-inferiority to chemotherapy alone would be insufficient, said Soliman.

Furthermore, the impact of CDK4/6 inhibitor treatment still remains to be seen, said Vahdat. As per the abstract, 69% of patients had received prior CDK4/6 inhibitors. All experts said combinations of CDK4/6 inhibitors with hormone therapies have been the SOC in HR+ Her2-negative, since the first approval of a CDK4/6 inhibitor; i.e., for Pfizer's (NYSE:PFE) Ibrance (palbociclib) in 2015. Previous use of CDK4/6 inhibitor will influence the responses to an ADC like sacituzumab in later lines of treatment, said Ahmad. Efficacy data after CDK4/6 inhibitor use in more patients would also better contextualize sacituzumab's positioning against current treatments, said Dr Krystal Cascetta, assistant professor, Medicine, Hematology and Medical Oncology, Mount Sinai, New York.

In addition to being effective, sacituzumab is also well tolerated, most likely because the ADC design makes the chemotherapy more targeted to the tumor, said Tkaczuk. An improved toxicity profile could give sacituzumab leverage for an approval if further validated in more patients, but differentiated patient characteristics -- in terms of number and type of therapies or HR status -- make it difficult to analyze any comparable information on quality of life, said Soliman.



Unfitting comparisons to TNBC subset

Compared to TNBC, where sacituzumab has also been studied, the HR+ breast cancer space is more competitive, despite there being no drug specifically approved for use after exhausting hormone therapies or CDK4/6 inhibitor and hormone therapy combinations, said Pusztai. An accelerated approval for the drug in mTNBC based on a small dataset has greater validity, since there is no accepted SOC after a few lines of chemotherapy, said Soliman.

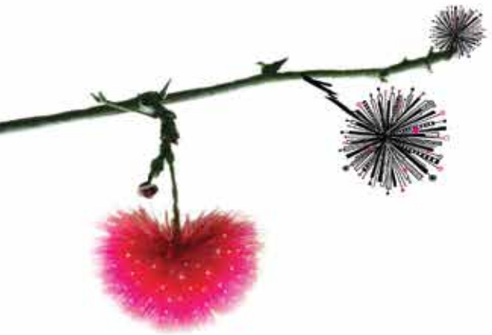
Immunomedics submitted a BLA to the FDA for sacituzumab in TNBC, as per a 4 June press release. This news service reported in November 2017 that while the company's registrational TNBC dataset may also be inadequate for an FDA approval, the unmet need may boost its approval chances.

While there is a greater unmet need in TNBC due to the absence of targeted therapies unlike in HR+Her2-negative breast cancer, once endocrine resistance to hormone therapies develops, chemotherapy remains the only available option, said Cascetta. Tkaczuk agreed, adding that these patients do not tend to do well with chemotherapy either.

Both Tkaczuk and Cascetta singled out the fact that responses in the Phase I/II patient cohort were seen despite patients being heavily pretreated with chemotherapy, hormone therapies and some with CDK4/6 inhibitors. A lower response is expected in these patients versus one who received only one line of therapy, and this is encouraging for further exploration, they added.

Manasi Vaidya
Reporter, New York

Manasi Vaidya has a Master's 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 Master's 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.



Happy smile and hope after pain

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

Kyung Hee Medical Center patient
D. K. Lee

Cancer-free D.K. Lee

D.K. Lee attending
beauty classes while chemotherapy treatment

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BIOPHARMA REPORT II

Eisai's Lenvima for First-Line HCC Is Approvable but Noninferiority Data to SOC May Slow Uptake

Eisai's (TYO:4523) Lenvima (lenvatinib) has a clear path to approval in first-line hepatocellular carcinoma (HCC), with its positive Phase III noninferiority trial versus Bayer's (ETR:BAYN) Nexavar (sorafenib) displaying unmatched efficacy, experts said. However, even if approved, a noninferiority result -- despite being the first in a decade -- may fall short in persuading clinicians to switch from the established standard-of-care (SOC), they noted on the sidelines of the recently concluded ASCO meeting in Chicago.

Lenvima's Phase III secondary endpoint data could be a selling point over Nexavar, one expert noted but others said such results including progression-free survival (PFS) have limited clinical value in HCC. And while Lenvima's side-effect profile might discourage uptake in some patients, experts noted Lenvima's and Nexavar's side-effect profiles are different and the former's could therefore be a preferable option for certain patients.

The original PDUFA date was in May but was extended to August to allow more time to review the application, a spokesperson said, declining to comment on potential Lenvima uptake barriers. Eisai's share price barely fluctuated on the PDUFA delay announcement and it did not cause a reaction from interviewed experts.

In March, Eisai announced it made a deal with Merck (NYSE:MRK) for development and commercialization of Lenvima. Analysts have not provided any sales predictions for Lenvima in HCC alone but it is estimated to generate USD 1.83bn worldwide by 2024 in all indications. Eisai's market cap is JPY 2.4trn (USD 21.9bn).

Lenvima and Nexavar are both oral multikinase inhibitors. Lenvima was FDA approved for advanced renal cell carcinoma in May 2016 and differentiated thyroid cancer in February 2015.

Results approvable but may not be sufficient to drive significant uptake

Lenvima's noninferior primary endpoint result versus Nexavar is enough for FDA approval, said Dr. Tim Greten, deputy chief, Thoracic and Gastrointestinal Malignancies Branch, National Cancer Institute, Bethesda, Maryland, and Dr. Markus Peck-Radosavljevic, chairman, Department of Gastroenterology and Hepatology, Klinikum Klagenfurt, Austria. In the 1,492-patient Phase III REFLECT trial (NCT01761266), the median overall survival (OS) time in the Lenvima arm was 13.6 months, versus 12.3 months with first-line SOC Nexavar (Kudo, M. et. al. Lancet. 2018 Mar 24;391(10126):1163-1173).

In the past 10 years, there have been about eight trials that have failed in first-line HCC versus Nexavar, and thus Lenvima's positive Phase III is enough to draw approval, said a Phase III investigator, Greten and Peck-Radosavljevic. Nexavar is also a very high-performing therapy in the real world, which made it hard to match or beat as an established SOC, the investigator added.

Even though the Phase III was a noninferiority trial, Lenvima showed superior data in the secondary endpoints, which would help convince clinicians to prescribe the therapy, noted the investigator. The Phase III trial shows Lenvima was statistically superior to Nexavar in the secondary endpoints of PFS (7.4 months vs 3.7 months), median time to progression (8.9 months vs 3.7 months) and objective response rate (24% vs 9%), according to a September 2017 release.

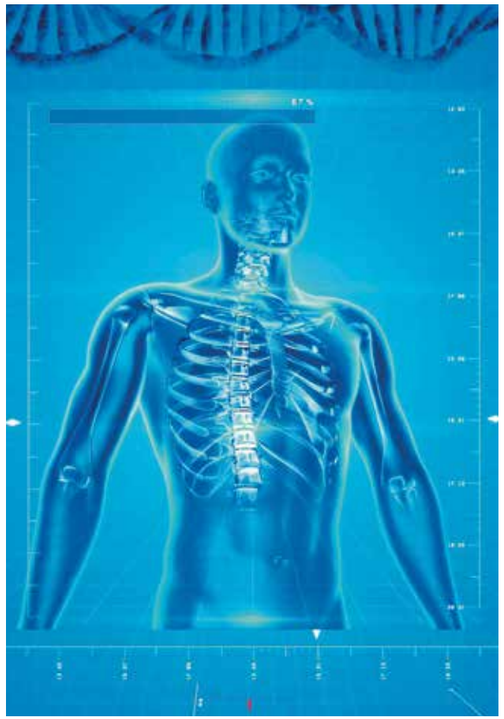
"Lenvima showed superior data in the secondary endpoints, which would help convince clinicians to prescribe the therapy"

However, although the secondary endpoints were encouraging, a noninferiority trial would still draw pause in clinicians switching to Lenvima, said Dr. Teresa Macarulla, attending physician, Gastrointestinal Tumors Service, University Hospital of Vall d'Hebron, Barcelona, Spain. Secondary endpoint data have little clinical value in HCC, where patients are after OS and not just stable disease, noted Peck-Radosavljevic. Positive secondary endpoints provide limited guidance if the patient could live long enough to be able to access second-line therapy if the cancer persists, he added.

Lenvima was approved in Japan in March 2018, and the investigator noted that in the first two months, some 1,300 patients were prescribed the therapy, showing its potential for swift uptake. However, since the Phase III is a noninferiority trial, it may come down to on-the-ground marketing to sell Lenvima, noted Peck-Radosavljevic. Eisai is a Japan-based company, so it would have more manpower on the ground to market the therapy, he said.

Different side-effect profile compared to Nexavar could be small upside

Lenvima's side effects seem to be severe based on available data in other tumors where it is approved, Macarulla said. However, some of Lenvima's side effects are unique compared to Nexavar, which may make Lenvima worth using in the real world for patients who are sensitive to Nexavar's side effects, noted Peck-Radosavljevic. In fact, patients can be switched from Nexavar to Lenvima if the former is not tolerable, thus giving patients an option, a hepatologist added.



Phase III Lenvima data in HCC shows the most common adverse events were hypertension (42%), diarrhea (39%), decreased appetite (34%) and

decreased weight (31%). In contrast, patients who received Nexavar experienced palmar-plantar erythrodysesthesia (52%), diarrhea (46%), hypertension (30%) and decreased appetite (27%), according to the aforementioned Lancet paper.

Lenvima seems to cause less skin toxicity in HCC compared to Nexavar, noted the investigator and Peck-Radosavljevic. According to the Lenvima label, all grades skin and subcutaneous tissue disorders include palmar-plantar erythrodysesthesia (32%), rashes (21%), alopecia (12%) and hyperkeratosis (7%). But skin-related side effects are more of a predominant issue in patients with Asian descent, as observed in Asian countries, said Peck-Radosavljevic. Asian patients experiencing more skin-related side effects may be due to genetic differences from Caucasian patients or Asian patients having a higher dose relative to weight, he explained. However, this could mean that Lenvima may have more success in Asian countries, with Nexavar maintaining as the main choice in Western countries, he said.

Reynald Castaneda
Reporter, London

Reynald Castaneda, prior to moving to London, was a journalist for healthcare newspaper New Zealand Doctor, covering primary care health politics and medical research. He has a BSc in Biological Sciences from the University of Auckland and a postgraduate diploma in journalism from AUT University. Prior to venturing into journalism, Reynald worked as a laboratory technician for Massey University's Institute of Molecular Biosciences.

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FOLLOW THE JOURNEY OF VIREAD

COMPLETE RESPONSE RESULTS AT YEAR 1...

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

AT YEAR 1

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

THROUGH YEAR 8

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

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

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

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

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

INDICATION AND USAGE

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

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

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

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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).*

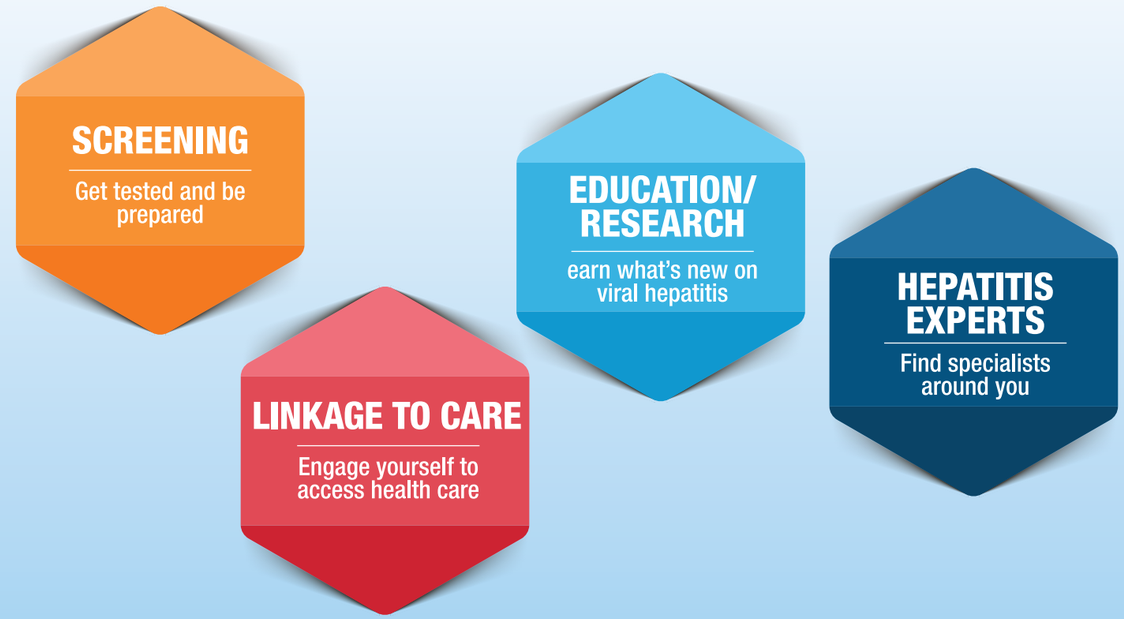
For detailed information, please see full Prescribing Information. To learn more call 1-800-GILEAD-5 (1-800-445-3235) or visit www.VIREAD.com.

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

Public Health Informatics Conference
August 20-23, 2018 | Atlanta, GA, USA

Website: http://phiconference.org
Contact: phinformatics@naccho.org

The theme of the Public Health Informatics Conference is “Connecting Systems and People to Improve Population Health.” Held biennially, the conference aims to provide a forum for new and seasoned public health, healthcare, and information technology professionals to exchange experiences, ideas, and strategies about public health informatics that are paramount to the advancement of public health practice and health equity. The Public Health Informatics Conference delivers opportunities to connect with colleagues, share new research, and discover how to navigate the increasingly connected public health enterprise.

Boston Biotech Conference BD Boston
September 4, 2018 | Boston, MA, USA

Website: https://lifesciences.knect365.com/bd-boston
Contact: suzanne@bbbiotechconference.com

Boston Biotech Conferences (BBC) are thought-leader forums for senior biopharma executives. The conference is highly interactive and co-hosted by healthcare industry leaders to foster discussions and facilitate information-sharing, networking and corporate development within the biopharma community. The number of participants is limited to allow for one-on-one interaction with the most influential leaders in the life sciences. The attendees are able to derive the ability to network with the decision makers in the industry.

Healthcare Innovation Forum: Blockchain, AI, and Beyond
September 13, 2018 | Lowell, MA, USA

Website: http://www.masslifesciences.com/events
Contact: info@masslifesciences.com

The Healthcare Innovation Forum is created for healthcare startups and medtech innovators. The half-day workshop allows the attendees to gain authoritative insights on leading-edge technologies, new best practices, business intelligence, and networking opportunities. The event is hosted by M2D2, and the guest speakers include Kris Srinivasan, CEO of Alpha MD, and Edward Bukstel, CEO of Clinical Blockchain.

Breast Imaging from A to Z: How to Read Like (Or Better Than!) the Experts
September 15-16, 2018 | New York City, NY, USA

Website: http://advancedbreastimaging.com/september-2018-nyc
Contact: info@cmescience.com

The Breast Imaging from A to Z: How to Read Like (Or Better Than!) the Experts provides an integrated full discussion aimed at comprehending the basis and applications of breast imaging in five distinct sessions, using a case-based approach supported by evidence-based literature review. The five sessions will take the attendees through the histopathologic basis for breast disease with imaging correlates. They also explore the issues of medical legal accountability in interpretation and communication.

2018 Health Data Policy and Strategy Orientation
September 26-27, 2018 | Washington D.C., USA

Website: http://academyhealth.org/events/2018-09/2018-health-data-policy-and-strategy-orientation
Contact: http://academyhealth.org/contact

The 2018 Health Data Policy and Strategy Orientation is designed to support professionals in emerging data-centric roles within the changing healthcare system. It provides an engaging forum to gain insights on the trends in federal policies and programs along with information and tips to help meet their organization’s information strategy needs. Health policy experts, government program leaders, data users, entrepreneurs who have deep knowledge in data use, and data experts from technology and health care applications fields will be featured in the presentations.

BIO Investor Forum
October 17-18, 2018 | San Francisco, CA, USA

Website: https://www.bio.org/events/bio-investor-forum
Contact: info@bio.org

The BIO Investor Forum is an international biotech investor conference focused on investment trends and opportunities in life sciences. It features plenary sessions, company presentations, workshops on the latest market and investment opportunities, BIO One-on-One Partnering™ meetings, and premier opportunity to network with industry executives and investors focused on life science.

11th Annual Conference on the Science of Dissemination and Implementation in Health
December 3-5, 2018 | Washington D.C., USA

Website: http://academyhealth.org/events/2018-12/11th-annual-conference-science-dissemination-and-implementation-health
Contact: http://academyhealth.org/contact

The Annual Conference on the Science of Dissemination and Implementation in Health (D&I) helps to optimize health and health care by bridging the gap between research, practice, and policy. The event is co-hosted by the National Institutes of Health (NIH) and AcademyHealth. The theme of this year’s event is scaling up effective health and healthcare by advancing the research agenda and necessary infrastructure. The conference will focus on strategies for scaling up effective interventions across communities, health systems, and efforts to build capacity for D&I science.

Europe

17th European Congress of Internal Medicine
August 30-September 1, 2018 | Wiesbaden, Germany

Website: https://ecim2018.eu
Contact: ECIM2018@wikonect.de

The European Congress of Internal Medicine (ECIM) is an event where physicians, scientists and other experts in the field of Internal Medicine exchange the latest information on advances in science and clinical practice. ECIM is a platform for the interdisciplinary interaction of European internists, including those practicing related specialities, as well as for young internists to share their experiences and networking.

Europe

30th European Congress of Pathology

September 8- 12, 2018 | Bilbao, Spain

Website: https://www.esp-congress.org

Contact: ecp-amsterdam@cpo-hanser.de

The theme for the ECP 2018, “Pathology: Path to Precision medicine” highlights pathology as the cornerstone of precision medicine and underlines the central role of the pathologist in the multidisciplinary teams that guide patient management in the 21st century. Pathologists collaborating with molecular biologists, geneticists, bioinformaticians, and information technologists provide accurate diagnoses, prognostic and predictive information essential for treatment decisions tailored to the individual patient.

19th Meeting of the European Association for Haematopathology 2018

September 29- October 4, 2018 | Edinburgh, United Kingdom

Website: http://www.eahp-sh2018.com

Contact: eahp@mci-group.com

The 19th Meeting of the EAHP is an interdisciplinary program that includes an Educational Session, together with Bone Marrow and Lymphoma Symposia and Workshops, highlighting the latest scientific discoveries. Internationally renowned speakers will deliver Keynote and Topic Lectures, as well as the ever-popular ‘Meet the Professor’ sessions. An abstract submission and selection process gives delegates the opportunity to showcase their recent research as platform presentations or poster displays and discussion.

18th Annual Biotech in Europe Forum

October 4-5, 2018 | Basel, Switzerland

Website: http://www.sachsforum.com/bef18-about.html

Contact: SachsTeam@SachsForum.com

The 18th Annual Biotech in Europe Forum is the leading international stage for those interested in investing and partnering in the biotech and life science industry. This event will be covered by regular media partners and will feature twelve plenary panels/ workshops covering BD & Licensing in the main therapeutic areas. The Forum will provide a number of networking opportunities via our online One-2-One meeting system, which allows pre-book meetings with all the attendees with dedicated meeting facilities.

The International Congress on Precision Medicine Beyond Cancer (PMBC2018)

October 15–16, 2018 | München, United Kingdom

Website: http://www.pmbc2018.com

Contact: info@bioevents-congress.com

PMBC2018 will showcase cutting-edge Precision Medicine companies from around the world while panels and keynote presentations aim to enable best informed decision making in strategy and policy design to implement Precision Medicine into every day healthcare. It aims to broaden the perspective to other non-communicable diseases and reduce the cost burden to society.

4th Annual Cell & Gene Therapy Congress 2018

October 25-26, 2018 | London, UK

Website:https://www.oxfordglobal.co.uk/celltherapy-congress

Contact:info@oxfordglobal.co.uk

As one of the Cell Series programs, the 4th Annual Cell & Gene Therapy Congress of 2018 is featured with 7th Cell Culture and Bioprocessing, 5th Stem Cell and Regenerative Medicine and Biobanking Congresses. The congress will feature prominent biotech companies, and these companies will present case studies on commercialising CAR T Cell Therapy, successful cell and gene therapy development and effective technologies for bioprocessing and manufacturing.

BioFIT

December 4-5, 2018 | Lille, France

Website:https://www.biofit-event.com

Contact:biofit@eurasante.com

BioFIT is the place where academia-industry collaborations get started. BioFIT has become the meeting point in Europe for tech transfer and for sourcing early-stage innovations stemming from public research institutions, academic spin-offs, and emerging biotech companies. Together with big pharma, biotech and diagnostics companies, BioFIT operates as a platform to build partnerships for all public and private actors. Throughout the conference, attendees can participate in one-on-one meetings, roundtable discussions as well as networking opportunities.

Asia

CPhI Korea Conference

August 28-29, 2018 | Seoul, South Korea

Website: https://www.cphi.com/korea/agenda/conference

Contact: https://www.cphi.com/korea/about/event-contact

CPhI Korea is a leading learning platform for trends and issues confronting the pharmaceutical industry in Korea, and provides a dynamic meeting place for a wide range of industry suppliers to engage with purchasers and decision makers from the pharmaceutical industry in Korea and the surrounding region. The conference gives a realistic assessment of the industry challenges and strategies for dealing with them. It also offers high-level sessions featuring opinion leaders from government and academia.

17th Biennial Meeting of the International Gynecologic Cancer Society

September 14-16, 2018 | Kyoto, Japan

Website: https://igcs2018.com

Contact: jmargo@kenes.com

The 17th Biennial Meeting of the International Gynecologic Cancer Society (IGCS 2018) is the event to discuss and debate the latest medical and scientific information, treatment, and care in the field of gynecologic oncology. IGCS 2018 is being held in collaboration with the Japanese Society of Gynecologic Oncology. This educational forum allows individuals to develop unique approaches to best care practices, and establish new professional contacts around the world.

Asia

Shenzhen International Biotech and Health Industry Expo

September 20-22, 2018 | Guangdong, China

Website: http://www.biotech-expo.com/index

Contact: info@biotech-expo.com

Shenzhen International Biotech and Health Industry Expo (Biotech 2018) is hosted by the Shenzhen Municipal City Government, the China Medicinal Biotechnology Association, the Shenzhen Development and Reform Commission, and the Shenzhen International Trade Promotion Committee. Biotech 2018 includes 4 main exhibit areas: Life Information & Innovative Biotechnology, High-Quality Modern Health Services and Products, Medical Devices and Digital Health Equipment, and Agricultural Products and Biological Breeding.

World Cancer Congress Malaysia 2018

October 1-4, 2018 | Kuala Lumpur, Malaysia

Website: https://www.worldcancercongress.org

Contact: http://www.globaleventslist.elsevier.com/contact

The World Cancer Congress is a recognized international conference which encourages effective knowledge transfer and practices exchange amongst 3,500 cancer control and public health experts from 150 countries. The event is hosted by the National Cancer Society of Malaysia. The Congress aims to strengthen the participants' action and impact on national, regional and international scales through a multidisciplinary programme that features the latest successful interventions in cancer prevention, diagnosis, treatment and care.

32nd International Papillomavirus Conference (IPVC 2018)

October 2–6, 2018 | Sydney, Australia

Website: https://ipvc2018.org

Contact: lprodanova@kenes.com

The conference theme is 'Towards Global Control of HPV Disease' and through workshops, invited lectures, and oral and poster sessions presenting the latest research results, the conference will cover papillomavirus (PV)-related topics from basic science to global health impact. Special attention will be paid to HPV control in populations that are most vulnerable to HPV disease worldwide, including those in Low and Middle Income Countries and Indigenous communities.

7th International Conference on Biomedical Engineering and Biotechnology

October 17-20, 2018 | Nanjing, China

Website: http://www.icbeb.org

Contact: icbeb@icbeb.org

The 7th International Conference on Biomedical Engineering and Biotechnology (ICBEB 2018) is hosted by the Southeast University & Nanjing Medical University. It aims to provide a forum for prestigious specialists and scholars to share their experiences and demonstrate frontier research results in all respects of Medical Imaging Technology and Application, Biomedical Signal Processing and Medical Information, Biomechanics and Biomechanical Engineering, Molecular Biology, Chemistry, Pharmacology and Toxicology etc., and open doors for discussing the practical challenges and recommended solutions for better living.

NEW YORK
Health Forum

Connection to Improve the Human Health

Collaboration for Success: Multi-Regional Clinical Development
9th Forum | May 25, 2018

The Powerful Transformers of the Beauty Industry
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

(201) 402-1400

1. Diabetes Patients at Risk from Rising Insulin Prices

A Yale study found that one in four patients admitted to cutting back on insulin use because of cost. Between 2002 and 2013, the price of insulin jumped, with the typical cost for patients increasing from about $40 a vial to $130. Due to the rising cost of the drug, a large number of people with diabetes are using less insulin than prescribed, putting themselves in danger of serious complications. Not getting enough insulin can have severe consequences for someone with diabetes who does not produce enough of the hormone, which regulates levels of glucose in the blood. Those who reported underusing insulin because of cost were more likely to have dangerous blood glucose levels compared with those who said they did not underuse.

https://www.nytimes.com/2018/06/22/well/diabetes-patients-at-risk-from-rising-insulin-prices.html

2. FDA Approves First Cannabis-Based Drug

The US Food and Drug Administration approved a cannabis-based drug for the first time. The twice-daily oral solution is approved for use in patients 2 and older to treat two types of epileptic syndromes: Dravet syndrome, a rare genetic dysfunction of the brain that begins in the first year of life, and Lennox-Gastaut syndrome, a form of epilepsy with multiple types of seizures that begin in early childhood, usually between 3 and 5. According to GW Pharmaceuticals, the drug is the "first pharmaceutical formulation of highly-purified, plant-based cannabidiol (CBD), a cannabinoid lacking the high associated with marijuana, and the first in a new category of anti-epileptic drugs."

https://www.cnn.com/2018/06/25/health/fda-approves-first-cannabis-drug-bn/index.html

3. Amazon Shakes Up Drugstore Business With Deal to Buy Online Pharmacy PillPack

Amazon is acquiring online pharmacy PillPack in a deal that is already shaking up the drugstore industry. It threatens to remove one of the few distinguishing factors pharmacy chains have relied on to fend off Amazon, the sale of prescription drugs. Retailers like Walgreens Boots Alliance, CVS Health, and Rite Aid have seen their so-called front of store sales threatened as shoppers increasingly buy household staples online or from convenience stores. These retailers lost about $12.8 billion in market value.

https://www.cnbc.com/2018/06/28/amazon-to-acquire-online-pharmacy-pillpack.html

4. Trump to Drop Call for Medicare to Negotiate Lower Drug Prices

President Trump will lay out a broad strategy to reduce prescription drug prices, but in a break from one of his most popular campaign promises, he will not call for Medicare to negotiate lower prices with drug manufacturers, senior administration officials said. The White House will issue a blueprint that represents "the most comprehensive plan to tackle prescription drug affordability of any president," according to the senior official. The plan would not include direct negotiations by Medicare.

https://www.nytimes.com/2018/05/10/us/politics/trump-prescription-drug-costs.html

5. F.D.A. Approves First Drug Designed to Prevent Migraines

The Food and Drug Administration approved the first medicine designed to prevent migraines, ushering in what many experts believe will be a new era in treatment for people who suffer the most severe form of headaches. The drug, Aimovig, is a monthly injection with a device similar to an insulin pen. Aimovig blocks a protein fragment, CGRP, that instigates and perpetuates migraines. Three other companies, Lilly, Teva, and Alder, have similar medicines in the final stages of study or awaiting FDA approval.

https://www.nytimes.com/2018/05/17/health/migraines-prevention-drug-aimovig.html

6. J&J Agrees to Sell LifeScan Unit for $2.1B

Johnson & Johnson accepted Platinum Equity's $2.1 billion offer for LifeScan, the company's blood glucose monitoring unit known for its OneTouch brand of glucose meters and insulin pumps. LifeScan is known to diabetes patients worldwide for its OneTouch brand of glucose meters, insulin pumps, and related products. J&J said the deal is expected to close by the end of the year, assuming it clears regulatory requirements and other customary closing conditions. LifeScan earned $1.5 billion in revenue in 2017.

https://biospectrumasia.com/news/30/11075/jj-agrees-to-sell-lifescan-unit-for-2-1b.html

7. Pharma Shells Out $100B on M&A in 2018 So Far, With More to Come: Report

After an unusually slow 2017, deal-making in Big Pharma roared back to life in the first half of this year, with $100 billion spent on mergers and acquisitions so far. And with such names as Johnson & Johnson and Allergan mulling both acquisitions and selloffs of some of their core assets, it's likely the M&A boom will continue through 2018. All in all, the M&A landscape in Big Pharma this year is already a far cry from 2017, when there were 101 deals, only 14 of which were worth more than $1 billion, BioSpace reported. The industry is well on its way to surpassing last year's M&A total already.

https://www.fiercepharma.com/pharma-shells-out-100b-m-a-2018-so-far-more-to-come-report

8. Biogen to Spend $700M to Build Its Stake to 49.9% in Biosims Joint Venture With Samsung

After Biogen reported first-quarter results back in April, CFO Jeff Cappello said the company would get further involved in an "attractive value creation" opportunity: its biosimilars joint venture with Samsung BioLogics. Biogen says it'll pay Samsung BioLogics about $700 million to build its stake in the joint venture to 49.9%. The exact value will depend on timing and exchange rates. Biogen's move to scoop up more share comes as its stalwart multiple sclerosis franchise operates in an increasingly competitive field.

https://www.fiercepharma.com/biogen-spending-700m-to-build-stake-biosims-joint-venture-samsung

9. Johnson & Johnson Has the Most Bucks for Biopharma M&A, Astellas the Easiest Target: Analyst

The recent surprise of Takeda's acquisition of Shire and available financing provide further evidence that almost any such potential transaction could be possible. After going through the balance sheets of 20 biopharma companies with the largest market caps, Porges and colleagues found that, at peak leverage ratios, the group could collectively borrow $460 billion in M&A war chests even without counting leverage capacity of target or potential synergies. The top three companies with the most options for takeovers coincide with the top three with the highest 2017 revenues. Johnson & Johnson, Roche and Pfizer have $65 billion, $55 billion and $41 billion leverage capacity, respectively—cash and debt—while Novartis, Merck & Co. and Gilead also have mid-level options, according to Leerink's report.

https://www.fiercepharma.com/pharma/johnson-johnson-wealthiest-buyer-astellas-easiest-target-biopharma-m-a-analyst

10. Universal Flu Vaccine Biotech Seeks Big Pharma Partnership for Phase 3 Testing: CEO

Problems with seasonal flu shots have been well documented, and now U.K. biotech Imutex believes it has the next big advance for flu vaccine technology. The company reported phase 2b data showing that its universal flu shot, FLU-v, boosted immune responses and lowered infection rates. Other companies, including global giants Sanofi and Johnson & Johnson, are also working on advancing flu vaccine technology. FluGen and Vaccitech are among the biotechs with universal flu programs.

https://www.fiercepharma.com/universal-flu-vaccine-biotech-seeks-big-pharma-partnership-for-phase-3-testing-ceo

11. When a Health Insurer Also Wants to Be a Hospice Company

Hospice, the business of caring for those who are nearing death, has become a booming multibillion-dollar industry that is attracting more and more for-profit companies, including one of the nation's major insurers, Humana. Humana plans to buy two hospice chains that together would create the industry's biggest operator with hundreds of locations in dozens of states. The Medicare Payment Advisory Commission, which does research for Congress, estimates that for-profit companies running hospices, which make up about two-thirds of the industry, had an overall profit margin of 16 percent, compared to about break-even for nonprofits.

https://www.nytimes.com/2018/06/22/health/hospice-humana-private-equity.html

12. Amazon, Berkshire Hathaway and JPMorgan Name C.E.O. for Health Initiative

Amazon, Berkshire Hathaway and JPMorgan Chase, the powerful triumvirate that announced its hope to overhaul the health care of its employees and set an example for the nation, said that it had picked one of the country's most famous doctors to lead the new operation: Dr. Atul Gawande. Dr. Atul Gawande, a Harvard surgeon and staff writer for The New Yorker magazine, will become chief executive of the new company. He said he was not stepping down from his current medical and other duties to take the job.

https://nyti.ms/2K5McQB

13. Disability Applications Plunge as the Economy Strengthens

The number of Americans seeking Social Security disability benefits is plunging, a startling reversal of a decades-old trend that threatened the program's solvency. It is the latest evidence of a stronger economy pulling people back into the job market or preventing workers from being sidelined in the first place. In addition to stronger economic growth, the drop reflects newly tightened standards for eligibility and the increasing number of baby boomers who are leaving the program because they have become eligible for Social Security retirement benefits and Medicare.

https://nyti.ms/2tb0WqR

14. Gilead's Kite Taps Eisai Cancer Vet Amoroso to Lead the Charge for CAR-T Sales

Just one month after naming a new head of corporate development, Gilead is strengthening its top management team again—this time plucking an oncology vet to head up its entrance into the burgeoning market for CAR-T cancer treatments. Gilead unit Kite, which won FDA approval for the CAR-T drug Yescarta last year, has hired Michael Amoroso as SVP and head of worldwide commercial efforts in cell therapy. Amoroso's previous experience as SVP of Eisai's oncology business group in the U.S. will help as Gilead seeks to build on its existing portfolio, expand its commercial presence in cell therapy in the U.S. and around the world, and advance new products to market.

https://www.fiercepharma.com/pharma/gilead-s-kite-taps-eisai-oncology-vet-amoroso-to-helm-car-t-commercial-strategy

15. Success of Blood Test for Autism Affirmed

One year after researchers published their work on a physiological test for autism, a follow-up study confirms its exceptional success in assessing whether a child is on the autism spectrum. A physiological test that supports a clinician's diagnostic process has the potential to lower the age at which children are diagnosed, leading to earlier treatment. Results of the study, which uses an algorithm to predict if a child has autism spectrum disorder (ASD) based on metabolites in a blood sample, published online today, appear in the June edition of Bioengineering & Translational Medicine.

https://www.sciencedaily.com/releases/2018/06/180619122434.htm

www.kumc.or.kr

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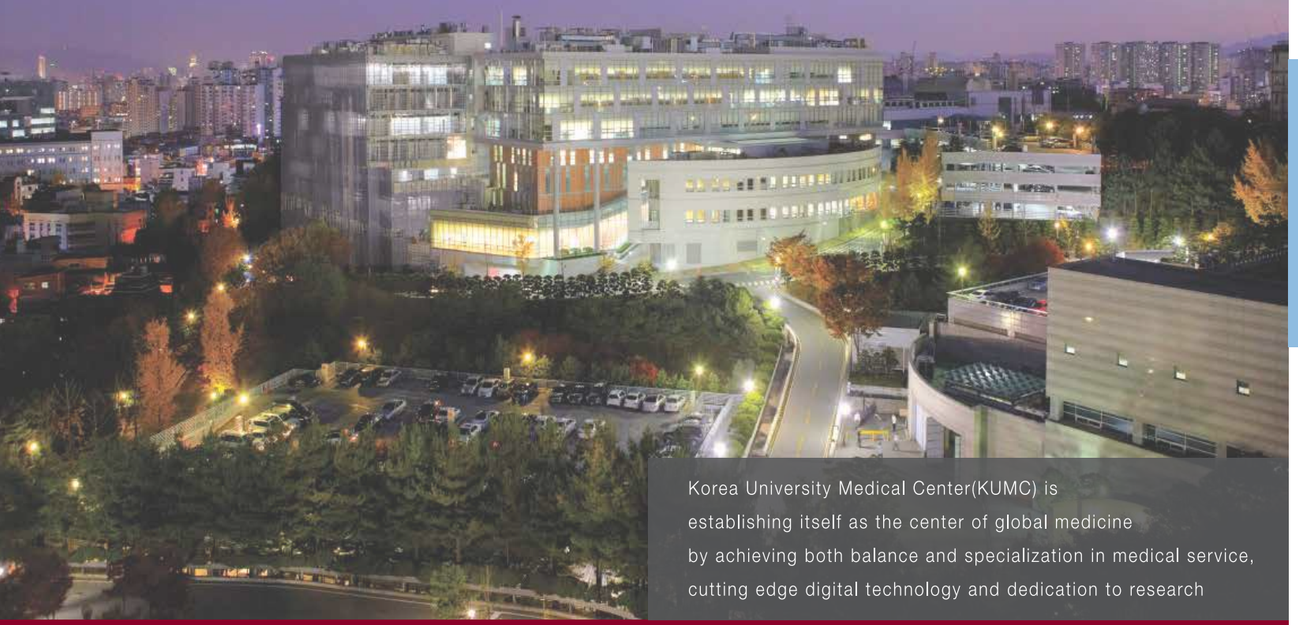

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