November 2017 - ISSUE 15

WKMJ

World Korean Medical Journal

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President of the American Academy of Dermatology

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Jinmin Lee, Chief Executive Officer and Founder of isoi

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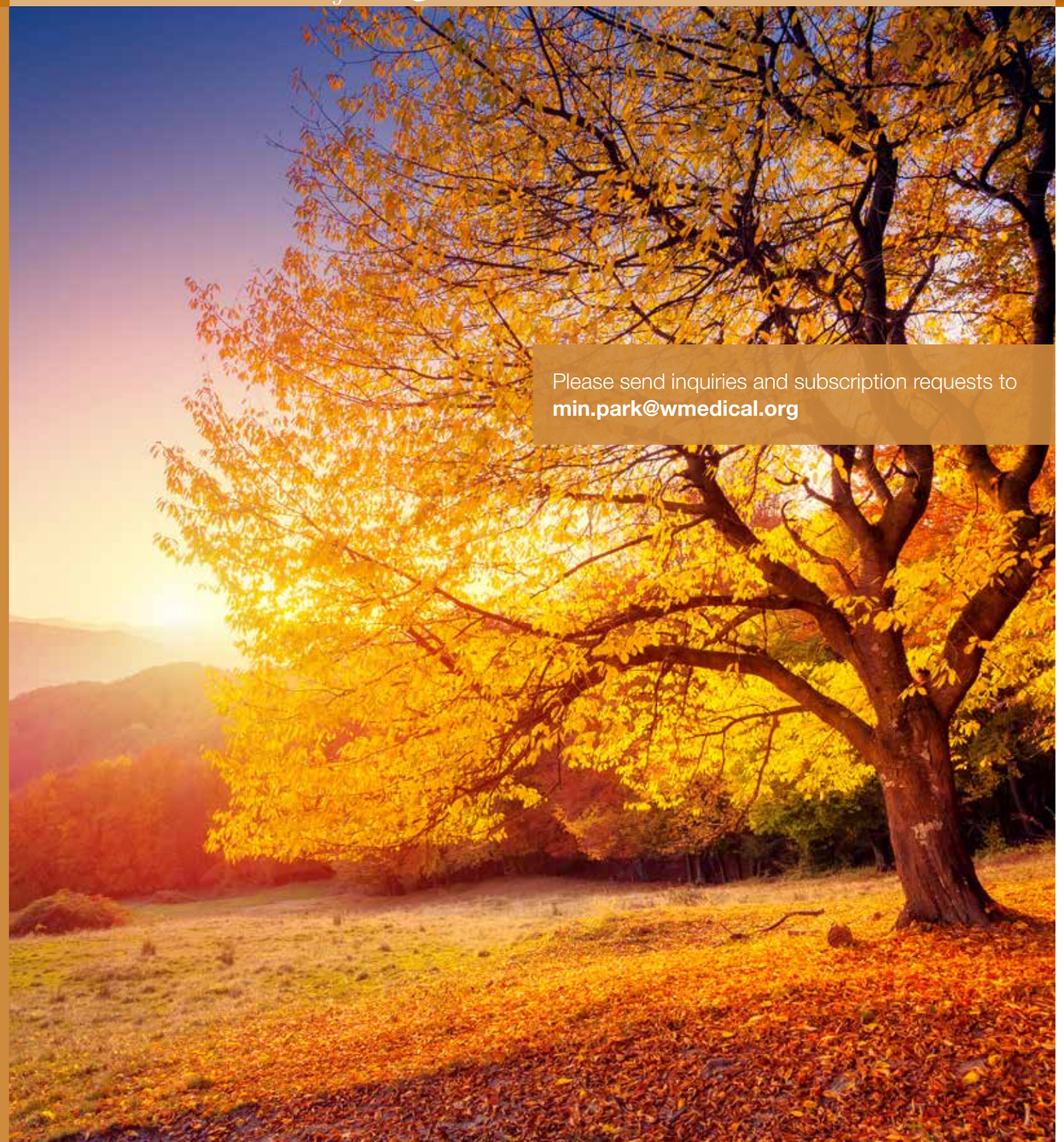

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FROM THE PUBLISHER

Korea has been in the forefront of the news in 2017, but unfortunately, the focus is on the war rhetoric between the leaders of the North Korea and the US. As 2018 approaches, the focus of the world will shift to South Korea with the Winter Olympics. The world will gather for the highest level of competition without politics and only the friendly competition with true human drama will remain. In this Winter Olympics, the North Korean figure skating team may join to compete in South Korea. Although relations between the South and the North Korea are icy, hopefully we will see a thaw moment at this Olympics to remind us of our common bond and give us hope of unification that we witnessed in Germany.

In the 15th issue of WKMJ, the cover story and the entrepreneur interviews feature a common theme which involves skin, the largest organ in our body. The cover story interview is with Dr. Henry W Lim, the President of the American Academy of Dermatology (AAD). In his interview, Dr. Lim highlights skin conditions that arise as we age and as skin damage accumulates over the years. Skin health is very dependent on lifestyles and there is no doubt that it is an important measure of overall health. As Dr. Lim mentioned, using tanning machines or extra sun exposures, in efforts to have a tanned skin, may cause skin damage and even skin cancer. Thus, improving public health education is critical to improve overall concerns and most importantly, patients must be amenable in changing their lifestyles. Over the years, AAD had an increasing international participation and Dr. Lim targets to increase underrepresented minorities in the competitive field of dermatology. Hope Dr. Lim a productive Presidency at AAD.

The entrepreneur interview is with Jinmin Lee, the founder of isoi skincare company from South Korea. Korea has been a leading expert of skin care industry for years. The skin health is affected by many factors including exposure to environmental stressors, physiological processes, as well as daily product use. Skin care products such as deodorants, perfumes, soaps, and makeup may often contain harmful chemicals. Since skin protection and using right products together is the key to promoting healthier skin, isoi's philosophy of using less chemicals seems prudent. Following the science behind human skin, isoi uses natural skin care additives from plants that are similar to human skin oil. Like a beautiful flower, beautiful skin is easily seen and like botany, maintaining it for as long as possible is the best we can do.

Even when Trump recently visited South Korea, the focus was on North Korea and Trump's surprise attempt to visit DMZ. His speech highlights the historic but tragic division of North and South Korea and we need to work to undo this. On a final and brighter note, I would like to congratulate Dr. John Oh on his election to be the President of Korean American Medical Association.

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

FROM THE EDITOR-IN-CHIEF

For the last decade, many household and personal product manufacturers announced they would reduce or eliminate a range of questionable ingredients from their product lines. As a result, hundreds of cosmetics and personal care products had been reformulated. Non-profit organizations such as Campaign for Safe Cosmetics, a nationwide coalition hugely funded by the Breast Cancer Fund, has educated millions of people about the problem of toxic chemicals in cosmetics, which has led to an increased demand for safer products in the marketplace. Evermore strengthened government regulations such as "the Frank R. Lautenberg Chemical Safety for the 21st Century Act", a law passed by the U.S. Congress in 2016 and administered by the Environmental Protection Agency (EPA) started to regulate the introduction of new or already existing chemicals. Continuous and recurrent Public Private Partnerships (PPP), had led industry to pay more attention to sustainability of environment and human health and safety. Another driving force for emphasizing human safety has been led by medical community. Medical researchers and clinical practitioners including dermatologists, constantly raised issues with skin safety and product ingredients. As our November edition highlights skin and skin health, we featured leading figures in the arena of skin.

As the Cover Story, WKMJ interviewed Dr. Henry W Lim, MD, FAAD, President of the American Academy of Dermatology. As a physician, his achievements in the area of dermatology had been significant. He navigated arduous and formidable pathways to apprehend the molecular mechanism of the development of skin diseases and identifying what is effective for better treatment. As a healthcare leader and educator, his visions on human health became an inspiration for the young generation. In our Entrepreneur Interview, we meet Jinmin Lee, CEO of isoi cosmetics. Having had extensive experience in marketing and pursuing the best ingredients in skin care products, she founded and grew isoi into one of the leading natural and clean product manufacturer.

New trends and issues of bio-health industry, as well as special report on global initiative of Korean leading CRO, C&R Research and W Medical Strategy Group's partnership were featured in this issue.

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. On this edition, we introduced first non-Korean healthcare leader in the cover story. While the traditional 'ethnic focus' has evolved to diverse figures, the core value of the content remains the same, "providing inspirational stories on healthcare."

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.

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 Ki-Young Sohn, Chairman and Chief Executive Officer at Enzychem Lifesciences, Corp.

Ki-Young Sohn is the CEO and Chairman of the biopharmaceutical company, Enzychem Lifesciences Corporation, a number one leading corporation in the KONEX stock market of Korea. Enzychem's innovative new drug development program is backed by 17-year history of API manufacturing. Prior to Enzychem, Chairman Sohn served as the Chairman of Bridget Lifesciences Corporation, a professor at the International Management Institute of Federation of Korean Industries and as a Director of Samil Accounting Corporation, now known as PWC. A successful entrepreneur, Chairman Sohn shares his insight in the global and the Korean biopharmaceuticals. To read more about Chairman Sohn, please read Issue 14 of WKMJ.

Entrepreneur Interview
Thomas Seoh, President and Chief Executive Officer at Kinexum

Thomas Seoh, J.D. is the current President and CEO of Kinexum, a distinguished resource for research development and commercialization of the life science products. Mr. Seoh is a life science executive and entrepreneur with ample experience and functional expertise in corporate and business development as well as law. Mr. Seoh has held senior and leadership positions in numerous companies including biotech, medtech, and pharmaceutical companies and continues to act as an invaluable advisor to academic teams on commercializing their research. To learn more about Mr.Seoh's entrepreneurship and his insights, please refer to Issue 14 of WKMJ.

Biopharmaceutical Report I
Eisai's Lenvima Should See FDA Approval in Hepatocellular Carcinoma (HCC)

Many drugs have failed in Phase III and showed inferiority in first line HCC. However, Eisai's (TYO: 4523) Lenvima (lenvitanib) has a convincing FDA approval rational based on positive Phase III results for first line unrespectable HCC versus Bayer's (ETR: BAYN) Nexavar (Sorafenib), a high efficacy drug. Experts have commented that Lenvima's potent anti-angiogenic mechanism is ideal for HCC; however, some experts state that even though Lenvima's side effect profile is within the known scope, Lenvima's hypertension rates are higher than Nexavar. To read more about Eisai's Lenvima, please refer to Issue 14 of WKMJ.

Biopharmaceutical Report II
Medical Device: Growing Cybersecurity Threat and Need for more Regulation

Despite an expected increase in the frequency in cybersecurity threats in the near future that will affect networked medical devices, experts debated whether the existing U.S. and European guidelines are adequate to ensure device manufacturers are up to date with the highest security. Any devices connected to a hospital network can be compromised. Since medical device cybersecurity is largely covered by FDA guidance and not regulation, there are constant debates whether tightening regulation will be productive or counterproductive. To read more, please refer to Issue 14 of WKMJ.

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INSPIRATIONAL GLOBAL HEALTHCARE LEADER

Henry W. Lim, MD, FAAD
President of the American Academy of Dermatology

COVER STORY

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

- When I was growing up, I developed an avid interest towards science, and found great fulfillment in helping others. Thus, despite there being no physicians amongst my immediate family members, a profession in the medical field seemed to be something that I would truly enjoy and feel gratified in. I grew up in Indonesia, but moved to Canada for college, and subsequently applied for and attended medical school in the U.S.; that encapsulates why and exactly how I became involved in the field of medicine. In terms of specifically dermatology, that was actually by chance. Throughout my time in medical school, I was initially looking to become a pediatrician and this thought was largely influenced by the fact that my first year clinical mentor was a pediatrician. I truly did enjoy working with children and adolescents, and believed it to be a specialty I would like to pursue myself. Towards the end of medical school, however, which was my fourth year, I deduced as a prospective pediatrician, I would need to know more on dermatology as clearly in kids, you see a lot of rashes.

At that time, I was in New York and NYU was reputably known to have a very good dermatology program, which ultimately led me to complete a clinical elective during my fourth year of medical school at NYU. From my time there, I was very much impressed with how dermatology was taught and practiced, and made me seriously consider dermatology as a specialty I would work towards in lieu of pediatrics. The subject matter was intellectually stimulating, and dermatology, I discovered, was a field I found immense satisfaction in. So with that, after applying for a pediatric internship at various hospitals, I decided to also submit an application to the dermatology program at NYU, and only at NYU. I had received an acceptance from pediatric hospital, but when I was also notified of my acceptance into NYU's dermatology program, I became sure that dermatology is what I sought to pursue.

> **"The subject matter was intellectually stimulating, and dermatology, I discovered, was a field I found immense satisfaction in"**

2. As a successful dermatologist with nearly 40 years of experience, you may have gone through various obstacles; can you share some of the most difficult moments in your career?

- No doubt, I have truly enjoyed my career thus far in dermatology. However, likely the most difficult decision I had to make occurred towards the end of my residency at NYU in dermatology, and that was whether to go into private practice or to instead further pursue my academic career. At the time, which was in 1978 or 1979 or so, private practice was a very popular path to follow for many graduating residents, although it no longer is today due to administrative burdens. One prevailing reason for this was the income difference between a profession in private practice and an academic career in dermatology. Having had a young family with two kids at the time made this decision all the more arduous, as supporting them was an obvious consideration I had to make. However, I truly thrived in an academic setting, as I was constantly intellectually stimulated and challenged. Furthermore, I was fortunate to have two mentors who helped me in making the decision, which was to ultimately remain in academic dermatology. This was a very difficult moment, but in retrospect, I'm confident to say that it was also the most correct and probably the best decision I have made, as it has led me to a still ever so stimulating and fulfilling career in dermatology for nearly 40 years now.

3. Dr. Lim, you have previously been a professor of Dermatology at NYU school of Medicine and today, you are a professor at Wayne State University as well as a Senior Vice President for Academic Affairs at Henry Ford Health System. How do you view yourself as an educator? What are your principles or philosophies as a teacher?

- This is namely one of the aspects in which I take tremendous enjoyment and gratification in. Having been an educator, and having mentored and interacted with younger students or faculty members meant witnessing them grow professionally. In fact, there are a number of faculty members in our department today whom I first met and knew as medical students, as well as several others in other respective departments all over the country whom I've also had the great experience of mentoring in the past. I take a lot of gratification in that – knowing that I have contributed not only to their growth as a clinician, educator, or researcher, but also that I have made my contribution in giving back to the specialty. As an educator and as someone who's been in this specialty for nearly four decades, the one philosophy I prescribe to myself and others is to always a find a way to give back to the field. The younger individuals just entering the field are the very people who will be contributing and shaping dermatology in pending years. After all, the young people will become the clinicians and the academics in dermatology who continue to propel our specialty forward, as well as those who provide the best care and service to our patients.

Dr. Lim and his wife, Dr. Mamie Wong-Lim at the Henry Ford Dermatology grand opening at the New Center One location

Dr. Lim examines a patient

4. Do you have any words of advice for those who are pursuing to be a physician?

- What I wish to impart to all those seeking to become future physicians is firstly, to know that medicine still is a very noble profession. Medicine remains one of few, if not the only profession that endows you various options of continuing to pursue your career, be it in full-time practice or academic medicine, conducting research, becoming an educator and mentor for medical students and residents, or if you feel inclined, managing administrative leadership activity. All in all, it is truly a wonderful profession, as you simultaneously also develop the core with your patients by getting to know them as individuals as well as getting to know their family. This leads me to a second piece of advice: to work hard, but to also truly appreciate and take satisfaction in interacting with the patients, and to thereby give back to the profession.

5. You have become the president of American Academy of Dermatology. What are your key roles, responsibilities, and principles of leading the world's largest dermatologic society that represents more than 18,000 physicians? Can you also share your visions and goals as the president of this organization.

- It is truly a great honor and privilege to have been elected as President, especially since this was a position elected by the entire membership. Now, there are two major responsibilities we uphold ourselves to at the Academy.

The first is education. As the American Academy of Dermatology, we pride ourselves as a professional organization that continues to provide top quality, and what I believe to be the best medical education for dermatology across the globe. While our members remain the largest demographic, we are noting that our international audiences are increasingly attending the summer and annual meetings, which are what I would describe as the two biggest meetings we host here. In fact, the growth of our international membership has been exponential as of recent years, and it is within our objectives that we continue to evaluate, improve, and utilize many of our resources to better our education system in the AAD.

The second responsibility entails ensuring health and stability in our members. We are well aware of how demanding the practice of medicine can be nowadays, namely due to the administrative burden. As a matter of fact, that is one of the leading causes of physician burnout. Although dermatology is stated to have a lower rate of burnout amongst all other specialties, it truly depends on the individual physician. Therefore, the AAD has made it an ongoing mission to ease such administrative burdens for our members. Particularly, prior authorization tends to be the most strenuous for the members, and in order to combat this hitch, we are currently developing a website to assist our physicians with the especially laborious process. Moreover, we continue to work with legislators as well as the payers in making sure that these administrative duties do not render the actual practice of medicine as onerous for the physicians, including our members.

As for my vision in regards to the Academy, there are two goals I hope to accomplish with the members at the AAD.

We stand as a professional organization for all dermatologists, primarily in the U.S., as it is a great imperative for the AAD to advocate for this specialty and our members. One principal goal, I believe, is to encourage our members to be active participants in the activities of the house of medicine, be it in the American Medical Association or at the State Medical Societies. This way, our voice in dermatology continues to be heard and this way, we are able to continuously make positive contributions on the healthcare discourse, in the local, city, state, or national level.

Secondly, it is our earnest intent to provide an apt environment and to generally support the increase in diversity in dermatology. Specifically, we seek to increase the percentage of what we call underrepresented minority (URM), which by definition includes groups of ethnic racial groups where the proportion in medicine is less than the proportion of the general population, namely African-Americans and Hispanics. The URM percentage in dermatology, particularly, is quite low, as it is in a number of other areas and specialties in medicine. Hence, it is within our top priorities to address this disproportionate representation, and to ultimately help rectify it. However, I find it critical to mention that this is a challenge that goes beyond our capabilities at the AAD, as it is indubitably more of a pipeline issue. We, as a society, first have to increase the qualified pool of high school and medical school students in order to join dermatology, or other medical specialties.

Dr. Lim receiving the Fred W. Whitehouse Distinguished Career Award, Henry Ford Medical Group. Oct 2016

Dr. Lim at Global Chinese Dermatological Summit, Xian, China.

6. You have conducted hundreds of research and served as an editor or co-editor in multiple textbooks. As an eminent opinion leader in dermatology, what are some major changes or trends happening in dermatology currently? Also, what do you forecast the major changes would be in dermatology in the next five years?

- It is truly an exciting era in dermatology now. As aforementioned, having been in the field for approximately four decades now, I've personally witnessed the science of dermatology mature and advance over the years. Even so today, our understanding of dermatology continues to improve and become more sophisticated. Due to this evolution in the study of dermatology, for example, we are now able to apprehend the mechanism of the molecular pathway of the development of skin cancer, as well as the molecular pathway of development of vitiligo, which is a condition where one loses pigment in the epidermis, resulting in the development of white patches on the skin. These cases are exemplary of the idea that simply understanding the pathway itself, as in identifying what is effective and what is abnormal, can manifest in better treatment.

The most exciting aspect of this is that all of this is still ongoing, and that current changes are reflective of changes that I look forward to in coming years. Within the next five years, I expect further advancements in the findings and drug developments for various skin disorders, some of which especially include treatments for psoriasis, as well as dermatitis and eczema.

7. We have learned that you also specialize in sun damage and photosensitivity. Recently, there have been many public issues regarding sunscreen ingredients as well as skincare products. Do you have any concerns regarding this issue or any advice you would like to share with our readers?

- The issue regarding the ingredients in sunblock and now skincare products reemerges every spring, from what I've observed. There is no doubt that there are positive effects in being outdoors, whether that is the benefits in physical activity or receiving a dose of sun-derived vitamin D. Yet, we're also very much aware as a society that the sun's ray can result in sunburn and the tanning of the skin. It also causes what we call photo-aging, which is essentially the development of wrinkles and possibly skin cancer. What we prescribe as the AAD is that maximum protection should begin with measures that go beyond sunscreen application.

However, this is not to say that individuals shouldn't participate in outdoor activities. We simply advocate for proper protection. Returning to sunscreens, they are no doubt a proven and very effective means in shielding exposed skin, and while the concern regarding the various ingredients in sunscreen is valid, the scientific data behind the substances that receive negative press are, in truth, unsubstantial. So in conclusion, my response to concerned patients is that what's most important is protection, and that ultimately boils down to applying sunscreen onto exposed areas.

I've also received inquiries and concerns regarding the "chemical ingredients" in some brands of sunscreen. Such ingredients are also known as "organic filters" in dermatology, where the ingredients sink into the skin and function as agents that absorb the harmful rays. On the other hand, there are inorganic filters, including zinc oxide and titanium dioxide that simply sit on top of the skin and reflect the rays as opposed to absorbing them. Sunscreens containing one or both of these latter ingredients are inert agents that do not lead to any other issues. Therefore, I often recommend such products to the patients who are tentative of using organic filters. However, there is a challenge in using those sunscreens, as they often leave a white sheen. Consequently some patients dislike such sunblock products for cosmetic reasons. Nonetheless, the benefits of using sunscreen as part of protection still significantly outweighs all other concerns one may have.

Dr. Lim with House Officers (Residents) of the Henry Ford Dermatology Department

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

- What I would like to impart as my final thoughts include one, as I've mentioned earlier, that I view medicine as a very noble profession, where physicians can not only further the current understanding of the mechanisms and treatments for various diseases, but also, and most importantly, help the patients. This is what gives me the greatest satisfaction. Secondly, I am incredibly grateful to have interacted with and mentored younger generations within the medical field, as teaching such individuals has been an enlightening and a truly gratifying experience for myself. I strongly and truly encourage other experienced physicians to offer their time and knowledge towards educating the medical students and residents just entering their specialty, or the overall field. Lastly, I would like to convey to all the WKMJ readers that today is truly an exciting time in medicine, as there is an incredible amount of new information acquired from research, and that with such new knowledge, there is much to be expected in new and improved treatments for various disorders and conditions, and therefore a greater welfare for our patients.

Henry W. Lim, MD, FAAD

President, American Academy of Dermatology

Chair Emeritus, Department of Dermatology, Henry Ford Hospital

Dr. Henry Lim is the Chair Emeritus of the Department of Dermatology, Henry Ford Hospital, and Senior Vice President for Academic Affairs, Henry Ford Health System, Detroit, Michigan, USA. As of March 2017, he is the President of the American Academy of Dermatology, the world's largest dermatologic society. Prior to coming to Henry Ford Hospital, he was a Professor of Dermatology at NYU School of Medicine, as well as the Chief of Staff of the New York VA Medical Center. He has published more than 400 articles, and edited 7 textbooks. He is a recognized world authority on photodermatology. He has also been on Best Doctors list annually since 1994. Dr. Lim has served as President of Michigan Dermatological Society, Vice President of the American Academy of Dermatology, President of the American Board of Dermatology, and President of the American Dermatological Association. In 2016, he was selected as the recipient of the Fred W. Whitehouse, MD, Distinguish Career Award of the Henry Ford Medical Group. Dr. Lim is also an elected honorary member of dermatology societies in Austria, France, Spain, the Philippines, China, and the Baltics.

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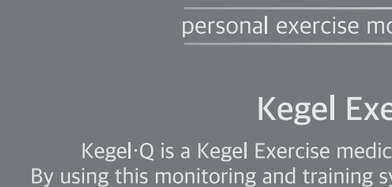

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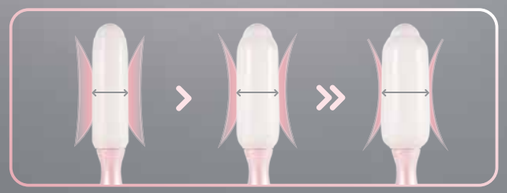

※ *Multicenter clinical trials are currently recruiting participants at reputable university hospitals in South Korea including Seoul National University Bundang Hospital and these trials are sponsored by Korea Health Industry Development Institute.*

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Entrepreneur Interview

Jinmin Lee, Chief Executive Officer and Founder of isoi

1. isoi is one of the leading natural Korean skincare brands that is reputable for refusing to use harmful, synthetic chemicals in its products. After successfully launching in Whole Foods Market stores nationwide and being the first ever Korean brand to receive top scores from the EWG, isoi is rapidly gaining a reputation in the U.S. as a leading natural skincare brand. What was the motivation and inspiration behind isoi?

When I was younger, I had a phase of acne and I had used various steroid creams to combat it. However, my skin had become incredibly sensitive and dry as side effects of the medications, and often times my face reddened, with skin peeling off as colder seasons approached. At the time, a task as simple as rinsing my face with water was painful. This led me to reach out to online community by creating a forum website. My question gained much traction and many people have tried to help me with my skin concern, but the various tips made little difference for my condition. In 1999, however, I happened to read a report issued in Europe that would change my perspective on skincare.
The article stated how the use of chemically-derived synthetic ingredients has a high likelihood of disrupting the skin's natural processes, and that applying exclusively naturally-derived compounds can help treat skin symptoms. I followed this radical advice and incorporated a blend of Bulgarian Rose Oil as well as other plant-based oils and extracts into my skin regimen. In less than a year, I saw incredible changes. My skin had become clearer and more radiant, and exuded this healthy glow that was beyond what I had originally hoped to see. For the next

isoi products in Whole Foods Market

decade, I travelled the world to gain expertise in developing natural cosmetics, and sought after these key components: safe, healthy, and quick yet long lasting results.
After much research and trial-and-error, I succeeded in launching isoi in 2009, providing natural cosmetics without any harmful ingredients. Since then, the brand has substantially grown thanks to the consumers who appreciate and love our products and philosophy.

2. As the CEO of a globally-revered Korean cosmetic brand and as a successful entrepreneur, what are the top three priority assets or skills that you believe lead to such success?

If I had to choose three assets that led isoi to its success, the first would be a sense of mission one would hold as a CEO. This one in particular has great personal meaning to me. Since the establishment of the brand, our team at isoi have run the company with a mission to upgrade not only the outer appearance of women, but also their quality of life. We've also carried out various communication activities, and made it a top priority to always be in touch with our consumer-base as not mere customers, but women with struggles that we know too well of. I firmly believe that we were able to expand our company at the rate we did because we never forgot our core goal in improving the welfare of women.

Next, we encompass a set of values. Among them include one, the "no additive principle," where we pledge to never add toxic, or any high-risk ingredients that may pose harm to the human body. Two, we make it a priority that the raw materials be the primary ingredients in our products, which we call the "best ingredient principle." Three, the "low skin irritation principle" ensures that our products minimize skin irritation through the use of high quality, gentle ingredients. By employing these principles in the production and development of isoi's cosmetics, we've been able to achieve a rapid growth in sales and an increase in brand awareness.

The last asset I would like address are the employees of isoi. The growth of a company is primarily contingent upon the employees, and not on the CEO alone. Therefore, it is incredibly vital to me that a healthy and stimulating work culture is cultivated for them, and that they genuinely recognize themselves as invaluable contributors to our brand. Furthermore, employee satisfaction ultimately leads to positive consumer experience of our products and service. isoi has spared no effort to support the education, leisure, and cultural activities for our employees in order to ensure that they are truly content with their work environment. A few examples of our educational support include sending our employees abroad to experience worldwide trends of cosmetics and offering to enroll in an MBA curriculum to all our team members. Also at our company, we provide corporate dining with organic and healthy food options as well as pilates classes and refreshment rooms for optimal health and relaxation.

Jinmin Lee with Dr. Weiland at isoi laboratory in Germany

isoi uses prime grade rose oil certified by the Bulgarian government

3. Korean beauty, often termed as K-beauty, became a big trend in the global beauty industry. How do you differentiate isoi from competing cosmetic companies? Can you please explain isoi's strategies, mission, and activities to our readers?

isoi is a brand offering functional cosmetic products that exclusively use natural ingredients to enhance the skin's self-sustenance abilities, as I've mentioned earlier. The most distinguishing feature of our products, I would say, is our unique, yet carefully thought out selection of raw materials. Bulgarian Rose Oil, for instance, is isoi's signature ingredient, and offers an incredible array of benefits for the skin.

We acquire this particular rose extract by repeatedly boiling and cooling 3,000 Bulgarian roses, and among the various grades of Bulgarian Rose Oil, we specifically employ the initial extract oil, which is namely used for medical purposes, in order to help improve the skin's natural repair and maintenance mechanisms. Our unique selection of raw materials is consistent with isoi's brand philosophy that "good ingredients are destined to change the skin," which is something we remain committed to despite the rising prices in such raw materials every year.

Another distinguishing quality of isoi amongst other cosmetic brands is our brand concept of completely banning the use of harmful, toxic, and synthetic ingredients in our products.

With growing industrialization across the globe, adverse effects related to chemically formulated, and potentially toxic ingredients have risen amongst consumers. Despite this, a number of cosmetic companies give insufficient regard to the source of their products' ingredients, and therefore isoi has built its own territory and differentiated itself by committing to making products completely free of high-risk, toxic ingredients. Going beyond what are in our products, isoi also puts an emphasis on helping women learn of, select, and use healthy and safe cosmetics with the execution of our brand promotion and marketing activities.

We also carry out various communication activities aimed at promoting women's health and their rights by relaying self-empowering, positive messages.

Continuing on into the future, we, at isoi, are keen on becoming more than a simple cosmetics brand. By expanding our practices in social movements and relaying more women-positive messages, we anticipate that isoi gains recognition as a company that centers its values and principles on the health and happiness of women.

4. What are some significant changes you have noticed in the beauty industry for the past years? And how do you forecast the global and Korean beauty industry will be like within the next five years?

Today's cosmetics market is saturated with a variety of trends, many of which are rapidly changing as we speak. However, what we personally pay most attention to is the increased consumers' awareness of the ingredients making up the cosmetics they apply regularly.

There has always been a high demand for "newer", "more convenient", yet still "effective" cosmetics, but nowadays, a new buzzword has emerged. Consumers now prioritize their health, and now also search for "safe" products that still uphold the previously mentioned qualities. Beauty companies have long been involved in social activities, especially those promoting women's health. Yet, ironically, their products continue to contain significant amounts of potentially harmful and high-risk ingredients that, in the end, are likely to compromise the health of so many of their consumers.

Due to the lack of information on the ingredients themselves and a stronger emphasis on the general values these beauty companies would like to represent, consumers continue to purchase and use such products, not knowing their health may be negatively impacted by them. In recent years, people have begun to pay better attention to what goes into the cosmetics they use, and thus they're becoming more aware of this irony.

The past few years have especially headlined various incidents where consumers reported adverse effects from the hazardous ingredients in their cosmetic products, as well as those related to the environmental surroundings. In either case, their skin and other parts of their body have been affected, and has led to the eventual increase in their demand for safe cosmetics.

This change in what the consumers now seek for in beauty products is now being reflected in the marketing strategies of beauty brands. Unlike the past, where cosmetic companies put a greater emphasis on the aesthetic appeal of their products, especially through their use of models and vibrant color schemes, brands are now advertising that their cosmetics are "free" of a disreputable ingredient, or that they are formulated with "non-toxic ingredients" in order to reestablish and gain the consumers' trust. Isoi expects that this isn't a mere trend, but a fundamental criterion that will remain.

Jinmin Lee during product development meeting

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

isoi will continue to preserve its philosophy in providing safe and natural cosmetics, and remain committed to further research and development in order to meet the healthy beauty standard held by people all over the globe. As one of the few pioneering Korean cosmetic brands founded on the natural concept, we seek to become the top company within this realm of the beauty industry, and will always strive to achieve this objective in an honest and transparent manner, never to disrupt the trust we've established with our consumers.

isoi storefront located in Garosu-gil, Seoul

The team at isoi, including myself, kindly bid to the WKMJ readers that they become more aware of their skin health, and thereby the ingredients in the beauty products they currently use. We would also greatly appreciate that the readers accompany us on our journey, which can be at times difficult due to our growing, yet still niche concept, and watch over us with encouragement. Please keep an eye on isoi, as it will hopefully grow into a beauty company that can fulfill its social roles and responsibilities as an integral member of global society. W

** For isoi brand inquiries, please contact at greenalleyshop.com, official US distributor for isoi.*

Jinmin Lee, M.A.

Chief Executive Officer and Founder, isoi

Jinmin Lee is the Founder and current Chief Executive Officer of isoi, a South Korean beauty brand founded on the philosophy that beauty should never compromise one's health. Her previous titles include being the youngest Creative Director at Cheil, a marketing company under the Samsung Group, where she participated in brand consultation for the Samsung Anycall TV Commercial in South Korea. With an especial interest in women's health and rights, She is also a founding member of Miclub, the South Korean internet portal site for women. Furthermore, she is a member of the Board of Directors at the Hope Institute, as well as an Advisory Board Member at the Seoul Culture Forum with interests in promoting civic duties around social, educational, environmental and political topics. Jinmin Lee has earned a Master of Arts degree in Korean Language Education at the Ewha Womans University.

SPECIAL REPORT

C&R RESEARCH IN GLOBAL OUTREACH WITH
W MEDICAL STRATEGY GROUP

SPECIAL REPORT

C&R RESEARCH IN GLOBAL OUTREACH WITH W MEDICAL STRATEGY GROUP

C&R Research Inc., Korea's leading contract research organization (CRO), has launched its major global initiative by establishing C&R Healthcare Global Pte. Ltd., a subsidiary company specialized in promoting global business partnerships and securing investments. The initiative will facilitate licensing, strategic partnerships and investment opportunities for promising bio-pharmaceutical companies based in Korea.

C&R Research has partnered with Korea's health and medical industries in clinical development for the past 20 years, since its foundation in 1997. To date, C&R Research has carried out a total of 1,200 clinical trials, coupled with drug license services, thus emerging as Asia's representative CRO beyond Korea.

On October 13th 2017, C&R Healthcare Global completed a MOU with W Medical Strategy Group, a New York based consulting firm with diverse medical and pharmaceutical networking portfolio, to further explore global strategic partnerships.

MoonTae Yoon (left), Chairman of C&R Research, and DoHyun Cho (right), CEO of W Medical Strategy Group at the MOU ceremony

Under the new partnership, W Medical Strategy Group supports global outreach of C&R Research and provides strategic consulting to provide an essential bridgehead in North America for Korean bio-pharmaceutical industry.

C&R Healthcare Global provides service to bio-health companies and recruits companies to move into Singapore Incubating Center. Detailed information can be found at C&R Healthcare Global official webpage at www.cnrhg.asia.

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Biopharma Report

BIOPHARMACEUTICAL REPORT I

CORBUS' PHASE II ANABASUM IN DERMATOMYOSITIS GARNERS MIXED EXPERT EXPECTATIONS

BIOPHARMACEUTICAL REPORT II

BEIGENE'S PHASE III BGB-3111 IN WM HAS UNCLEAR EFFICACY ADVANTAGE OVER IMBRUVICA

Corbus' Phase II Anabasum in Dermatomyositis Garners Mixed Expert Expectations

Corbus Pharmaceuticals' (NASDAQ:CRBP) Phase II study of anabasum in skin-predominant dermatomyositis could miss its co-primary endpoint based on its small sample size and the disease's heterogeneous nature, some experts said. However, others noted a narrow focus on a particular aspect of the disease may actually lead to a strong outcome, considering the sensitive measure used.

Whilst some experts said the 22-patient Phase II, double-blind, randomized, placebo-controlled study (NCT02466243) to investigate anabasum (formerly known as JBT-101/resunab) has a reasonable co-primary endpoint for efficacy, another said it is not as fully validated as older scales.

The mechanistic rationale behind treating dermatomyositis with anabasum is based on the drug's effect on the cytokine interferon-alpha (IFN-alpha), which has shown positive results in similar studies, according to an analyst report. However, experts this news service interviewed said dermatomyositis is more closely linked to interferon-beta (IFN-beta), another of the drug's targets.

Positive results in previous trials against scleroderma and cystic fibrosis have given experts confidence in the drug's safety profile in dermatomyositis patients, but one cautioned efficacy can't be extrapolated. Experts said mechanistically it should have fewer side effects than treatments currently in use. Dermatomyositis is a rare inflammatory disease with variable symptoms which can include a skin rash, muscle weakness and muscle inflammation.

Data is expected in 4Q17, the analyst report stated. Principal investigator Dr. Victoria Werth, professor of Dermatology, The Hospital of The University of Pennsylvania, added data is expected in the next few months, possibly at a dermatology or rheumatology meeting. The analyst report also predicted USD 575M in peak sales for the drug, though it stated dermatomyositis is the smallest contributor to this valuation.

Small sample size but a limited focus increases optimism

Experts had divided opinions on how the co-primary endpoint may pan out given the small number of patients. The efficacy co-primary endpoint is the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) at 84 days for Part A and 364 days for Part B, according to ClinicalTrials.gov. Safety and tolerability is the study's other primary endpoint.

Dr. Chester Oddis, director, Myositis Center, University of Pittsburgh School of Medicine, Pennsylvania, said 22 patients is adequate for a proof-of-concept-trial. But Dr. Paul Plotz, scientist emeritus, National Institute of Arthritis and Musculoskeletal and Skin Diseases and

> "Positive results in previous trials against scleroderma and cystic fibrosis have given experts confidence in the drug's safety profile in dermatomyositis patients"

medical advisor to the Myositis Association, and Dr. Dana Ascherman, specialist in idiopathic inflammatory myopathy, University of Miami, Florida, countered that 22 could be too small to see a statistically significant effect considering the disease heterogeneity. That said, 22 patients could be enough if anabasum affects a pretty dramatic response and may still show a good side-effect profile and tolerability data, Ascherman said.

A Corbus spokesperson said the study is not formally powered for efficacy. But if the study does show a statistically significant benefit, that would be profound, she noted. Whilst anabasum, may benefit other disease aspects, the focus on skin was a requirement for government study funding, she said.

Focusing just on the skin in this Phase II actually makes sense considering the disease heterogeneity, Werth and Ascherman noted. Testing the drug's impact on skin-predominant disease allows for a sensitive, easily measurable outcome that doesn't require many patients, they said. But Dr. Fred Miller, chief, Environmental Autoimmunity Group, National Institutes of Health, said 22 patients may still not be enough, adding "the skin many not be more responsive than any other organ."

CDASI reasonable for skin evaluation

Not all interviewed experts were familiar with the CDASI scale, but those who were said it was a reasonable measure for analyzing the severity of the skin rash in dermatomyositis patients. The spokeperson said the CDASI endpoint is the best measure for skin disease in the indication.

The CDASI scale is helpful for distinguishing between past activity and ongoing disease when looking at the skin rash, Ascherman noted. Werth,

who designed the index, said it's been validated including a study comparing CDASI measures to genetic signatures for IFN-beta (Huard, C. et al. Br J Dermatol. 2017 May;176(5):1224-1230). However, Miller said it hasn't been as fully validated or accepted as older scales such as the IMACS outcome (Aggarwal, R. et al. Ann Rheum Dis. 2017 May;76(5):792-801) which measures the whole disease including the muscle and the skin.

The analyst report noted a 5-point change is indicative of clinical benefit, and Ascherman said this is achievable and clinically valuable. The number would encourage patient adoption, he added, especially with a favorable side-effect profile.

Anabasum has been tested in Phase II trials in scleroderma (NCT02465437) and cystic fibrosis (NCT02465450), and according to Corbus presentations, these trials had good safety results as well as improvements in efficacy end points and disease-related biomarkers. Scleroderma is more closely linked to dermatomyositis than cystic fibrosis, Oddis and Ascherman noted but Werth said she could not extrapolate from the scleroderma results to say anabasum might work in dermatomyositis.

Sound scientific rationale though different from lupus

Although the detailed mechanisms involved are not fully known, experts said the trial is merited by the evidence linking interferon and dermatomyositis. However, Werth said it is a different interferon to that involved in lupus, contrary to the previous analyst report.

In a recent study co-authored by Werth (Robinson, ES. et al. J Invest Dermatol. 2017 Jun 23. pii: S0022-202X(17)31668-8), anabasum was shown to reduce the level of several cytokines in the cells of dermatomyositis patients in-vitro: IFN-alpha, IFN-beta and TNF-beta. These three cytokines are known to mediate inflammation, according to Werth.

The analyst report stated the theory behind treating dermatomyositis with anabasum is based on the IFN-alpha reduction, which has shown clinical benefit in lupus studies, but Werth said lupus and dermatomyositis are not the same in this respect. She explained that it is in fact IFN-beta that appears to be more important in dermatomyositis (Wong, D. et al. PLoS One. 2012;7(1):e29161).

The challenge is working out the detailed mechanism, noted Ascherman. Any drug that has the potential to attack the autoimmune mechanism has a possibility of working, Plotz said. Miller and Oddis agreed the evidence for a drug targeting IFN is more compelling than the evidence for a drug targeting TNF (Arshanpalli A. et al. Cytokine. 2015 June; 73(2):319-25), adding this mechanism could treat the disease's muscular aspects as well as the skin.

Corbus continues to explore the various etiologies behind dermatomyositis, the spokesperson said.

> "Past trials have promising evidence for safety, and mechanistically anabasum shows more promise than treatments currently in use"

Safety is promising

Past trials have promising evidence for safety, and mechanistically anabasum shows more promise than treatments currently in use, experts said. However, one expert noted there is a risk of negative impact on other aspects of dermatomyositis.

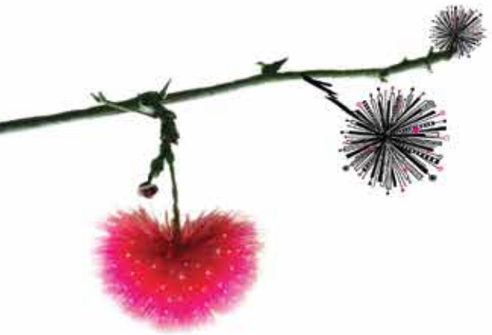
Safety success in the scleroderma trial, where there was no serious or severe drug treatment-emergent adverse events, is reassuring for demonstrating safety given they are both autoimmune diseases, said Werth, Ascherman and Miller. The side effects listed in Corbus' trial presentations, such as dizziness and fatigue in the scleroderma trial and dry-mouth in the cystic fibrosis trial, were not a cause for concern, added Werth and Ascherman. These are common in myositis, so it might be difficult to assess if they are drug-related or not, Miller said.

However, Miller noted there haven't been extensive in vitro or animal model studies, which is somewhat concerning for safety. He also said that in his experience, many agents used in dermatomyositis can help some disease aspects whilst making other worse, and so the trial should measure muscle strength, lung and cardiac function as well as assessing the skin rash. Oddis also said there have been some anecdotal reports that anti-TNF therapy might worsen muscle disease. Ascherman added he does not think focusing on the skin presents a safety risk, and he expects future trials will assess other disease aspects.

Part of the appeal of anabasum is that it is not a global immune-suppressing drug, Ascherman said, so it should have far fewer risks than therapies in use. There were no trial drop-outs due to adverse events, Werth said. W

Hannah Wilgar
Reporter, London

Prior to working for BioPharm Insight, Hannah investigated and wrote public engagement articles for the Wellcome Genome Campus, part of the Wellcome Trust. She has a BSc in Genetics from the University of Sheffield and an MSc in Developmental Cell Biology from the University of Sussex. After graduating, Hannah taught science and wrote and developed biomedical training materials for a broad range of clients, from Roche Pharmaceuticals to the World Health Organization. While Hannah's primary area of expertise are genetics, oncology and personalized medicine, she has experience writing about a broad range of topics including universal healthcare policy, stem cells and infectious disease.



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
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BeiGene's Phase III BGB-3111 in WM Has Unclear Efficacy Advantage Over Imbruvica

BeiGene's (NASDAQ:BGNE) BGB-3111 for Waldenström's macroglobulinemia (WM) will need longer patient follow-up in its Phase I study to ultimately determine if it is superior to AbbVie (NYSE:ABBV) and Johnson & Johnson's (NYSE:JNJ) Imbruvica (ibrutinib), experts said. Despite impressive early data, its prematurity led experts to say for now it appears comparable to the Imbruvica, which like BGB-3111 is a Bruton's tyrosine kinase (BTK) inhibitor.

Analysts said the Phase I (NCT02343120) data appeared to show superiority over Imbruvica for BGB-3111, which BeiGene describes as a more selective inhibitor than drug from AbbVie/ Johnson & Johnson (J&J).

BGB-3111 is in a global, 167-patient, head-to-head Phase III study (NCT03053440), but experts said at least a couple more years will be needed to fully assess whether it is superior. The trial's completion date is in June 2021. Rather than simply the current response rate figures, duration of response and toxicity -- both secondary endpoints in the Phase III study, along with the complete response (CR)/very good partial response (VGPR) rate primary endpoint -- will be the distinguishing factors, experts noted.

Meanwhile, experts said they do not expect surprises from an anticipated update at the 2017 ASH meeting. Phase I study data in B-cell malignancies was presented at the International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland, on 15 June. This news service reported 16 October that as of 3 October the Phase III study had enrolled 53 patients, and Parexel (NASDAQ:PRXL) is the CRO.

The 48-patient dataset for BGB-3111 is comparable in size to the 63-patient dataset that led to Imbruvica's WM label expansion in January 2015, a BeiGene spokesperson said, adding the response quality appears very favorable compared to what was observed with Imbruvica.

Efficacy advantage over Imbruvica unclear

Experts said they did not expect significant surprises in terms of efficacy or toxicity at ASH assuming Phase I data is updated from the ICML data given the short follow-up. However, they agreed that it will take another two or three years before a clear efficacy picture emerges due to WM's indolent nature, and duration of response will be a better way than response rates alone to differentiate BGB-3111 from Imbruvica.

The WM Phase I efficacy data presented at ICML looks comparable to Imbruvica, with the possibility that it could be better with longer-term follow-up, agreed an investigator, Dr Bertrand Coiffier, head, Department of Hematology, University Claude Bernard, Lyon, France, and Dr Stefan Barta, associate professor, Department of Hematology/ Oncology, Temple University Fox Chase Cancer Center, Philadelphia, Pennsylvania.

While the efficacy data for the moment appears comparable to Imbruvica, it does not have sufficient follow-up to get a firm sense of efficacy, said Dr Martin Hutchings, hematologist, National Hospital, Copenhagen, Denmark. The BeiGene study data from ICML showed an ORR of 90% among 42 efficacy-evaluable patients including a 40% VGPR rate, according to a 15 June press release.

While the BGB-3111 data looked comparable to Imbruvica or potentially better, an important factor to consider when comparing the two drugs is how heavily pretreated patients were, Barta said. Dr Marco Ladetto, head, Hematology

"While the BGB-3111 data looked comparable to Imbruvica or potentially better, an important factor to consider when comparing the two drugs is how heavily pretreated patients were"

Division, Saints Antonio Biagio and Cesare Arrigo Hospital, Alessandria, Italy, agreed, adding that newly diagnosed patients tend to show very high response rates. Imbruvica's label expansion was entirely for relapsed/refractory patients, while BeiGene's press release noted the Phase I study included treatment-naïve patients.

Patients in the BGB-3111 study received between 0-8 prior therapies, according to the ICML abstract (no. 59). WM patients in the study that led to Imbruvica's label expansion had received 1-9 prior therapies and achieved a 61.9% ORR, including 11.1% VGPRs and 50.8% PRs (Treon et al. N Engl J Med 2015; 372:1430-1440). Subsequent Phase III data at ASH 2015 from a Phase III study of Imbruvica in WM patients refractory to Roche's (VTX:ROG) Rituxan (rituximab) and with 1-8 prior therapies showed an 84% ORR.

Potential for toxicity advantage

BGB-3111 appears to show hints of a toxicity difference from Imbruvica, the investigator and Ladetto agreed. Indeed, added Ladetto and Coiffier, toxicity will be an important differentiating factor for the drug relative to Imbruvica, especially with respect to bleeding and cardiac events.

According to the BeiGene release, adverse events occurring in more than 10% of the 48 safety-evaluable patients included Grade 1-2 petechiae/ purpura/contusion (35%), upper respiratory tract infection (31%), constipation (25%), diarrhea (19%), epistaxis (19%), nausea (17%), cough (15%), anemia (15%), headache (15%), neutropenia (13%) and rash (13%). In addition, there were three Grade 1-2 cases of atrial fibrillation (AF) and one case of hemothorax, defined as serious hemorrhage at Grade 3 or higher.

There is clearly a lower rate of AF and serious bleeding than is seen with Imbruvica, Barta said, but it is unclear whether it represents a BTK inhibitor class effect or is an effect specific to Imbruvica. Given BGB-3111's greater specificity to BTK, the investigator expected fewer off-target drug effects. With respect to the cardiac toxicity, the patients who get WM tend to have a higher risk of cardiac events anyway, the investigator added.

Imbruvica's label warns that Grade 3 or higher bleeding events -- including fatal events – have occurred in up to 6% of patients treated with the drug. AF and atrial flutter have occurred in 6-9% of patients. W

Alaric DeArment
Reporter, New York

Alaric DeArment joined in March 2014 as a reporter primarily focusing on hematology oncology indications. In addition to analysis of clinical trials, regulatory issues, market uptake and pricing and reimbursement, he has broken news on material drug developments and provided coverage from major medical conferences including ASH, ASCO, EHA and others. In 2016, he moderated a panel discussion at the Clinical Trials Innovation Programme in Miami and was also awarded a fellowship with the Association of Health Care Journalism Comparative Effectiveness Research in Washington. Alaric previously covered prescription drugs as associate editor of Drug Store News, from August 2008 until January 2013. He has a bachelor degree in journalism from Ball State University. A native of Seattle, he also lived in China from September 2001 until September 2004.

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

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

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

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

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

INDICATION AND USAGE

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

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

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

Viread® 300 mg tablets
tenofovir disoproxil fumarate

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

...AT 8 YEARS: NO RESISTANCE WAS

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

- **In HBV-infected subjects with compensated liver disease:** Most common adverse reaction (all grades) was nausea (9%). Other treatment-emergent adverse reactions reported in >5% of patients treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash
- **In HBV-infected subjects with decompensated liver disease:** Most common adverse reactions (all grades) reported in ≥10% of patients treated with VIREAD were abdominal pain (22%), nausea (20%), insomnia (18%), pruritus (16%), vomiting (13%), dizziness (13%), and pyrexia (11%)

DRUG INTERACTIONS

- **Didanosine:** Coadministration increases didanosine concentrations. Use with caution and monitor for evidence of didanosine toxicity (e.g., pancreatitis, neuropathy). Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD and in patients weighing <60kg, the didanosine dose should be reduced to 200 mg once daily when coadministered with VIREAD

DETECTED AT YEAR 1 THROUGH YEAR 8

NO HBV RESISTANCE DEVELOPED YEAR 1 through YEAR 8

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

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS (cont'd)

- **HIV-1 protease inhibitors:** Coadministration decreases atazanavir concentrations and increases tenofovir concentrations; use atazanavir given with ritonavir. Coadministration of VIREAD with atazanavir and ritonavir, darunavir and ritonavir, or lopinavir/ritonavir increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity
- **Drugs affecting renal function:** Coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir

DOSAGE AND ADMINISTRATION

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

DOSAGE ADJUSTMENT FOR PATIENTS WITH ALTERED CREATININE CLEARANCE

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

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

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

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

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

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

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

300 mg tablets
Viread®
tenofovir disoproxil fumarate

VIREAD® (tenofovir disoproxil fumarate) tablets

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

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

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

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

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

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

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

Dosage Adjustment for Adult Patients with Altered Creatinine Clearance

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

a. Calculated using ideal (lean) body weight.

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

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

CONTRAINDICATIONS: None.

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

Bone Effects

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

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

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

Mineralization Defects: Cases of osteomalacia associated with proximal renal tubulopathy, manifested as bone pain or pain in extremities and which may contribute to fractures, have been reported in association with the use of VIREAD *(See Adverse Reactions)*. Arthralgias and muscle pain or weakness have also been reported in cases of proximal renal tubulopathy. Hypophosphatemia and

Brief Summary (Cont'd)

osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms while receiving products containing tenofovir DF *(See Warnings and Precautions).*

ADVERSE REACTIONS: Clinical Trials in Adult Subjects with Chronic Hepatitis B and Compensated Liver Disease: *Treatment-Emergent Adverse Reactions:* In controlled clinical trials in subjects with chronic hepatitis B (0102 and 0103), more subjects treated with VIREAD during the 48-week double-blind period experienced nausea: 9% with VIREAD versus 2% with adefovir dipivoxil. Other treatment-emergent adverse reactions reported in >5% of subjects treated with VIREAD included: abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash. No significant change in the tolerability profile was observed with continued treatment with VIREAD for up to 384 weeks.

Laboratory Abnormalities: in Studies 0102 and 0103 (0–48 Weeks) laboratory abnormalities (Grades 3–4) reported in ≥1% of subjects treated with Viread (n=426) and adefovir dipivoxil (n=215), respectively, were: any ≥Grade 3 laboratory abnormality (19%, 13%); creatine kinase (M: >990 U/L; F: >845 U/L) (2%, 3%); serum amylase (>175 U/L) (4%, 1%); glycosuria (≥3+) (3%, <1%); AST (M: >180 U/L; F: >170 U/L) (4%, 4%); and ALT (M: >215 U/L; F: >170 U/L) (10%, 6%). Laboratory abnormalities (Grades 3–4) were similar in subjects continuing VIREAD treatment for up to 384 weeks in these trials.

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

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

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

DRUG INTERACTIONS: Didanosine: Coadministration of VIREAD and didanosine should be undertaken with caution and patients receiving this combination should be monitored closely for didanosine-associated adverse reactions. Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. When administered with VIREAD, C_{max} and AUC of didanosine increased significantly. The mechanism of this interaction is unknown. Higher didanosine concentrations could potentiate didanosine-associated adverse reactions, including pancreatitis and neuropathy. Suppression of $CD4^+$ cell counts has been observed in patients receiving VIREAD with didanosine 400 mg daily. In patients weighing >60 kg, the didanosine dose should be reduced to 250 mg once daily when it is coadministered with VIREAD. In patients weighing <60 kg, the didanosine dose should be reduced to 200 mg once daily when it is coadministered with VIREAD. When coadministered, VIREAD and didanosine EC may be taken under fasted conditions or with a light meal (<400 kcal, 20% fat). For additional information on coadministration of VIREAD and didanosine, please refer to the full Prescribing Information for didanosine. **HIV-1 Protease Inhibitors:** VIREAD decreases the AUC and C_{min} of atazanavir. Viread should not be coadministered with atazanavir without ritonavir. Lopinavir/ritonavir, atazanavir coadministered with ritonavir, and darunavir coadministered with ritonavir have been shown to increase tenofovir concentrations. Tenofovir disoproxil fumarate is a substrate of P-glycoprotein (Pgp) and breast cancer resistance protein (BCRP) transporters. When tenofovir disoproxil fumarate is coadministered with an inhibitor of these transporters, an increase in absorption may be observed. Patients receiving VIREAD concomitantly with lopinavir/ritonavir, ritonavir-boosted atazanavir, or ritonavir-boosted darunavir should be monitored for VIREAD-associated adverse reactions. VIREAD should be discontinued in patients who develop VIREAD-associated adverse reactions. **Drugs Affecting Renal Function:** Since tenofovir is primarily eliminated by the kidneys, coadministration of VIREAD with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of tenofovir and/or increase the concentrations of other renally eliminated drugs. Some examples include, but are not limited to cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir, aminoglycosides (e.g., gentamicin), and high-dose or multiple NSAIDs *(See Warnings and Precautions).* In the treatment of chronic hepatitis B, VIREAD should not be administered in combination with adefovir dipivoxil.

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

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

CVH

Center for Viral Hepatitis

바이러스간염진료센터

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

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Get tested and be prepared

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Engage yourself to access health care

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Conference Alerts

North America

8th New York Health Forum
December 6, 2017 I New York, New York, USA

Website: www.newyorkhealthforum.net/
Contact: 201-402-1400

8th New York Health Forum, titled “Powerful transformers of Beauty Industry” will be a stimulating platform of the beauty industry. This forum will provide the setting for an informative discussion on the beauty insights, expertise and trends. Manufacturer, brand representatives, distributors and powerful social influencers will all come together to connect, learn and share.

59th American Society of Hematology (ASH) Annual Meeting & Exposition
December 9 – 12, 2017 I Atlanta, Georgia, USA

Website: www.hematology.org/Annual-Meeting/
Contact: 888-273-5704

The 59th ASH Annual Meeting and Exposition, in vibrant, fresh, and creative Atlanta, will provide an invaluable educational experience and the opportunity to review thousands of scientific abstracts highlighting updates in the hottest topics in hematology. Network with top minds in the field and a global community of more than 25,000 hematology professionals from every subspecialty.

IHI 29th Annual National Forum on Quality Improvement in Health Care - Institute for Healthcare Improvement
December 10 -13, 2017 I Orlando, Florida, USA

Website: www.ihi.org/education/Conferences/Forum2017/Pages/default.aspx
Contact: info@ihi.org

The IHI National Forum on Quality Improvement in Health Care will bring more than 5,000 brilliant minds in health care to Orlando, Florida, to find meaningful connections and gain actionable strategies for improving quality in health care. Enjoy more than 200 workshops, 9 keynotes and featured speakers, 10 new topic tracks, and endless networking opportunities, where attendees will gain ideas, insights, and tools needed to tackle a variety of health care challenges, from patient safety and behavioral health, to equity in care and population health management.

Orlando Derm Aesthetic & Clinical Conference
January 12-15, 2018 I Miami, Florida, USA

Website: www.orlandoderm.org
Contact: info@orlandoderm.org

Celebrating its 15th year, ODAC is now considered one of the largest and more prestigious conferences of the year. ODAC is a distinguished ACCME accredited educational event designed to meet the needs of medical and aesthetic dermatology practitioners in the 21st century. Founded in 2003, ODAC provides nearly 600 dermatologists, residents, nurse practitioners and physician assistants with important annual updates and fresh practical pearls in the field of medical, cosmetic and surgical dermatology in a highly interactive format.

International Meeting on Simulation in Healthcare (IMSH 2018)
Jannuary 13-17, 2018 I Los Angeles, CA, USA

Website: www.imsh2018.com
Contact: imsh@ssih.org

The International Meeting on Simulation in Healthcare (IMSH) is the world’s largest conference dedicated to healthcare simulation learning, research and scholarship, offering 250 sessions in various formats, from large plenary sessions to small, interactive immersive courses. It is also considered to be the educational and networking event for the simulation world. It will provide an experience in which one can completely immerse in situations that may result in lives being improved or even saved.

BIO CEO & Investor Conference
February 12 – 13, 2018 I New York, New York, USA

Website: www.bio.org/events/bio-ceo-investor-conference/about
Contact: register@bio.org

The BIO CEO & Investor Conference is one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies. Each year the BIO CEO & Investor Conference provides a neutral forum where institutional investors, industry analysts, and senior biotechnology executives have the opportunity to shape the future investment landscape of the biotechnology industry. The conference features issue-oriented plenary sessions, educational sessions focused on hot therapeutic areas and key business issues, company presentations, one-on-one meetings, and networking opportunities.

International Beauty Show (IBS) New York 2018
March 4-6, 2018 | New York, NY, USA

Website: www.ibsnewyork.com
Contact: 877-398-6938

IBS New York is the longest-running professionals-only event in beauty and draws 65,200 serious beauty pros. Attendees come to IBS New York to learn new techniques and trends from industry icons, refine skills, and stock up on salon and professional needs. Filled with top-notch education, excitement and inspiration, IBS New York aims to elevate any career to new heights.

HIMSS18 Conference & Exhibition
March 5-9, 2018 | Las Vegas, NV, USA

Website: www.himssconference.org/about/general-info/himss18-save-date
Contact: himss@compusystems.com

The 2018 HIMSS Annual Conference & Exhibition brings together 40,000+ healths IT professionals, clinicians, executives and vendors from around the world. Exceptional education, world-class speakers, cutting-edge health IT products and powerful networking are hallmarks of this industry-leading conference. More than 300 education programs feature keynotes, thought leader sessions, and roundtable discussions and workshops, plus a full day of pre-conference symposia.

18th Annual Minimally Invasive Surgery Symposium (MISS)
March 6 – 9, 2018 I Las Vegas, Nevada, USA

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

The Annual Minimally Invasive Surgery Symposium (MISS) is the premier meeting of thought leaders in minimally invasive surgery for metabolic/bariatric disorders, hernia, foregut, and diseases of the colon. The conference is led by Executive Director Philip R. Schauer, MD, Cleveland Clinic, along with a faculty of internationally known advanced laparoscopic surgeons and bariatric specialists. In addition to general didactic sessions, the conference will offer optional hands-on workshops in laparoscopic suturing and endoscopic interventions.

2018 Annual CUGH Global Health Conference: Health Disparities: A Time for Action

March 16 – 18, 2018 | New York, New York, USA

Website: www.cugh.org/events/2018-annual-cugh-global-health-conference

Contact: info@cugh.org

The Annual CUGH Global Health Conference brings together health professionals, clinicians from around the world to discuss global health disparities. This year's conference will include educational keynotes, discussions and workshops that deal with themes of global health law, human rights, communicable diseases, and social determinants of health. Held in New York, this conference will be a great foundation for many experts to gain information and insights.

International Pharmaceutical Conference & Expo

March 21-23, 2018 | Philadelphia, Pennsylvania, USA

Website: www.ipharmaconference.com

Contact: info@ipharmaconference.com

The International Pharmaceutical Conference and Expo aims in Bridging Pharma Academia with the Industry. iPharma Congress includes nearly every permutation of knowledge, innovation, technology and networking; and has an objective of creating an international forum for academicians, practitioners and business professionals to discuss the soundest issues related to Pharma, Medical and Health Care. iPharma 2018 offers unparalleled business opportunities and access to new markets in Pharma and Health Care industry.

GHIC 2018: Global Health & Innovation Conference

April 14 – 15, 2018 | New Haven, Connecticut, USA

Website: www.uniteforsight.org/conference/

Contact: ufs@uniteforsight.org

The Global Health & Innovation Conference (GHIC) is the world's leading and largest global health conference as well as the largest social entrepreneurship conference, with 2,200 professionals and students from all 50 states and more than 55 countries. This must-attend, thought-leading conference convenes leaders, change makers, and participants from all sectors of global health, international development, and social entrepreneurship.

Europe

7th World Congress on Clinical Pharmacy and Pharmacy Practice

December 7 – 9, 2017 | Rome, Italy

Website: www.hospital-clinicalpharmacy.alliedacademies.com/registration

Contact: clinicalpharmacy@alliedconferences.org

Clinical Pharmacy 2017 is a global annual event to discuss and learn more about Clinical Pharmacy and Pharmacy Practice. The conference aims to bring together leading academic scientists, researchers, and research scholars to exchange and share their experiences and research results on all aspects of Clinical Pharmacy. It also provides a premier interdisciplinary platform for researchers, practitioners, and educators to present and discuss the most recent innovations, trends, and concerns as well as practical challenges encountered and solutions adopted in the fields of Clinical Pharmacy.

Europe

Social Media in the Pharmaceutical Industry

January 22 – 23, 2018 | London, United Kingdom

Website: www.smi-online.co.uk/pharmaceuticals/uk/social-media-in-the-pharmaceutical-industry

Contact: events@smi-online.co.uk

Social media is the perfect channel for pharmaceutical companies to educate, market, listen and connect with customers, patients and physicians. How the pharmaceutical industry utilize social media is particularly complex as regulators such as the FDA have not yet written the rules about how pharmaceuticals can engage with potential customers and patients. Join SMi's 10th Annual Social Media in the Pharmaceutical Industry Conference to learn the best way a company can benefit from social media. Hear from industry experts on how to leverage social media platforms to develop a robust digital strategy and discuss the latest challenges and techniques in the field of 'social pharma'.

IMCAS World Congress 2018

February 1-3, 2018 | Paris, France

Website: www.imcas.com/en

Contact: contact@imcas.com

IMCAS marks two decades of being at the forefront of multi-specialty conferences dedicated to aesthetic science. A record of 8000 delegates, from dermatology, plastic surgery, and related professions, will be seizing this exceptional opportunity to explore the hottest topics related to the medical aesthetic field. Join IMCAS as they analyze innovative technical procedures, discover cutting edge products and devices, and explore up-to-the-minute marketing and management approaches. In addition to hundreds of the world's experts and innovators sharing their insights, IMCAS Annual World Congress will also host 250 international exhibiting companies.

Asia

8th Emirates Otorhinolaryngology Audiology and Communication Disorders Congress

January 17 – 19 | Dubai, United Arab Emirates

Website: www.emiratesrhinologyandotology.ae/registration.php

Contact: eroc@mci-group.com

The 2018 congress will provide a platform to share experiences and discuss breakthroughs in various specialist fields, a necessary prerequisite to successfully assess and expand practices. The congress includes keynote lectures, round table discussions, instructional courses, video sessions and abstract sessions covering a wide array of topics and introduces latest technologies and techniques in the field. There will also be several live surgical pre-congress workshops on state of art anatomical specimens.

Cell-Weizmann Institute of Science Symposium: Next Gen Immunology

February 11 – 14, 2018 | Rehovot, Israel

Website: www.cell-symposia.com/next-gen-immunology-2018

Contact: k.russell@elsevier.com

The Cell-Weizmann Institute of Science Symposium: Next Gen Immunology brings together leading scientists who think about immunity in different contexts and have in common the perspective of an immune system that is an integral part of the meta-organism. The Cell Symposium aims to stimulate exciting discussions, to foster new interdisciplinary collaborations, and to promote cross-pollination of ideas that can help us to move on to the next generation of immunology research.

NEW YORK
Health Forum

Connection to Improve the Human Health

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. Former CDC Chief Launches $225 Million Global Health Initiative

Tom Frieden, former director of the Centers for Disease Control and Prevention, is starting a new initiative to tackle some of global health's thorniest issues: cardiovascular disease and epidemics. The $225 million initiative, called Resolve, announced September 12th in New York, aims to reduce the global burden of heart disease and stroke, the world's leading causes of death. It also will focus on helping low- and middle-income countries fight infectious disease epidemics by strengthening laboratory networks so emerging threats are identified promptly, and training disease detectives to track and investigate disease outbreaks, including those that circulate in animals and jump to humans.

https://www.washingtonpost.com/news/to-your-health/wp/2017/09/12/former-cdc-chief-launches-new-global-health-initiative/?utm_term=.5b631effed9c

2. Amgen Is Taking On a $3 Billion Cancer Drug. But Will It Cut Costs for Patients?

The Food and Drug Administration (FDA) continued its potentially record-breaking pace of new drug approvals, green lighting the first-ever "biosimilar" copycat of a cancer drug. The new treatment, U.S. biotech Amgen's Mvasi, has a big target in its crosshairs: Avastin, a versatile cancer therapy from drug maker Roche that rings in nearly $7 billion in global annual sales, including $3 billion in America. Avastin is, like many cancer drugs, extremely expensive. And that was one of the motivations for introducing a clinically-proven competitor like Mvasi (also known as bevacizumab-awwb) to the market. It's unclear how Amgen and partner Allergan will price Mvasi.

http://fortune.com/2017/09/15/amgen-roche-avastin-biosimilar-price/

3. Pfizer Alleges J&J Thwarted Competition to Remicade, in Legal Test of Biotech-Drug Copies

Pfizer Inc. filed suit against Johnson & Johnson alleging J&J thwarted competition to its arthritis therapy Remicade, in a case that could shatter arrangements pharmaceutical companies make with insurers to protect their franchise products and threaten efforts to bring down the costs of the most expensive drugs. The lawsuit is the first antitrust action to surface amid the emergence of biosimilars, which are copies of popular biotech drugs, after years of litigation over patents and timing of launches. Pfizer's Inflectra is the biosimilar of Remicade. Inflectra was developed by Celltrion Inc. of South Korea. Pfizer has the rights to sell the drug in the U.S. Scott Hemphill, a professor of antitrust law at New York University School of Law, said Pfizer will need more than J&J's contracts with health insurers and hospitals to prevail.

https://www.wsj.com/articles/pfizer-files-antitrust-lawsuit-alleging-j-j-thwarted-use-of-biosimilar-rival-to-remicade-1505913080

4. F.D.A. Approves Second Gene-Altering Treatment for Cancer

The Food and Drug Administration approved the second in a radically new class of treatments that genetically reboot a patient's own immune cells to kill cancer. The new therapy, Yescarta, made by Kite Pharma, was approved for adults with aggressive forms of a blood cancer, non-Hodgkin's lymphoma, who have undergone two regimens of chemotherapy that failed. Before it was approved and named Yescarta, Kite's treatment was known by other names: axi-cel, axicabtagene ciloleucel, or KTE-C19. The company also hopes that Yescarta will eventually be approved for earlier stages of lymphoma, rather than being limited to patients with advanced disease who have been debilitated by multiple types of chemotherapy that did not work, said Dr. David D. Chang, Kite's chief medical officer and executive vice president for research and development.

https://nyti.ms/2zjEtsf

5. How Would CVS and Aetna Fit Together?

CVS Health Corp. is reportedly in talks to buy Aetna Inc. for more than $66 billion. Aetna became the biggest customer of CVS's PBM unit under a 12-year deal struck in 2010 between the two companies. A combination with CVS would let Aetna push further into the health-care-delivery space, as well as integrating the health coverage it provides with all of CVS's pharmacy-focused services and clinics. The real growth opportunity for CVS is in the pharmacy-benefits business. Revenue and profits for CVS's pharmacy-services operations, comprising mainly the PBM business, have been growing at a faster clip than the company's retail business.

https://www.wsj.com/articles/behind-the-potential-cvs-aetna-deal-1509129970

6. U.S. Hospitals Wrestle With Shortages of Drug Supplies Made in Puerto Rico

Hospital pharmacists across the country are racing to find vital drugs after Hurricane Maria halted production at the factory in Puerto Rico. In addition to creating a humanitarian crisis on the island, the storm knocked out production at the Puerto Rican factories that make vital drugs, medical devices and medical supplies that are used around the world. In a recent interview, Dr. Gottlieb said he was worried that if conditions don't improve, more shortages — of both drugs and medical devices — might follow by early next year. Pharmaceutical products made in Puerto Rico account for nearly 10 percent of all drugs consumed by Americans, and about 80 firms make medical products there.

https://nyti.ms/2zyhiup

7. Courts Reverse Johnson's Baby Powder Judgments for Nearly $500 Million

In back-to-back victories for Johnson & Johnson, the courts have reversed two judgments against the consumer products giant totaling nearly $500 million. The money had been awarded to women who said that they developed ovarian cancer after using the company's talcum powder for decades. In her ruling, Judge Maren E. Nelson granted the company's motion for a new trial. The judge cited the "insufficiency of the evidence" and said that the damages awarded were excessive. The potential dangers of talcum powder are a subject of debate within the medical field, in part because the evidence varies. National health organizations are cautious about drawing any firm conclusions.

https://nyti.ms/2zwL3f5

8. Samsung Reports Operating Profit, Extends Collaboration With Merck KGaA

Samsung reported a KRW 20.5 billion operating profit ($18.2 million), on KRW 127.5 billion ($113.4 million) in revenues for the quarter as its first plant runs at full pace and its second facility continues to draw new contracts, the company said. Its net loss, however, widened to 31.7 billion won ($28.2 million) from 9.6 billion won in the same quarter a year ago, primarily because of "call option valuation losses on its subsidiary company," it reported. Under the reiterated deal first struck in 2014, Merck will provide process development and some technical training for its Mobius single-use technology which Samsung BioLogics uses.

http://www.fiercepharma.com/manufacturing/samsung-reports-operating-profit-extends-collaboration-merck-kgaa

9. Novartis Picks Centerview To Explore Sale of Dermatology Unit: Sources

Novartis is working with Centerview to review options for its dermatology business, including a possible sale, as it trims non-core assets. The mandate, which comes after Novartis' $3.9 billion purchase of French radiopharmaceutical firm Advanced Accelerator Applications (AAA), is likely to pave the way for a sale of the group's dermatology drugs, which could fetch up to $ 1.5 billion.

http://www.reuters.com/article/us-novartis-dermatology-m-a/novartis-picks-centerview-to-explore-sale-of-dermatology-unit-sources-idUSKBN1D22PA

10. As Amazon Entry Into Pharma Looms, CEOs See Plenty of Room for Change in Distribution

Online retailing giant Amazon has yet to publicly disclose any plans to get into drug sales, but the mere speculation has pharma CEOs thinking, and speaking, about how it could entirely remake their world. Goldman Sachs analysts have put out a 30-page report outlining several options for Amazon in pharmaceuticals, writing that a partnership with an existing PBM is a "path of least resistance." One Bernstein analyst said he believes the company will have its pharmacy business set up by 2019 and ready to compete for business in 2020, while a Leerink analyst has said "it's a matter of when, not if" that Amazon will move into drugs.

http://www.fiercepharma.com/pharma/drug-execs-see-amazon-s-potential-to-shake-up-distribution

11. New York City and State Battle Over Health-Care Funding

New York City and state officials clashed over funding for the city's public-health system amid looming federal cuts. Officials with NYC Health + Hospitals, which runs the city's 11 public hospitals, disclosed in a letter to the state that they have enough cash on hand to operate for only about two weeks because they haven't received $380 million from the state that they expected to be paid out earlier this year. Gov. Andrew Cuomo's administration said that the city is exaggerating its case, as state officials prepare for a loss of about $2.6 billion in federal funding over several years to hospitals statewide and look to reorganize state dollars. The city's public-health system already is in dire financial straits.

https://www.wsj.com/articles/new-york-city-and-state-battle-over-health-care-funding-1506985681unit-sources-idUSKBN1D22PA

12. CVS Will Offer Next-Day Delivery of Prescription Drugs

CVS Health said that it would begin offering next-day delivery of prescription drugs and same-day service in some big cities next year, reflecting the company's worries about potential competition from Amazon and as its retail sales declined in the third quarter of this year, a dip that the company said occurred because of the three major hurricanes that forced many stores to close. A CVS spokeswoman, Erin Pensa, said the company's delivery partner has not been announced, but that they have been able to use their scale to negotiate low-cost, affordable options for all CVS Pharmacy customers.

https://nyti.ms/2j4HWYS

13. Korean Cosmetics Maker Buys U.S. Firm for US $50 Million

Cosmax Co., a South Korean cosmetics maker, has acquired a U.S. company for US$50 million to expand its foothold in the North American market. The Korean company said it recently signed a contract to buy all of NuWorld Beauty. Cosmax is the country's leading original design manufacturer (ODM), making products ranging from skincare to haircare and facial masks. Cosmax said it will strengthen its production and marketing capabilities, research and development following the acquisition, with an aim to post 200 billion won ($178 million) in revenue in the U.S. market alone by next year, and 3 trillion won worldwide by 2020.

http://english.yonhapnews.co.kr/news/2017/11/13/0200000000AEN20171113008200320.html

14. Trump Chooses Alex Azar for Health and Human Services Secretary

President Trump nominated a pharmaceutical executive to be the next secretary of the Health and Human Services Department. The nominee, Alex M. Azar II, served as a deputy at the department under former President George W. Bush. From 2011 to 2017, he was the head of the pharmaceutical company Eli Lilly's United States Division where he worked for a decade. Mr. Trump said that Mr. Azar will play a key role for better health care and lower drug prices but the choice immediately raised new doubts among some lawmakers and industry observers about the president's stated commitment to rein in drug companies.

https://nyti.ms/2hwZgoN

15. Bill Gates Makes $100 Million Personal Investment to Fight Alzheimer's

Billionaire Microsoft co-founder Bill Gates is to invest $50 million in the Dementia Discovery Fund. The investment – a personal one and not part of Gates' philanthropic Bill & Melinda Gates Foundation – will be followed by another $50 million in start-up ventures working in Alzheimer's research, Gates said Despite decades of scientific research, there is no treatment that can slow the progression of Alzheimer's. Current drugs can do no more than ease some of the symptoms. Gates said, however, that with focused and well-funded innovation, he's optimistic that treatments can be found, even if they might be more than a decade away.

http://www.reuters.com/article/us-health-dementia-gates/bill-gates-makes-100-million-personal-investment-to-fight-alzheimers-idUSKBN1DD0S3

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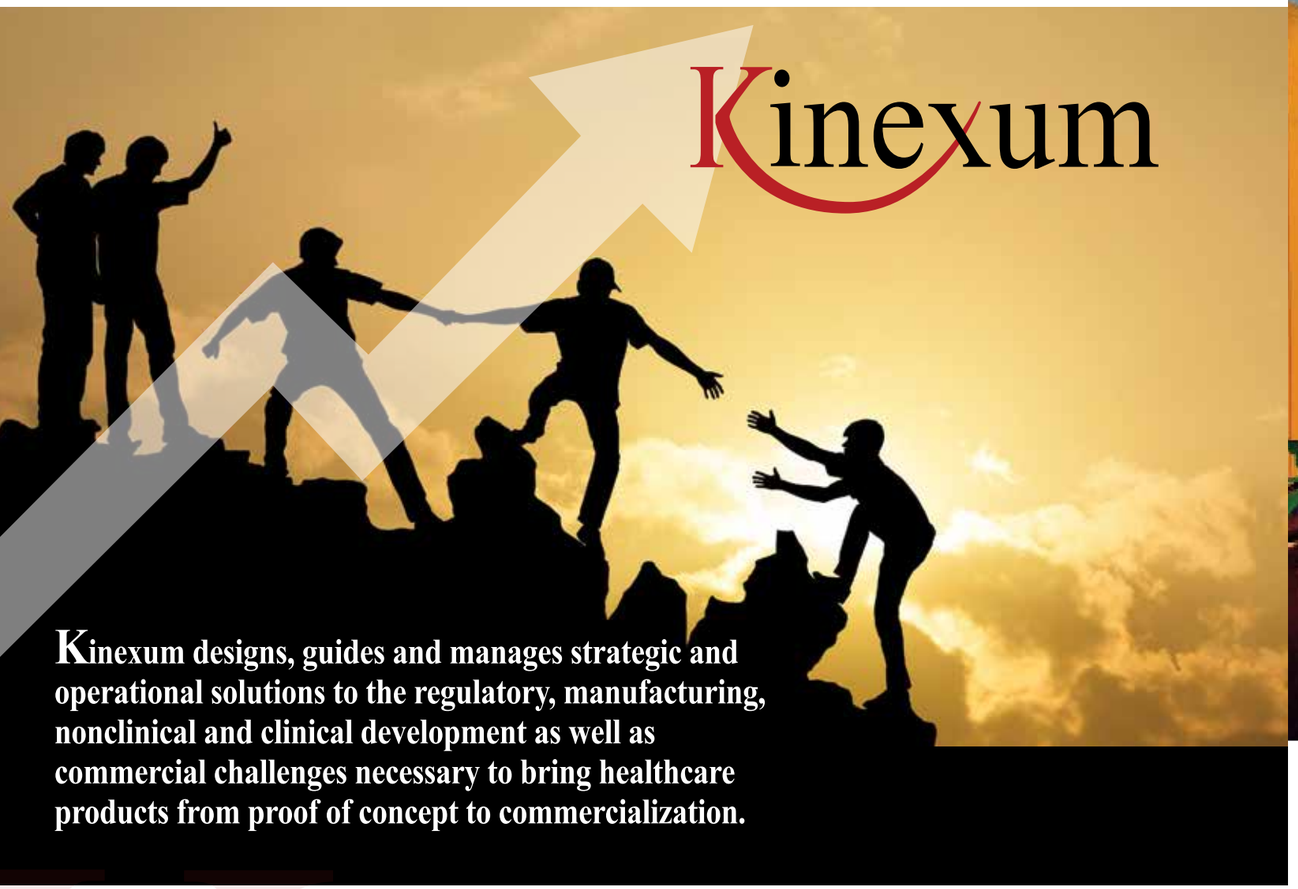

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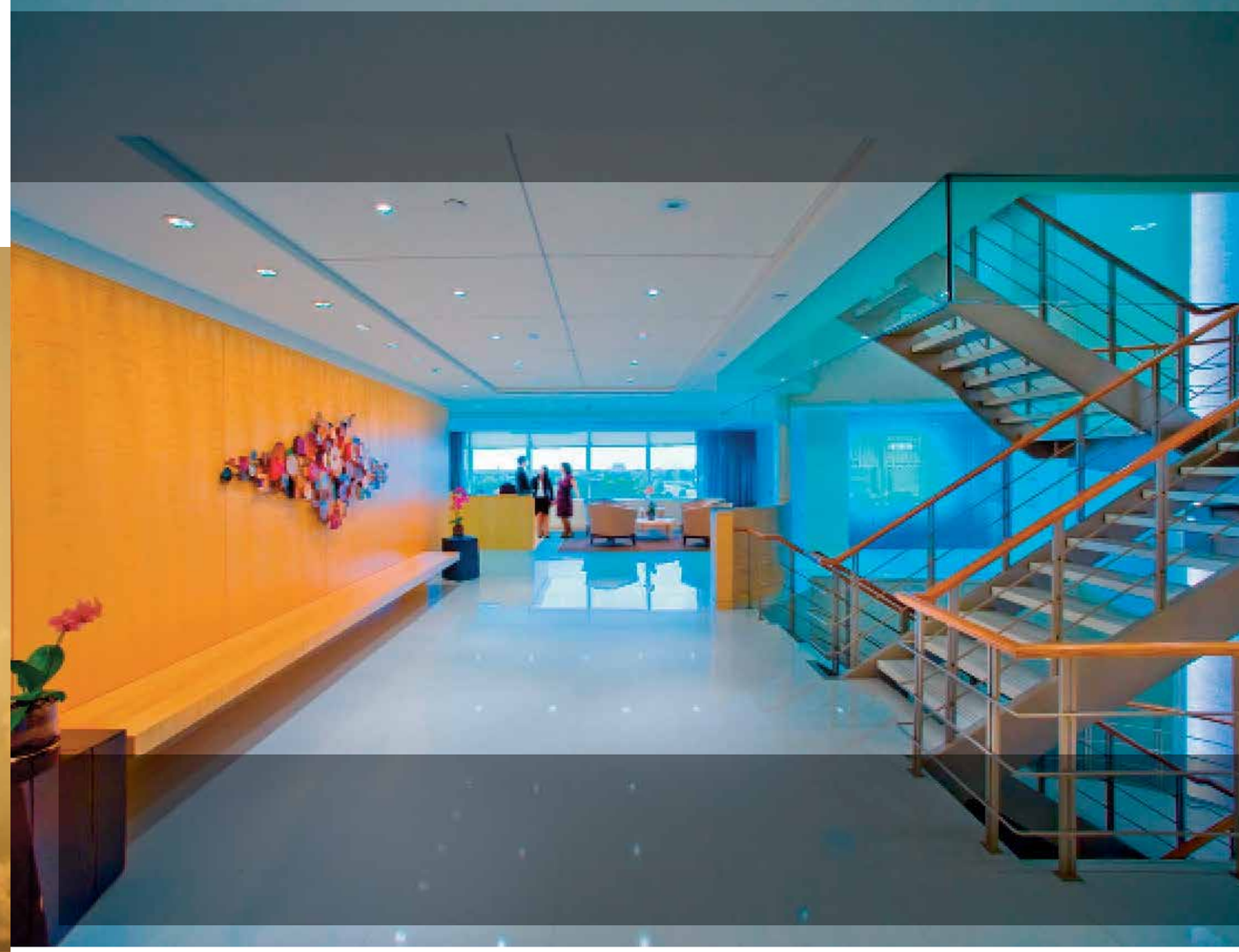

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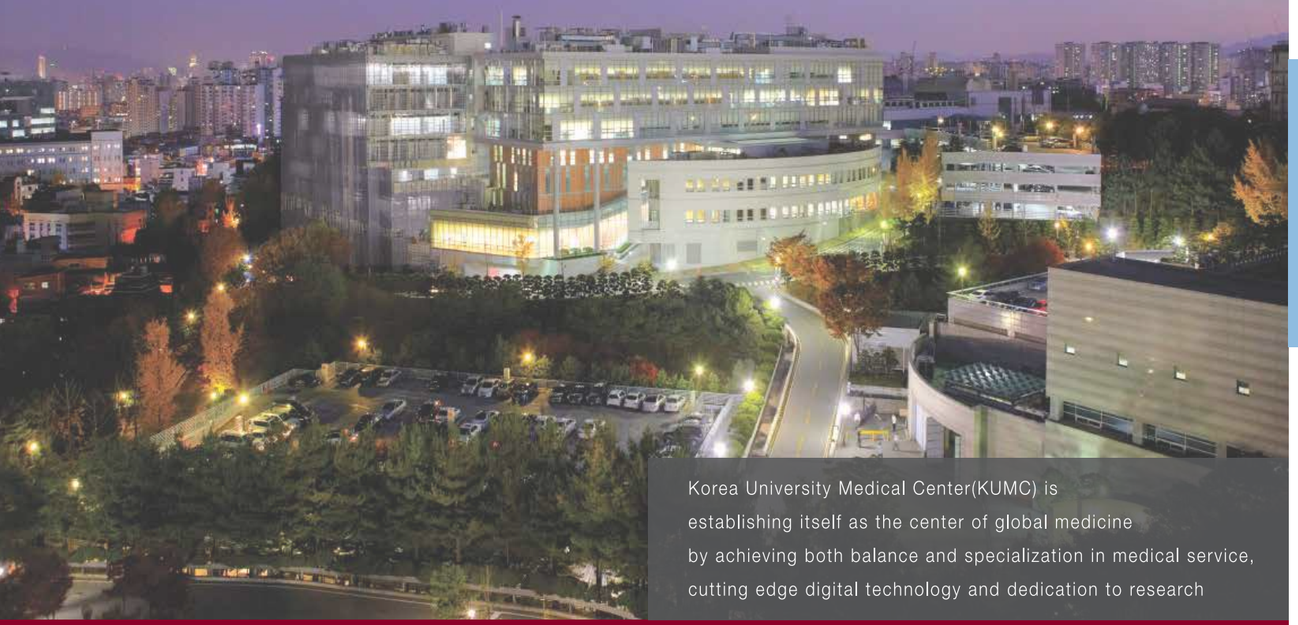

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30th ANNIVERSARY

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