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WAMJ

World Asian Medical Journal

Inspirational Asian Healthcare Leader

EUL-SIK YOON

Chairman and Board of Director,
Korean Society of Plastic and Reconstructive Surgeons

SPECIAL REPORT I
Enzychem Lifesciences' Innovative Drug Gives Cancer Patients Hope

SPECIAL REPORT II
Latest Update for Surgical Treatment of Lymphedema

BIOPHARMA REPORT I
Innovative Value-Based Price Programs Back in the Spotlight

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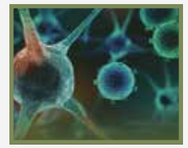

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From the Publisher

If you are a fan of Korean dramas, you most likely have heard of the Netflix series Squid Game, which has attracted audiences around the world. Cultural content created in Korea, also known as 'K-drama' or 'K-pop', is gaining significant attention worldwide. This 'K-' phenomenon is not limited within the culture arena and extends itself into industry, technology and science. In the field of medicine, K-medicine or Medical Korea is also a well recognized term, and, in this edition, we have featured one of the eminent leaders of K-medicine.

For this edition of our World Asian Medical Journal, we had an opportunity to spotlight Dr. Eul-Sik Yoon, Chairman and Board of Directors for the Korean Society of Plastic and Reconstructive Surgeons and also the president of Korea University Medical Center Anam Hospital. Dr. Eul-Sik Yoon is undoubtedly one of the most highly respected physicians and an accomplished expert in reconstructive surgery. While preparing his edition, I was impressed by his humility, thoughtfulness and perspective on patient care and quality of life. Also, he is a true champion and supporter of innovation, which is significant for exploring breakthrough technologies and treatment in medicine. I hope our WAMJ readers find great delight and enlightenment in reading his story and philosophy in the medical field.

In our special report, we feature an article about a Korean biotech company's journey of new drug development. Enzychem Lifesciences, a clinical stage biopharmaceutical company, recently completed a U.S. Phase 2 clinical trial of its lead candidate EC-18 in chemoradiation-induced oral mucositis (CRIOM). CRIOM is a painful and debilitating side effect of chemoradiation in which patients experience severe mouth ulcerations that significantly impact everyday activities. The pain from severe ulcerations leads to malnutrition and dehydration in patients. In a study, patients showed a substantial reduction in the duration and incidence of severe oral mucositis compared to placebo arm. Such stories of Korean companies' success in clinical developments signal a bright future for Korean and Asian therapeutic companies in the U.S.

Various writers and experts impart their knowledge and insights as co-authors in this edition of WAMJ. I sincerely hope that our readers will find these exciting selections of articles to be helpful and inspiring.

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

From the Editor-in-Chief

In our 25th issue, WAMJ is pleased to continue our proud tradition of highlighting a medical leader with impeccable credentials and a dazzling resume.

Eul-Sik Yoon, M.D., Ph.D. is both Chairman and Board of Director of the Korean Society of Plastic and Reconstructive Surgeons (KSPR) and the President of Korea University Anam Hospital (KUAH), Seoul. After completing his education and training in plastic surgery and three years in the Korean Public Health Service, Dr. Yoon pursued an academic career including stints as a Visiting Associate Professor and researcher at the University of California, Irvine, where he investigated tissue engineering and regenerative medicine. He has also spent time as the Professor and Director of the Department of Plastic & Reconstructive Surgery, KUAH. In 2014, Dr. Yoon became the Director of the Scientific Program Committee of the Korean Society for Aesthetic Surgeons. Two years later, he was named Vice President of Planning & Coordination at the Korea University Medical Center (KUMC). Also, the KSPR recognized him with its Best Academic Award. The following year, Dr. Yoon became the Acting President of KUAH while simultaneously serving as KSPR's Director of the Training & Education Committee. As the leader of the KSPR, Dr. Yoon established a new mission and vision for the organization, alongside strategies to achieve them.

Throughout his career, Dr. Yoon has always studied and explored innovation in his field. In 2012, using robot-assisted technology, he introduced scarless breast reconstructive surgery to Korea. Currently, he is developing navigation surgery, combining cycling probe technology with real-time imaging, allowing surgeons to precisely track instrument positions and apply them to preoperative imaging data. Among his many innovations, Dr. Yoon helped to pioneer lymphovenous anastomosis (LVA), which connects 0.3 mm diameter (thinner than human hair) lymphatics to small veins, helping those with limb lymphedema and tissue fibrosis. He also developed the vascularized lymph node transfer (VLNT), which transplants healthy lymphatic tissue. Dr. Yoon has published work on a diverse range of topics such as autologous breast reconstruction, lymphovenous bypass for extremity lymphedema, and robotic surgery. As he says himself, Dr. Yoon "helps patients restore their lives through reconstructive surgery." His story is an inspiration for us all.

In this issue, we also offer pieces exploring the latest surgical treatments of lymphedema and Enzychem Lifesciences' innovative drug for oral mucositis in cancer patients. Moreover, you can find biopharma reports on value-based price programs after deals involving Pfizer and Takeda, Merck/Ridgeback's COVID-19 antiviral licensing deal and its impact on upper middle-income countries.

We hope you enjoy this provocative and exciting issue.

Joseph P. McMenamin, MD, JD, FCLM
Editor in Chief
EVP of W Medical Strategy Group

WAMJ Recap of the Last Issue

COVER STORY
Jaewon Ryu, M.D., J.D., President and Chief Executive Officer, Geisinger

Dr. Jaewon Ryu is the president and CEO of Geisinger, a regional healthcare provider serving more than 1 million people with more than half a million members enrolled in Geisinger health plan. At Geisinger, he has largely contributed to putting forward initiatives–such as primary care redesign, Geisinger at Home, which brings healthcare services to patients in their home, and Geisinger 65 Forward, senior-focused, concierge healthcare center–to provide people with easier access to top-notch clinical services closer to the home and communities. Prior to his tenure at Geisinger, he took on a variety of leadership roles in health systems including the University of Illinois Hospital & Health Sciences Systems, Centers for Medicare and Medicaid Services, and the Department of Veterans Affairs as a White House Fellow. To learn more about Dr. Ryu, please read issue 24 of WAMJ.

BIOPHARMACEUTICAL REPORT I
Pepaxto's US Uptake to Stall in Multiple Myeloma Until FDA Provides Advice to Address Death Risk

Blood cancer oncologists will put a hold on the use of Oncopeptides' Pepaxto until FDA tables any mitigation strategy to reduce death risk of the treatment. Since Pepaxto's patient population has an unmet medical need with limited treatment options, Pepaxto might still be used in patients who have early progression from Blenrep and Xpovio. Recent data that show there are patients who may benefit from either Pepaxto or immunomodulatory imide drug Polymast are in an ongoing analysis–which is crucial in identifying patients who are best suited for Pepaxto. To learn more about Pepaxto's future, please read issue 24 of WAMJ.

BIOPHARMACEUTICAL REPORT II
Medicare's National Coverage Determination Could Boost Chances of Limited Aduhelm Coverage in Alzheimer's Disease Despite Current Backlash

By opening a National Coverage Determination (NCD) on Biogen's Aduhelm, Medicare signaled a willingness to provide some level of coverage in the US without outright denying its use. In an ideal scenario, Medicare would cover Aduhelm at the price of manufacturing, at approximately USD 2,500-5,000, plus a modest profit for Biogen. However, the enormous restrictions on Medicare are likely to keep out such an outcome. In addition, the NCD process can only determine if and to what extent a drug should be covered, and it does not deal with the amount Medicare will reimburse for a specific drug or device. To learn more about Medicare's National Coverage Determination, please read issue 24 of WAMJ.

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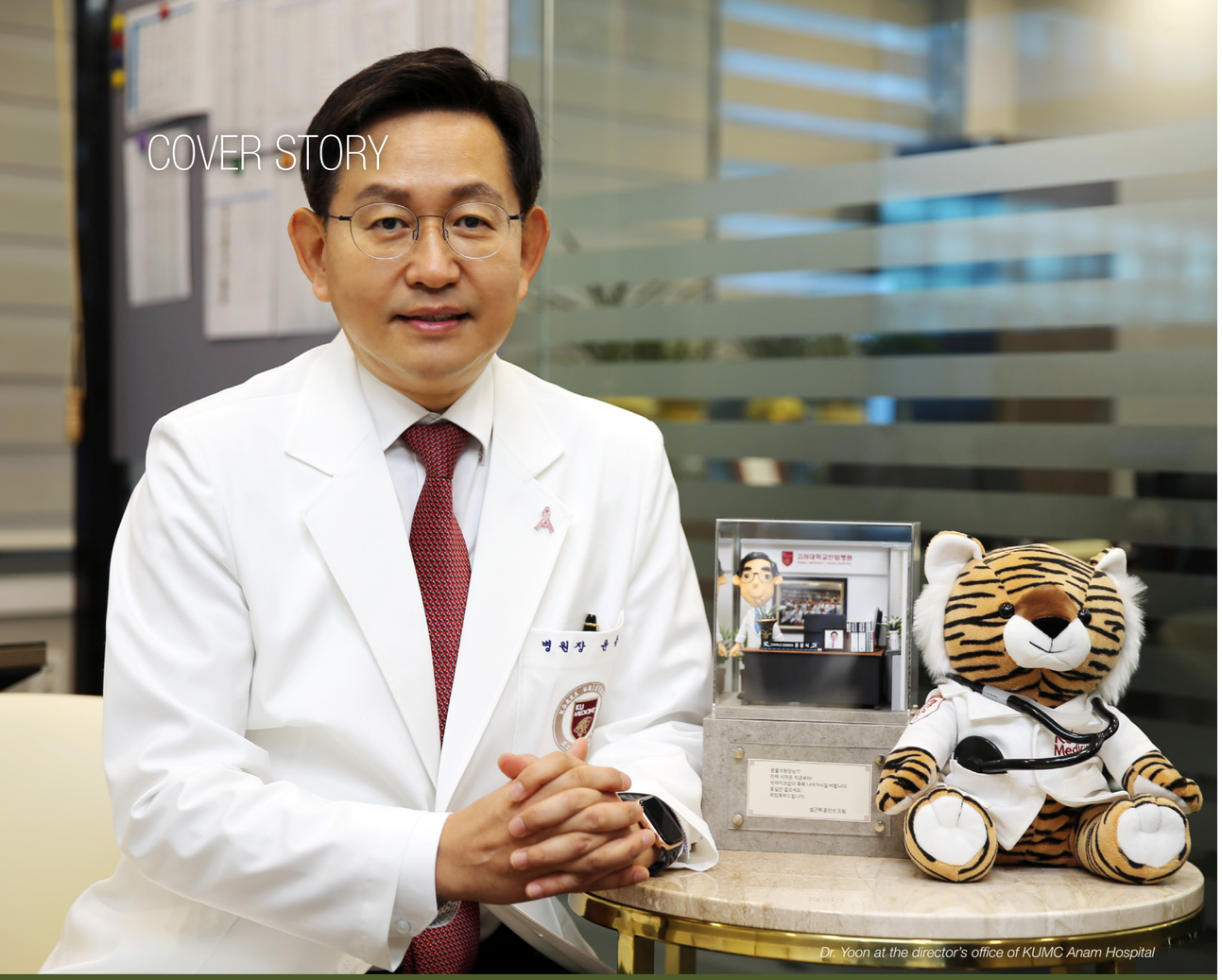


Dr. Yoon at the director's office of KUMC Anam Hospital

Inspirational Asian Healthcare Leader

Eul-Sik Yoon, M.D., Ph.D.

Chairman and Board of Director,
Korean Society of Plastic and Reconstructive Surgeons
President, Korea University Anam Hospital

COVER STORY

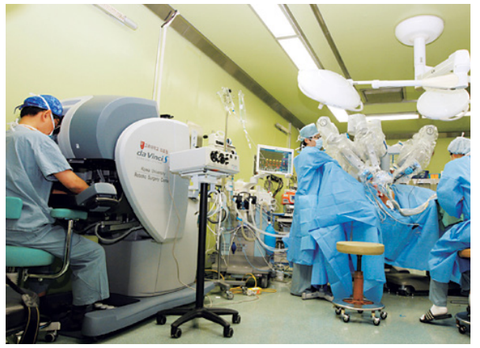
1. As a renowned plastic surgeon and respected member of the medical community, please share with our readers what motivated you to become a physician and go to medical school. What event in your career or training drove your decision to choose a career in plastic surgery?

- As a child, I never dreamed about becoming a physician. Without any family members or close relatives in the medical field, I had very little attachment or exposure to this career path. When I was in high school, I was just an ordinary student who studied hard but had a hard time deciding which career path was right for me. At the time I applied for college, going to medical school was a popular educational pathway for many students. Thus, as I outlined my career and future, I talked to my family members, who suggested that I become a physician. These conversations instilled in me values that continue to inspire and encourage me to pursue this profession.

After entering medical school, I joined a volunteer group called Korea Medical Student Association (KMSC), a joint club founded in 1957 that connects all medical schools in Seoul. Through this organization, participants engage in various volunteer opportunities during weekends and summer holidays. Such fulfilling experiences enabled me to think about my professional identity. More specifically, working with KMSC, I learned about the important expectations and responsibilities of a doctor.

During my studies, Professor Se-min Baek's lecture on reconstructive surgery pushed an ordinary medical student like myself to dream of becoming a plastic surgeon. Dr. Baek graduated from medical school in Korea and furthered his studies in the United States to become a board-certified surgeon in both general surgery and plastic surgery. By his mid-30s, Dr. Baek was the Chief of Plastic Surgery at Mount Sinai hospital in New York. To this day, he is a legendary plastic surgeon who developed cutting-edge concepts in microsurgery and craniomaxillofacial surgery.

I remember being dumbfounded when I first learned about microsurgery reconstruction and maxillofacial surgery from Professor Baek. My stubborn preconceptions about plastic surgery were completely broken as I learned that plastic surgery can not only enhance one's appearance but also restore function. Upon this realization, I set my heart on becoming a plastic surgeon who helps patients restore and improve their quality of life through reconstructive surgery.



Dr. Yoon performing the robot-assisted breast reconstructive surgery

2. As the first surgeon in Korea to introduce scarless breast reconstructive surgery using robot-assisted technology in 2012, please explain to us why robotic surgery is an exciting field category in the field of healthcare and medical technology. Can you share with our readers about specific robot-assisted technology and what drew you to this work? What is the biggest challenge you have faced as an early adopter of this technology?

- Robotic surgery, a surgical innovation that is far more advanced than conventional endoscopic surgery, allows surgeons to perform a variety of procedures using a mechanical hand attached to a robot. This hand mirrors that of the physician, eliminating any adverse effects caused by the surgeon's hand tremor. At only 5 to 8 millimeters thick, it can easily navigate narrow cavities and perform delicate tasks. The robot can also provide surgeons with high-resolution, enlarged images, offering a crucial tool and advantage during a procedure.

In the past, surgical robots with multiple arms had to create multiple incisions during a surgery. However,

Commemorative photo after performing Korea's first single port robotic reconstructive surgery

recent advances in robotic surgery have given full range of motion to the robotic arm, allowing three instruments to be maneuvered simultaneously through a single port. These advances in robotic surgery have introduced more precision and safety to operations.

I started performing robotic surgery in 2012. In those days, there were only a few plastic surgeons who were able to perform robotic surgery. As a result, there was very little precedent for me to follow. Thus, I had to learn everything from scratch and on my own. I observed robotic surgeries performed in other fields such as general surgery and urology to learn how to operate surgical robots. By compiling and synthesizing this research and experience, I eventually pioneered a new surgical method.

From the perspective of a plastic surgeon, the most desirable way to perform reproductive breast surgery is to produce optimal results with minimal incisions. Conventional methods cannot avoid complications, leaving a large scar ranging from as little as 10cm to as long as 30cm, along with seroma at the surgical site. However, with robotic surgery, surgeons can perform sophisticated resections that drastically reduce the scar length to around 5cm, minimizing damage to nerves and muscles and decreasing the recovery period. According to a statistical analysis conducted at our hospital, Korea University Anam Hospital, postoperative complications of robotic surgery were significantly minimal compared to those of conventional surgery. Thus, robotic surgery is the latest technology that can minimize pain and risk while offering optimal results when treating a patient.

Robotic surgery is a technology that also fulfills the needs of surgeons who have to perform delicate and complex procedures in the field of digital healthcare and telemedicine. In 2001, Dr. Michel Gagner of the Mount Sinai Medical Center in New York successfully performed robotic cholecystectomy on a 68-year-old woman living in Strasbourg, France, located more than 3,700 miles (6,000 km) away from him. This telesurgery took the same amount of time as the traditional gallbladder operation which lasts 54 minutes. Since then, laparoscopic surgery, as well as ablative procedures for the treatment of cardiac arrhythmia, has been successfully performed in the United States and Italy due to these newfound capabilities. Today, the technology continues to advance, with development in areas such as surgical assistance, transportation of medical supplies, and imaging analysis.

Telemedicine has become an especially salient topic of discussion worldwide due to the COVID-19 pandemic. Although regulatory issues and social consensus prevent the widespread implementation of the system, robotic surgery is expected to play an important role in providing better treatment for patients in remote areas such as military units, prisons, and hazardous areas.

Dr. Yoon with Dr. Evans while studying abroad as an exchange professor at UC Irvine

3. In your role as the chairman of the Korean Society of Plastic and Reconstructive surgeons, can you share with us some background about the organization and its mission and goals? What are your responsibilities, principles, and challenges as you are leading the professional body for board-certified plastic surgeons in Korea?

- The Korean Society of Plastic and Reconstructive Surgeons (KSPRS) is an academic organization that represents 2,600 plastic surgeons in the Republic of Korea and is celebrating its 56th anniversary this year. The capabilities of reconstructive surgery have allowed our group to both save lives and dramatically alter the course of patient's life. Through the capabilities of reconstructive surgery, our group has not only strived to save patients but also try to alter the course of patient's life.

When I first became the Chairman of KSPRS, I initiated a project, named "The Future Dream Project," with the aim of creating a globally recognized society that its members can be proud of. Nearly halfway into my term, the project is on track to achieve its objectives. Despite the difficulties of the ongoing COVID-19 crisis, the dedication and commitment of our members have made it possible for the project to stay the course.

My first goal was to lay the foundation for our organization and instill dignity in our members. As the new Chair of KSPRS, I established four strategies to achieve the mission and vision of our society. Specifically, I believe our society's mission to improve the health of humankind through the development of plastic and reconstructive surgery shows our willingness to become a leading academic society not only in Korea but also around the world. We undertake such a daunting task by remembering and taking pride in our history, captured by the "History Wall" on the back wall of our office. Moreover, we are taking measures to utilize online portals and social network platforms such as Instagram and Facebook to encourage global connection and communication amongst our members.

> "Robotic surgery is expected to play an important role in providing better treatment for patients in remote areas"

The next important agenda as the Chairman was to push our official journal "Archives of Plastic Surgery (APS)" to meet the international standards. Since KSPRS is fundamentally an academic organization, the quality of academic journals is directly tied to the dignity of the society. APS is published as an international journal six times a year, but it has not yet been indexed in Science Citation Index (SCI). To improve the quality of journals, we assigned a new global publishing company and appointed world-class scholars to produce and edit our work. In addition, our journal has been upgraded to an official journal in five Asian countries, including Indonesia and Hong Kong, maximizing journal exposure on social media and liaising with other academic societies overseas. We expect to be indexed within the next two years.

Third, we worked to improve the quality of residency training by reorganizing the educational experience for students. For example, we have implemented an international online platform to improve the current online educational portals. All qualifying examinations are now taken as computer-based test (CBT). In addition, the existing educational content has been modified to better reflect clinical situations that are applicable to real-life settings.

Finally, we are trying to protect the rights and interests of our patients and members by further improving the medical environment. We are currently working on establishing a diagnosis and operation coding system for plastic surgery. We also have a task force to develop new medical technologies. Of course, our organization has also continued to focus on combatting the shortcomings of the current National Health Insurance system in Korea.

Through these endeavors, I hope to make KSPRS the best academic society that ultimately earns the trust of the public through communication and collaboration.

After a lecture as an invited speaker in the 2019 ASBPRS (Asian Society for Breast Plastic and Reconstructive Surgery) at Chang Gung Memorial Hospital

4. As the president of Korea University Anam Hospital, do you serve patients who travel to Korea from other parts of the world? How do they learn about your specialized services? What are some benefits that international patients can receive by getting medical services in Korea?

- Foreign patients can receive the same treatment as domestic patients. Korea University Medical Center (KUMC) opened an International Health Care Center (IHCC) in 2009. This center provides high-quality medical services to foreign patients in a comfortable atmosphere with physicians, nurses, and administrative coordinators that are fluent in various foreign languages. In fact, KUMC has obtained the fifth certification from the Joint Commission International (JCI) and has been recognized for establishing the world's best system in patient safety and quality of medical services.

For the convenience of our foreign patients, we have made our website available in four languages. On this platform, patients can conveniently make their appointments online. On your first visit, a primary physician dedicated to foreign patients will assess your needs, and, when necessary, make referrals to a specific department. The IHCC coordinator will take care of all the necessary processes for treatment, from the moment you arrive in Korea to the time you receive treatment, including preparing documents for expected medical expenses and visa issuance.

5. As an eminent opinion leader in plastic surgery, what are some major changes or new trends in plastic surgery? Also, how do you forecast the field of plastic surgery will change in the next five years?

- The field of plastic and reconstructive surgery has always introduced new technologies and led changes. The COVID-19 crisis is demanding more adaptation and transformation in the field, particularly following the recent shift to a digital environment. PRS KOREA 2021, an international academic congress that I hosted last month as a chairman of the board, also tried to suggest a new direction in our field under the theme of "The Next Normal, A New Journey".

To adapt to rapidly changing demands, our department has recently focused on introducing cutting-edge technologies and exploring medical frontiers. Robotic surgery is a good example of this developed technology, and now, more and more hospitals continue to adopt it. In addition, navigation surgery, which combines the latest cycling probe technology and real-time imaging, is rapidly gaining popularity.

Dr. Yoon with members of the department of plastic and reconstructive surgery in KUMC Anam Hospital

The surgical treatment of lymphedema is a new field of reconstructive surgery that is also gaining attention. With the remarkable development of microsurgical techniques, various physiological surgical methods are being introduced. An example of these methods is lymphovenous anastomosis (LVA), which connects 0.3mm diameter (which is thinner than hair) lymphatics to small veins to create detours. Another example is vascularized lymph node transfer (VLNT), which transplants healthy lymphatic tissue. Moreover, prophylactic lymphovenous anastomosis, which is only performed in some countries such as the United States and Italy, is also gaining traction.

Transgender medicine and surgery also continues to progress in Korea in tandem with the LGBTQIA+ rights movement that has been growing in the country. To raise public awareness about the lack of Gender Affirming Clinics in Korea, KUMC took a step to launch the very first Gender Clinic in South Korea. We also aim to establish a research institute that will support and develop related fields. As a Physician and Chairman of the KUMC, we will always stand in the forefront to protect the rights of all patients needing treatment regardless of their gender, race, religion, and/or disability.

Vascularized composite allotransplantation (VCA) is an emerging field in transplant medicine, in which our fellow plastic surgeons and I are working continuously. In Korea, there were two cases of hand transplantation, and all of them have shown good results. There are still regulatory issues, but some hospitals are already preparing to undergo a facial transplantation.

3D printing, artificial intelligence (AI), and regenerative medical technology are expected to be the next new trend in plastic surgery. I think medical treatment that relies heavily on the physician alone is nearly over. From now on, it is a matter of how fast new technologies are introduced and how it will be implemented in the field of medicine. Many 3D printing and regenerative treatment techniques are already being adopted in the clinical setting, and AI is also expected to appear within two to three years.

6. Can you share your final remarks with our readers from around the world? Also, do you have any advice for physicians and healthcare professionals who wish to take part in the medical field and innovation?

- Medicine is changing rapidly with recent advances in technology and research. Treatment protocols are updated continuously and pose a challenge for textbook publishers who must keep up with all the new treatment modalities and techniques that are being introduced. What I want to emphasize to our readers, especially those in the healthcare professionals, is: In line with these changes, don't stick only to the existing techniques; always be innovative with goodwill. Your constant self-reflection and creativity will be a driving force behind your future success. W

> "Your constant self-reflection and creativity will be a driving force behind your future success"

Eul-Sik Yoon, M.D., Ph.D.

Chairman and Board of Directors, Korean Society of Plastic and Reconstructive Surgeons
President, Korea University Anam Hospital

Eul-Sik Yoon, M.D., Ph.D., is a distinguished Plastic and Reconstructive Surgeon with over 35 years of experience. Dr. Yoon is Chairman of the Korean Society of Plastic and Reconstructive Surgeons. He also serves as the President of Korea University Anam Hospital. As an influential and active figure in his field, Dr. Yoon is a widely celebrated member of the Korean Medical Association, Korean Society of Association of Microsurgery, Korean Society of Aesthetic Plastic Surgery, Plastic Surgery Research Council, International Plastic Reconstructive Surgery, and American Society of Plastic Surgery. Dr. Yoon has served as a prominent leader and innovator in his field. He has published various scientific papers and reviews. Dr. Yoon's commitment to progress and research in cosmetic surgery earned him the 2016 Best Academic Award at the 74th Congress of Korean Society of Plastic and Reconstructive Surgeons. He completed his medical education, receiving his M.D. degree at the Korea University College of Medicine. He also served as a Visiting Associate Professor and Researcher in the University of California, Irvine. Today, Dr. Yoon Eul-Sik continues to be a leader in South Korean and international cosmetic surgery.

Enzychem Lifesciences' Innovative Drug Gives Cancer Patients Hope as New Therapy for Oral Mucositis

Enzychem Lifesciences recently announced positive results for its lead compound EC-18 in chemoradiation-induced oral mucositis (CRIOM) for head and neck cancer patients, an area of significant unmet medical need for patients undergoing cancer therapy. There are currently no FDA-approved therapies for CRIOM for head and neck cancer patients. All the currently available therapies are palliative care that only reduce symptoms and pain.

ENZYCHEM LIFESCIENCES

Chemoradiation-induced oral mucositis (CRIOM) is an acute inflammation of the oral mucosa following systemic chemotherapy and radiation therapy. It can cause several problems including pain, malnutrition as a result of an inability to eat and increased risk of infection due to open sores in the mucosa. The symptoms have a significant effect on the patient's quality of life-including pain, nutritional problems as a result of inability to eat, and an increased risk of infection due to open sores in the mouth. More importantly, it can also lead to sub-optimal cancer treatment by limiting the doses and duration of the chemotherapy and radiation.

Ki Young Sohn, Chairman, Enzychem Lifesciences

In 2020, the annual global incidence of Head and Neck Cancer (HNC) was estimated to be around 930,000 and the number is expected to increase. In the United States, the annual incidence of HNC is approximately 66,000 and about 75% or 50,000 would receive CRT as the cancer treatment. Among those who receive CRT, over 90% or 45,000 of the patients would develop some degree of oral mucositis (OM).

Enzychem's EC-18 successfully met both its primary and secondary endpoints in terms of efficacy and safety in the Phase 2 U.S. study. Patients on EC-18 reported a reduction in the duration of severe oral mucositis (SOM) through a short-term follow-up period from 13.5 days to 0 day (100% reduction) in comparison to the placebo arm. EC-18 also reduced the incidence of SOM through completion of radiation by 37.1% in comparison to the placebo arm (65% vs. 40.9%). The incidence of SOM through a short-term follow-up period was reduced by 35.1% in comparison to the placebo arm (70% vs. 45.5%).

No serious adverse events (SAE) were reported between placebo and EC-18 groups and none of the SAEs were related to EC-18. Safety was also comparable across arms with all adverse events (AEs) attributable to expected chemoradiation-related toxicity. One-year long-term follow-up for tumor outcomes is ongoing.

SPECIAL REPORT I

What the Experts Say About EC-18

Christina Henson

According to Dr. Christina Henson, Residency Program Director for Radiation Oncology at Oklahoma University, and principal investigator for Enzychem's Phase 2 CRIOM study, "Oral mucositis is a common and debilitating side effect experienced by so many of our patients, with no promising therapies up to this point. That we've proven clinical efficacy of EC-18, especially one derived from nature, is incredibly exciting and holds the potential to decrease opioid pain medication use and also to avoid treatment breaks and delays that can adversely impact cancer prognosis."

Daniel Clayburgh

"The results of the Phase II trial of EC-18 suggest this medication is safe and effective at reducing severe oral mucositis in patients undergoing chemoradiation for head and neck cancer. This

is an incredibly difficult treatment for patients, and EC-18 is a promising new therapy that may provide significant benefits to patients. I look forward to seeing the results of the upcoming Phase 3 trial of EC-18," added Dr. Daniel Clayburgh, Associate Professor of Otolaryngology at Oregon Health & Science University.

"Severe CRIOM affects almost 75% of patients being treated with concomitant chemoradiation for head and neck cancers with symptoms that are so severe that they challenge a patients' ability to tolerate optimal treatment," said Dr. Stephen Sonis, Professor, Harvard School of Dental Medicine and Key Advisor for the U.S. Phase 2 CRIOM Study. "Despite its frequency and burden it places on patients and their caregivers, there is no approved pharmaceutical intervention. The results observed with EC-18 support its continued development and offer encouragement as an effective CRIOM therapy."

Stephen Sonis

There is no doubt that new therapies for oral mucositis are urgently needed. Enzychem Lifesciences' positive Phase 2 study data for its lead candidate EC-18, a small molecule oral immunomodulator could be a positive addition for patients with severe oral mucositis (SOM) in head and neck cancer patients undergoing concurrent chemoradiation. Experts also agree, and we look forward to hearing updates from the company as the clinical program progresses. W

Headquartered in Seoul, South Korea, Enzychem Lifesciences (KOSDAQ:183490) is developing novel small molecule therapeutics to target fundamental pathways in inflammation, patients with significant unmet needs in oncology, inflammatory, and severe respiratory diseases. Enzychem lead candidate, EC-18, has successfully completed US FDA phase 2 clinical testing in cancer patients. In response to the Korean government pledge for a Vaccine Hub, Enzychem has formed a consortium with several domestic companies in Korea to manufacture vaccines against COVID-19. The company plans to leverage its expertise in lipid chemistry and manufacturing to establish itself as a regional producer of lipid-based formulations for improved delivery of nucleic acids and other biologicals and drugs. For more information, please visit www.enzychem.com.

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Jane's Journey: The Rare Disease Landscape From a Mother's Perspective

When Jane discovered that her 15-month-old son had the autoimmune disorder Histiocytosis, suddenly she was forced to navigate the complex and unfamiliar terrain of what she called "rare disease land."

She began her journey with questions. The answers were not straightforward. Jane needed compassionate experts to translate the complex clinical language and guide her family through the steps. Fortunately, she connected with doctors who didn't define her son by his disease, as well as with advocates who provided resources for understanding and navigating the clinical landscape.

Over time, Jane became part of the support network, and now serves as a board member of the Histiocytosis Association, helping others who seek guidance for their own journeys.

At Atlantic Research Group, we have seen great things happen when passionate people like Jane combine their strengths to make things better. Together with our Sponsors and Partners around the world, we create smart, feasible studies that account for the challenges faced by people with rare diseases.

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Latest Update for Surgical Treatment of Lymphedema

1. Introduction

Lymphedema is a chronic, progressive condition caused by insufficient lymphatic drainage and the subsequent stasis of protein-rich interstitial fluid. A common symptom of the disease is the swelling of upper or lower extremities. In the early stages of the disease, patients feel heaviness or tightness of the affected extremity without swelling. As the disease progresses, significant swelling, inflammation, and fibrosis develop. Patients with lymphedema experience pain, discomfort, recurrent cellulitis, and overall decreased quality of life.

Peter C. Neligan, Jaume Masia, Neil B.Piller, Lymphedema complete medical and surgical management

Example of arm lymphedema

2. Causes

Lymphedema is classified into primary and secondary lymphedema. Primary lymphedema is caused by an intrinsic problem with the lymphatic system: dysplasia or agenesis of lymphatic vessels or lymph nodes. One of the leading causes of the secondary lymphedema is oncologic surgery with treatment including lymph node dissection, radiation, and chemotherapy. It is known that approximately 20% of breast cancer survivors experience lymphedema, and up to 50% of gynecologic cancer patients experience lymphedema after oncologic surgery. Overall, about 250 milion people worldwide suffer from lymphedema.

3. Diagnosis

Initial diagnosis of lymphedema can be performed by clinical examination. Lymphedema usually starts with unilateral extremity, following breast cancer or gynecologic cancer surgeries. It deteriorates in the evening after activity and gets better in the morning. Classical diagnosis was performed with lymphoscintigraphy, which has long been considered the gold standard in the diagnosis and evaluation of lymphedema. Radiolabeled tracer is injected subdermally at distal extremity. The tracer is then taken up by the lymphatic vessels and travels proximally along them to reach the lymph nodes. The transport is delayed or impaired in lymphedema patients. Although lymphoscintigraphy is helpful in the diagnosis of lymphedema, it has several drawbacks including painful injections and poor resolution.

ICG lymphography: normal arm

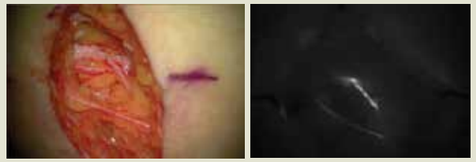
Recently, indocyanine green lymphography (ICG) has become a popular imaging technique for the diagnosis of lymphedema. ICG is injected subdermally in the distal extremity. The ICG binds to albumin and is taken up by lymphatic vessels. The lymphatic flow can be visualized in real time. This examination can be performed in an outpatient clinic room. The ICG lymphography is useful to evaluate stages of lymphedema and decide whether or not physiologic lymphatic surgery can be performed. New imaging techniques, including magnetic resonance angiography and ultrasound, have also been used.

Arm with lymphedema

4. Treatment

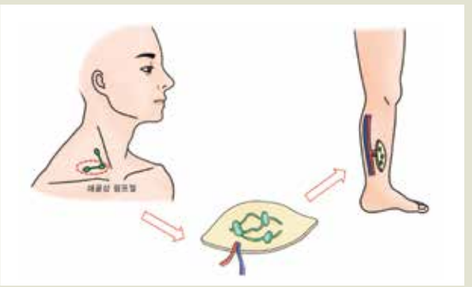
(1) Lymphatico-Venular Anastomosis, LVA
Llymphovenous Bypass LVB)
Because of recent advances in microsurgical technique and instruments, lymphatic vessels with a diameter of 0.3-0.8 mm can be anastomosed to venules or veins to create lympho-venous bypass. This surgery can restore physiologic lymphatic flow from lymphatic vessel to vein when the proximal part of the lymphatic flow is obstructed. Proximal obstruction of lymphatic flow is commonly developed in lymphedema following oncologic surgery.

Because LVA targets a superficial lymphatic vessel which is located in the superficial fat layer, the surgery is minimally invasive and causes little postoperative pain. The surgery can be performed with skin incisions less than 2-3 cm in length and can be performed by either local or general anesthesia. However, not all patients can be a candidate for this surgery since lymphatic vessels undergo degenerative change as the lymphedema progresses. An ICG lymphographic exam is a useful tool to evaluate whether or not lymphatic vessels are suitable for LVA surgery.



Lymphatic vessel anastomosed to side wall of vein. ICG lymphography shows flow from lymphatic vessel to vein after LVA.

(2) Vascularized Lymph Node Transfer, VLNT
Free tissue transfer of lymph nodes has been the most recent development in the treatment of lymphedema. Currently, there are two hypotheses commonly accepted as the principle of VLNT. First, the “pump theory” suggests that the VLN flap absorbs the lymph fluid like a pump and drains it into the vein through natural lymphaticovenular connections inside the flap. The other hypothesis, known as the “lymphangiogenesis theory”, suggests that the transferred lymph node has a high capacity for spontaneous regeneration and improves the drainage by forming a bridge to the lymphatic pathway. Recently, VLNT has gained consensus as a promising operative technique for lymphedema based on excellent outcomes, especially in patients in advanced stages.



Schematic illustration of VLNT
Lymph node flap is transplanted into the arms or legs with lymphedema in the form of a free flap.

> Korea's medical system is well-equipped with a cooperative system, displaying the capacity to treat lymphedema

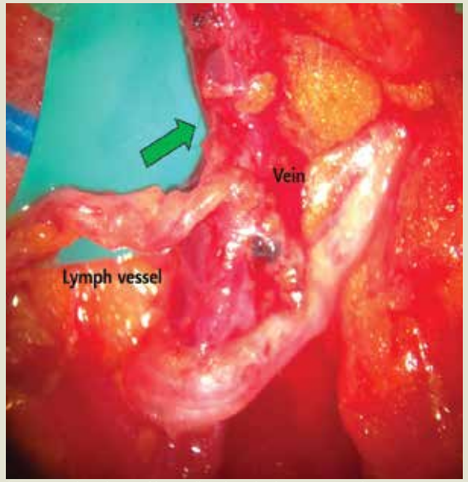
There are various donor sites for VLNT, such as groin, submental and supraclavicular areas. Just like the donor sites, the recipient sites also have great variability. In treating upper extremity lymphedema, recipient sites have included the wrist, elbow, and axillary regions. For lower extremity lymphedema, the ankle and groin are the most common recipient sites.While the literature for VLNT is still in its early stages, results have been favorable. Also, in many cases, it can be performed with simultaneous LVAs for better outcomes.

Pre- and postoperative clinical image of patient underwent VLNT
At 15 months, the postoperative circumference diameter of left leg was significantly decreased.

(3) Debulking Procedure

(i) Liposuction
In late-stage cases, adipose tissue depositions and sometimes fibrosis are the prominent manifestations of the disease. In this case, liposuction can be used to remove hypertrophic tissues and lessen edematous symptoms. It is a useful treatment option in conjunction with controlled compression therapy.

(ii) Excisional Procedures
Invasive reductive procedures such as the Charles operation can be used as a sole treatment option for patients with terminal refractory lymphedema. This method has not been used in a while because of extensive scarring and substantial morbidity including significant blood loss or infection. Recently, however, radical reduction of lymphedema with preservation of perforators (RRPP) and modified Charles procedure, composed of a negative dressing and delayed skin graft, provide optimal outcomes for patients with advanced extremity lymphedema.



Intraoperative photo of immediate lymphatic reconstruction

(4) Preventive Procedure: Immediate Lymphatic Reconstruction
Lymphedema is a refractory disease that is difficult to reverse once it occurs. Currently, immediate lymphatic reconstruction is drawing attention as a novel preventive technique. After reverse mapping with ICG lymphography, surgeons connect lymphatic vessels of upper/lower extremity to the surrounding vein. It can improve the drainage of lymphatic fluid and reduce the rate of lymphedema.

5. Basic Research in the Field of Lymphedema

Although the aforementioned surgical procedures exist to treat lymphedema, the disease is still considered to be a rare disease. In Korea, significant research has been conducted to develop animal models and research on stem cells and growth factors are also in progress to develop novel therapies. The ongoing research is showing the desired result and aiming to be approved for clinical trials soon.

6. Strengths of Korea

Lymphedema requires a systematic approach from diagnosis to surgery to rehabilitation due to the nature of the disease. Korea's medical system is well-equipped with a cooperative system, displaying the capacity to treat lymphedema. Also, Korean plastic surgeons are well known for their academic achievements. Korean plastic surgeons have considerable clinical experience in microsurgery, consistently showing highly satisfactory outcomes. W

Jae-Ho Chung, M.D., Ph.D.
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Executive Assistant Secretary, Korean Society of Plastic and Reconstructive Surgeons
Assistant Secretary at Surgery Committee, The Korean Society of Lymphedema
Jae-Ho Chung, M.D., Ph.D., is a physician, surgeon, assistant professor, and a researcher. He is now serving as an assistant secretary of surgery committee in the Korean society of Lymphedema. He is an expert in microsurgery and performs reconstructive surgeries such as head and neck or breast reconstruction. Since he was resident, he has been interested in the field of lymphedema and visited the world's leading center in lymphatic surgery such as the University of Chicago and the University of Tokyo. Based on these experiences, he performs various types of lymphatic surgery such as lymphovenous anastomosis, vascularized lymph node transfer, and prophylactic surgery. In addition, he has conducted animal experiments using stem cells and growth factor to find novel therapeutics for lymphedema, which is still considered a refractory disease. His research is supported as a national task. Also, in recognition of his research capabilities, he was awarded as an excellent basic researcher by the Korean Society of Plastic and Reconstructive Surgeons in 2021. Currently, he is recognized by the society as a young researcher with a promising future, publishing about 40 papers, including 23 SCI papers.

Kyong-Je Woo, M.D., Ph.D.
Assistant Professor and Chief of Department of Plastic and Reconstructive Surgery,
Mokdong Hospital, Ewha Womans University
Kyong-Je Woo, M.D., Ph.D., is an assitant professor and chief of Department of Platic and Reconstructive Surgery, Mokdong Hospital, Ewha Womans University. He graduated from Seoul National University College of Medicine, and finished training and fellowship of plastic surgery at Samsung Medical Center, Seoul. His specialty is microsurgical lymphatic surgery, and breast reconstruction following mastectomy for breast cancer. He established the surgical team at the lymphedema center at Mokdong Hospital and he has been actively performing surgical treatment of lymphedema of upper and lower extremities. The lymphedema center in Mokdong Hospital is one of the biggest lymphedema centers in Korea.

Biopharma Report

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INNOVATIVE VALUE-BASED PRICE PROGRAMS BACK IN THE SPOTLIGHT

BIOPHARMACEUTICAL REPORT II

UPPER MIDDLE-INCOME COUNTRIES LEFT OUT BY NEW MERCK/RIDGEBACK COVID-19 ANTIVIRAL LICENSING DEAL

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Innovative Value-Based Price Programs Back in the Spotlight

Value-based plans are emerging as particularly attractive coverage options for therapies that become available after an FDA accelerated approval. The lower amount of evidence that underscores such an approval provides an impetus to attempt alternative payment models, said two experts.

There is a real appetite to explore in the US warranties that are often seen in Europe, as demonstrated with a recently announced one with **Pfizer's** (NYSE:PFE) Xalkori (crizotinib) for non-small cell lung cancer patients with a certain mutation. Another buzzy value-based arrangement was **Takeda Pharmaceuticals'** (TYO:4502) risk-sharing agreement with Point32Health regarding ALK-targeted therapy Alunbrig (brigatinib) for NSCLC patients. The engagement of third parties to overcome any data-related challenges, and use of easy data points gleaned from pharmacy claims, is making the implementation of such plans possible.

Over the last decade, value-based reimbursement models have garnered a ton of interest at conferences and among academics. But challenges in building a data infrastructure that can identify outcome metrics and logistics to dispense payments have largely relegated these models to an anecdotal status. While these hurdles remain, experts have noted a few differences with the recent examples in value-based plans. These have included therapies that target patient subsets with certain cancers or orphan disorders, where long-term efficacy data is often scant when the drug is launched.

Larger healthcare plans with existing data capabilities do have an advantage, but even relatively smaller ones with an intent to invest in such plans are making headway in implementing value-based arrangements, experts noted.

Accelerated approval presents ideal stimulus

Value-based programs can be valuable regarding the immature data that supports an accelerated approval because they can build an evidence bridge for product use, said Jack Mycka, CEO, Medical Marketing Economics, an Indegene company, Montclair, New Jersey. Coupled with the high cost of rare disease products or oncology drugs, payers are concerned about whether there is enough data to demonstrate long-term efficacy in the case of accelerated approvals. This is especially relevant when it comes to gene therapies that have a high upfront cost, said Roger Longman, founder of Florham, New Jersey- based market-access advisory and platform company Real Endpoints. Value-based arrangements can help manage high-risk categories where there is an uncertainty about the economic impact, Longman said.

While he is working on value-based projects, Mycka said a therapy that has undergone accelerated approval would not automatically be part of such a program. Longman said his firm is also working on value-based solutions for therapies that have been through the regulatory pathway. Payers are certainly interested in these and so is biopharma, he added.

Despite the interest to use this tool, the implementation of such programs has been variable, but experts noted some emerging trends that signal change. The recent Pfizer arrangement for Xalkori is innovative in that it directly deals with patients and essentially acts as a warranty, Longman said. As per news reports, if Xalkori does not work within the first three months, Pfizer will refund the entire cost to any patient and health plan.
Ryan Cox, vice president, Access Experience team, Precision for Value, Oviedo, Florida, also made the distinction that Pfizer's arrangement is relatively novel, considering it does not involve just rebates that are commonly used in payer deals, but an insurance payment of sorts. This scheme is going in the direction of

"Value-based arrangements can help manage high-risk categories where there is an uncertainty about the economic impact"

shared-risk models that can creatively avoid impacting best price, he added. The Medicaid best price policy requires drug manufacturers to give Medicaid the best, or lowest price among nearly all purchasers. There has been a concern that this policy can affect insurer compliance with value-based arrangements.

In a crowded market, value-based plans may not be enough to give a competitive advantage from an access perspective, but it may keep the drugs at parity price, Cox said. In the case of Alunbrig, however, a payer will have a reimbursement incentive to prefer Alunbrig versus another, said Longman, who worked on the Takeda/Point32 deal. If a drug does not work for a patient, then the manufacturer would need to reimburse the payer, making it cost less than similar drugs that do not have such a value-based arrangement, Longman explained.

Cox also referred to another value-based program involving the targeted therapy for **Bayer's** (ETR:BAYN) NTRK gene fusion inhibitor Viktravi (larotrectinib), which also entered the compendium through an accelerated approval. Under the payer-agnostic deal, which was announced a few years ago, Bayer will refund up to 60 days worth of treatment if a patient does not benefit from the drug, as assessed by a physician.

It is difficult to adjudicate a deal based on subjective, qualitative assessments like radiographic test results, Longman said. This has been one of the challenges when it comes to wider use of value-based arrangements. On the other hand, pharmacy claims data can be a straightforward data point to use to judge treatment efficacy, Cox said. If a patient discontinues a drug, that would be noted in the claim system. A health plan can access a pharmacy claims database and can track doctor visits, blood tests and prescription continuation, Longman said. Since a number of these drugs are orally administered, including Xalkori and Alunbrig, pharmacy claims data can be analyzed in real time to fit with a value-based plan, Cox said. There may be some delays when it comes to medical claims, on the other hand, he added.

However, Jakub Hlavka, PhD, research assistant professor, Health Policy and Management, USC Price School of Public Policy, Los Angeles, pointed out that issues arise even with claims data, due to incorrect coding.

Both Xalkori and Alunbrig got their initial regulatory nods via accelerated approvals in 2011 and 2017, respectively. While Xalkori is currently approved for ALK+ or ROS1+ subsets, Alunbrig is indicated or ALK+ NSCLC.

Individual determining factors like plan size

Over the last decade, some payers have built the administrative infrastructure and data capabilities to engage value-based programs, said Cox. Larger national plans like **Humana** (NYSE:HUM) and **Anthem Blue Cross Blue Shield** (NYSE:ANTM) have their own data companies, and such entities may have access to pharmacy and medical claims data that others do not, he added. Administrative barriers do exist for those smaller players who did not build this infrastructure.

That said, some like Harvard Pilgrim Health Care have been on the forefront of exploring such alternative plans with other products for a long time, Mycka said. It isn't the biggest plan but is sizable in Massachusetts. Point32Health, which signed the Takeda deal, is a combination of the Tufts Health Plan and Harvard Pilgrim.

Payers that don't have extensive data capabilities can always employ third parties that can capture and analyze data for such value-based arrangements, Longman said. However, considering highly regulated

> "Considering highly regulated data-sharing requirements, that can bring challenges of data privacy"

data-sharing requirements, that can bring challenges of data privacy, Cox said. There is a need for greater transparency in the structure of these plans, but regulatory factors like the Medicaid best price rule that can influence price negotiation restrict that, Hvlaka said.

Value-based arrangements need to be used selectively such that they reach patients in an effective way, said Ed Schoonveld, managing principal, Value & Access, ZS Associates, Princeton, New Jersey. It's not a one-size-fits all approach and there is much investment needed to make them function, Mycka added. W

Manasi Vaidya
Associate Editor, New York

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

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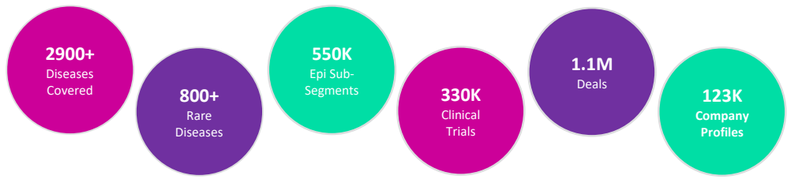

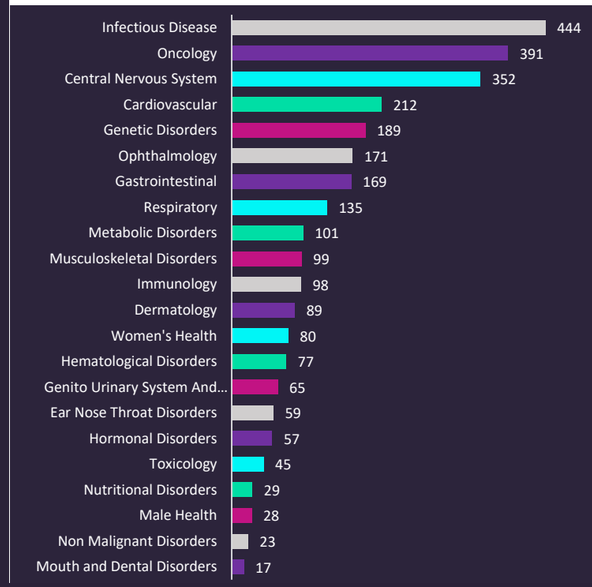

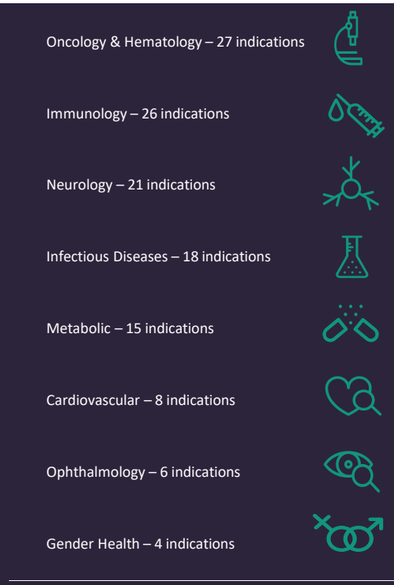

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Upper Middle-Income Countries Left Out by New Merck/Ridgeback COVID-19 Antiviral Licensing Deal

As **Merck** (NYSE:MRK) and **Ridgeback Biotherapeutics** sign on to a licensing deal to expand global use of their COVID-19 capsule molnupiravir, many upper middle-income countries could fall through the cracks.

Merck and the Medicine Patent Pool (MPP) announced a voluntary license for the generic manufacturing and sale of molnupiravir that covers 105 countries on Wednesday (27 October). Under the agreement, generic manufacturers can receive nonexclusive sublicenses to produce the antiviral. While many experts lauded the deal, some noted upper middle-income countries not covered in the agreement are left in a difficult position.

The agreement covers all low-income, most lower middle-income, and some upper middle-income countries, according to the MPP. But almost half of the world's population falls outside the deal, noted Dr Reshma Ramachandran, veterans affairs scholar, Yale University, New Haven, Connecticut. Specifically, this is where 70% of all COVID-19 infections in the first half of 2021 occurred, she added.

In Latin America and the Caribbean, over 80% of the population falls outside the agreement, according to an analysis from the Knowledge Ecology International (KEI). "Leaving out countries like Argentina or the Dominican Republic is the negative side of an overall positive agreement," added Luis Gil Abinader, senior researcher, KEI. Colombia, Costa Rica, Ecuador, Mexico, Panama, and Peru are among excluded upper middle-income countries from this region. Brazil is in separate negotiations with Merck.

For countries outside the deal, there is concern that wealthier countries with more purchasing power will corner the molnupiravir supply, said Rachel Cohen, North America Regional Executive Director, Drugs for Neglected Diseases Initiative. High- income countries like the US and UK have already entered molnupiravir prepurchasing agreements, raising concerns of "dose hoarding" seen with mRNA COVID-19 vaccines, she noted. The EMA has started a rolling review for molnupiravir and the FDA is holding an Advisory Committee meeting to discuss its data on 30 November.

However, the licensed area is large enough to induce generic entry, and the countries that were left out of Merck's deal can benefit from that, Abinader said. But the deal's fine print—specifically a clause that could curtail patent challenges from sublicensed manufacturers—had other experts more wary. Merck did not respond to a comment request.

High-income countries may set price benchmarks

Without a sublicense to produce molnupiravir, many upper middle-income countries (UMICs) will have to directly compete with high-income countries for supply, Ramachandran said. Similar to the case with mRNA vaccines, high-income countries with more purchasing power could buy excess doses of molnupiravir, Cohen added.

Expensive price points in high-income countries can set benchmarks for pricing in UMICs, Cohen said. In its initial molnupiravir prepurchasing agreement, the US will pay USD 712 per five-day treatment course. This is despite KEI estimating the drug costs less than USD 20 to produce. The Institute for Clinical Effectiveness Research declined to comment to this news service on molnupiravir's cost effectiveness until its draft evidence report is published in early February.

There is the risk of UMICs paying more than high-income countries. Drug makers can try to set a product's price as high as possible, as there are UMICs that could meet an even higher price. As an example, South Africa paid more for the **AstraZeneca** (LON:AZN) COVID-19 vaccine than the UK because the latter had a purchasing agreement with the company, explained Dr Mariana Socal, associate scientist Health Policy and Management, Johns Hopkins University, Baltimore, Maryland.

Once initial purchasing agreements are fulfilled, molnupiravir's price would be determined by the clinical experience, available evidence, and public opinion at that time, experts noted. Pfizer (NYSE:PFE) and BioNTech (NASDAQ:BNTX) secured a higher price for their COVID-19 vaccine once they had efficacy data in millions of people.

Patent provisions draw some concerns

The agreement provides a pathway for supplying molnupiravir to countries outside the licensed territory, where patents have not been granted, Abinader said. Under international law, individual countries can reject patents and grant compulsory licenses, he explained.

But Merck and MPP's agreement includes a clause that could prevent sublicensed generic companies from contesting molnupiravir patents, Cohen noted. This would preclude manufacturers who sign on to the terms of the sublicensing deal from challenging patents to facilitate generic production, she said.

Molnupiravir inventor Emory University pushed for allowing the MPP to terminate sublicensing agreements with any manufacturer that contests the patent, Ramachandran said. There's some reassurance from the MPP that it won't exercise this right as it runs contrary to their core principles, Ramachandran said. "But it's disappointing to see a university who received significant amounts of taxpayer money to discover and develop this drug promoting anti-access provisions in this license," she added.

Still, while such an agreement does not address global access completely, every bit counts, said Jacob Sherkow, professor of Law, University of Illinois, Urbana-Champaign College of Law. Work needs to be continued to develop solutions for the remaining countries, he added.

Experts interviewed by this publication commended the transparency of Merck's agreement as it is publicly accessible. But the lack of detailed clinical trial data—including the drug's ideal patient population—makes it difficult for countries to plan molnupiravir's eventual rollout, they added.

On 21 September, this news service reported it was critical to test and identify eligibility for molnupiravir early in disease progression. Healthcare providers' interpretations of severe COVID-19 risk factors will also prove key in determining the drug's use.

William Newton
Reporter, Texas

William Newton is a healthcare reporter for GlobalData focusing on central nervous system diseases and ophthalmology. Previously, he worked at the healthcare information firm Close Concerns, where he covered breaking news in diabetes therapeutics and technology for the company's industry-facing publication, and at the digital health startup Fitscript, where he assisted in researching digital health and lifestyle intervention approaches to treating diabetes. He graduated Williams College with a BA in Economics and Spanish and worked as a News Editor, Executive Editor, and Managing Editor of the Williams Record.

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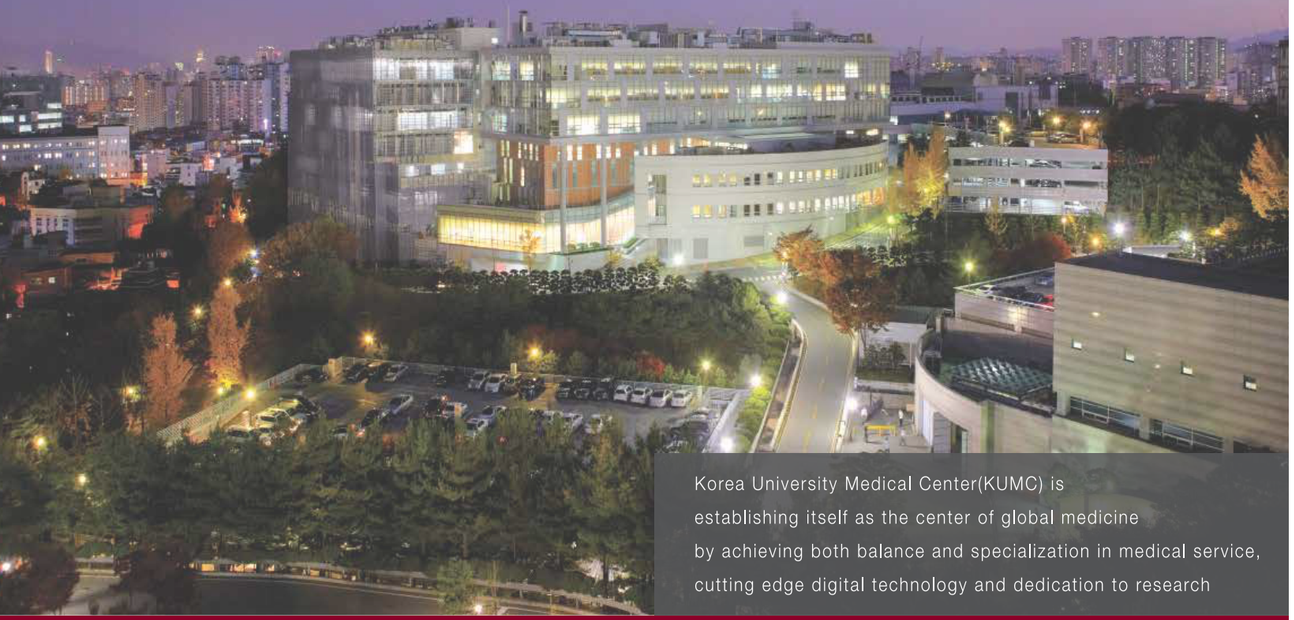

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FOLLOW THE JOURNEY OF VIREAD

COMPLETE RESPONSE RESULTS AT YEAR 1...

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

AT YEAR 1

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

THROUGH YEAR 8

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

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

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

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

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

INDICATION AND USAGE

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

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

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

Viread® 300 mg tablets
tenofovir disoproxil fumarate

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

...AT 8 YEARS: NO RESISTANCE WAS

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

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

ADVERSE REACTIONS

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

DRUG INTERACTIONS

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

DETECTED AT YEAR 1 THROUGH YEAR 8

NO HBV RESISTANCE DEVELOPED YEAR 1 through YEAR 8

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

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS (cont'd)

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

DOSAGE AND ADMINISTRATION

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

DOSAGE ADJUSTMENT FOR PATIENTS WITH ALTERED CREATININE CLEARANCE

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

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

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

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

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

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

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

300 mg tablets
Viread®
tenofovir disoproxil fumarate

VIREAD® (tenofovir disoproxil fumarate) tablets

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

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

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

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

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

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

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

Dosage Adjustment for Adult Patients with Altered Creatinine Clearance

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

a. Calculated using ideal (lean) body weight.

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

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

CONTRAINDICATIONS: None.

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

Bone Effects

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

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

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

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

Brief Summary (Cont'd)

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

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

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

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

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

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

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

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

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

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Contact: EBDcustomerservice@ebdgroup.com

Biotech Showcase is the 14th annual international partnering conference. It is an investor and networking conference devoted to providing private and micro-mid-cap biotechnology companies an opportunity to present and meet with investors and biopharmaceutical executives. Attendees can learn about the funding and partnership opportunities in these rapidly evolving spaces through the program sessions and company presentations.

International Meeting on Stimulation in Healthcare (IMSH 2022)

January 15-19, 2022 | Los Angeles, California, USA

Website: https://imsh2022.org/
Contact: admin@ssih.org

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

BIO CEO & Investor Conference

February 14-17, 2022 | New York, New York, USA

Website: https://www.bio.org/events/bio-ceo-investor-conference
Contact: info@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, where institutional investors, industry analysts, and senior biotechnology executives have the opportunity to shape the future investment landscape of the biotechnology industry.

HIMSS Global Health Conference & Exhibition

March 14-18, 2022 | Orlando, Florida, USA

Website: https://www.himss.org/global-conference
Contact: himss@csreg.zohodesk.com

The HIMSS Global Health Conference & Exhibition is the can't-miss healthcare event of the year, where professionals throughout the global health ecosystem connect for education, innovation, and collaboration. It will bring a huge variety of attendees across the global health ecosystem-including CIOs and senior executives, providers, IT professionals, government officials, innovators, consultants, market suppliers, and more.

13th Annual CUGH Conference

March 28-April 1, 2022 | Virtual Conference

Website: https://www.cugh2022.org/
Contact: info@cugh.org

The theme of the 13th Annual Consortium of Universities for Global Health is "Healthy People, Healthy Planet, Social Justice." Over 2,000 scientists, students and implementers from academia, NGOs, government, and the private sector will present, learn and collaborate to address some of the pressing challenges our world faces. Attendees will be inspired and challenged to learn new skills, gain new contacts and find ways we can improve the health of people and the planet.

Society for Healthcare Epidemiology of America (SHEA) Spring

April 12-14, 2022 | Colorado Springs, Colorado, USA

Website: https://sheaspring.org/
Contact: info@shea-online.org

The SHEA 2022 Program Committee combines decades of experience and expertise from across the SHEA membership and engages broad subject matter expertise in healthcare and epidemiology, antibiotic stewardship, long-term care, research methods, clinical microbiology, patient safety and quality, implementation science, and COVID-19. It also provides a wide range of opportunities for networking and communication with peers and experts in the field.

GHIC 2022 – Global Health & Innovation Conference

April 21-22, 2022 | Virtual Conference

Website: Website: https://ghic.uniteforsight.org/
Contact:ufs@uniteforsight.org

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

Conference Alerts

Europe

IMCAS World Congress 2022

January 27-29, 2022 | Paris, France

Website: http://imcas2022.com/
Contact: info@imcas2022.com

IMCAS (International Master Course on Aging Science) 2022 is the 23rd annual world congress in Paris and organized by IMCAS Society. The primary objective is to build a bridge between aesthetic plastic surgery and dermatology, reinforcing knowledge in each field as well as the areas of study in the junction of the two fields. Each edition is dedicated to the interdisciplinary research of plastic surgery and dermatology, with a scientific program built to bring the highest quality of education to more than 12,000 attendees.

15th International Conference on Alzheimer's and Parkinson's Diseases

March 15-20, 2022 | Barcelona, Spain

Website: https://adpd.kenes.com/
Contact: https://adpd.kenes.com/contact-us/

The 15th International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders, AD/PD™ 2022, built on the well-earned reputation of the groundbreaking series of Alzheimer's and Parkinson's Diseases Conferences, attracting international medical and scientific professionals.

BIO-Europe Spring

March 28-30, 2022 | Basel, Switzerland

Website: https://informaconnect.com/bioeurope-spring/
Contact: EBDcustomerservice@ebdgroup.com

The theme of BIO-Europe Spring is "Reconnecting and Facilitating Global Partnerships" and brings together the life science community for global dealmaking. It is also expected to bring together over 2,500 executives from biotechnology, pharmaceutical, and finance companies from around the world, who will engage in more than 15,000 partnering meetings.

DIA Europe 2022

March 29-31, 2022 | Brussels, Belgium

Website: https://www.diaglobal.org/Flagship/DIA-Europe-2022
Contact: americas@diaglobal.org

DIA Europe is the largest event in the life science industry and the most forward-looking neutral healthcare conference in Europe. It encourages open collaboration by bringing together representatives from the entire spectrum of the life science landscape and facilitating crucial multidisciplinary discussions across several tracks, such as Clinical Development, Regulatory Strategy, Pharmacovigilance and Drug Safety, Value and Access, and Health Policy.

Asia

12th Emirates Otorhinolaryngology Audiology and Communication Disorders Congress

January 12-24, 2022 | Dubai, United Arab Emirates

Website: https://www.emiratesrhinologyandotology.ae/
Contact: eroc@mci-group.com

The 12th Emirates Otorhinolaryngology Audiology and Communication Disorders Congress present an international congress covering all aspects of otorhinolaryngology, audiology, and communication disorders. The conference will bring inspired people together and will remain on the cutting edge with relevance to global discussions that address the current issues of ORL Head and Neck Surgery.

Asia Healthcare Analytics Summit 2022

January 25-26, 2022 | Singapore, Singapore

Website: : https://3novex.com/asia-healthcare-analytics-summit-2022/
Contact: info@3novex.com

Asia Healthcare Analytics Summit 2022 encourages discussions and networking with healthcare peers across Singapore and other ASEAN counties. Attendees will get insights on how technologies can be used to improve data management and healthcare systems around the world in assisting delivery care, improving patients' safety, and life sciences, etc.

The 5th Global Public Health Conference 2022 (GLOBHEAL 2022)

February 24-25, 2022 | Virtual Conference

Website: https://healthconference.co/
Contact: https://healthconference.co/contact-us/

The Global Public Health Conference is the 5th annual event organized by The International Institute of Knowledge Management (TIIKM). It will bring together more than 350 participants from 45 different countries, 75 professionals, health specialists, healthcare providers, researchers, policymakers, pharmaceutical developers, and scientists to collaborate, innovate, and help to shape the future of global public health.

CPhI Japan 2022

April 20-22, 2022 | Tokyo, Japan

Website: https://www.cphi.com/japan/en/home.html
Contact: https://www.cphi.com/japan/en/about/contact-us.html

CPhI Japan, together with co-located events ICSE, P-MEC, FDF, bioLIVE, InnoPack, and Natural Extracts, hosts more than 20,000 visiting pharma professionals from more than 55 countries. It will be a great opportunity to establish new business relationships, meet with global partners and stay updated on the latest industry trends. The exhibition showcases cover the pharmaceutical manufacturing and ingredients sourcing, offering products and services that cover the entire supply chain.

Happy smile and hope after pain

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

Kyung Hee Medical Center patient
D. K. Lee

Cancer-free D.K. Lee

D.K. Lee attending
beauty classes while chemotherapy treatment

LATEST HEALTHCARE INDUSTRY NEWS

OCT – DEC 2021

1. Merck Says Antiviral Pill Is Effective Against COVID-19, Lifting Hopes for First Oral Drug

An antiviral pill being developed by Merck & Co. and Ridgeback Biotherapeutics dramatically reduced the number of hospitalizations from COVID-19 in a clinical trial, a major finding that could mark a turning point in the coronavirus pandemic. Merck now plans to seek emergency authorization of molnupiravir in the U.S. "as soon as possible" and seek approvals in other countries as well.
https://www.biopharmadive.com/news/merck-molnupiravir-covid-antiviral-pill-reduce-hospitalization/607515/

2. Texas Abortions Pick Up After Federal Judge Allows Them

The law, known as the Texas Heartbeat Act, or SB 8, has been in effect for a month, barring physicians from knowingly performing an abortion if there is detectable embryonic cardiac activity. However, some Texas clinics again began performing abortions later than six weeks Thursday after a federal judge blocked a state law imposing a near ban on the procedure, while others are moving more slowly as legal challenges play out.
https://www.wsj.com/articles/federal-judge-blocks-texas-abortion-law-11633568447?mod=article_inline

3. WHO Will Announce New Team to Study Coronavirus Origins

Despite those considerable obstacles, more than 700 people have applied for spots, which will be unpaid positions, on a new committee charged with breathing life into the World Health Organization's stalled inquiry into the origins of the coronavirus pandemic. Its new advisory team will include specialists in fields like laboratory safety and biosecurity, a step that analysts say may help placate Western governments pressing for consideration of whether the virus emerged from a lab.
https://www.nytimes.com/2021/10/12/health/covid-lab-leak-who-china.html

4. FDA Spells Out Lower Sodium Goals for Food Industry

Food companies are coming under renewed pressure to use less salt after US regulators spelled out long-awaited guidelines aimed at reducing sodium levels in dozens of foods including condiments, cereals, french fries, and potato chips. To get people used to eating less salt, the Food and Drug Administration said reductions have to be gradual and across the entire food supply so people don't keep reaching for higher sodium options.
https://www.bostonglobe.com/2021/10/13/nation/fda-spells-out-lower-sodium-goals-food-industry

5. As Opioid Crisis Worsens, Ed Markey Pitches 2 Bills to Help Inmates Get Treatment

US Sen. Ed Markey is proposing two pieces of legislation that he says would help inmates who are suffering from drug abuse while they are behind bars and when they are released back into society. Citing a record high number of drug overdose deaths in 2020, Markey on Thursday said he's reintroducing a bill to ensure people in the justice system have access to opioid-use disorder treatment. Another bill would let people in custody awaiting trial to keep their federal health benefits.
https://www.bostonherald.com/2021/10/14/as-opioid-crisis-worsens-ed-markey-pitches-2-bills-to-help-inmates-get-treatment/

6. Walgreens Doubles Stake in Provider Network VillageMD with $5.2B Investment

Walgreens is doubling its ownership stake in value-based medical network VillageMD with an additional investment of $5.2 billion, the pharmacy chain said Thursday. The major investment should accelerate the opening of 600 "Village Medical at Walgreens" primary care practices in more than 30 U.S. markets by 2025, and 1,000 by 2027. More than half of the clinics will be in medically underserved communities.
https://www.healthcaredive.com/news/walgreens-doubles-stake-in-provider-network-villagemd-with-52b-investment/608229/

7. Biogen Alzheimer's Drug Is Struggling, and A Turnaround Might Not Be Coming Soon

Despite high expectations, Aduhelm, the first drug developed by Biogen and ever approved in the U.S. to slow Alzheimer's disease, has sought to get roughly 900 Alzheimer's centers to use Aduhelm, but so far, only around 120 are doing so. The FDA's approval of Aduhelm was also highly controversial. The debate over the drug's merits has hung over its launch and, seemingly, physician's willingness to prescribe it.
https://www.biopharmadive.com/news/biogen-aduhelm-earnings-alzheimers-drug-sales/608592/

Latest Healthcare Industry News

8. HHS Announces Nearly $800M in American Rescue Plan Funds to Support Domestic Violence and Sexual Assault Survivors and Their Children

The U.S. Department of Health and Human Services (HHS), through the Family and Youth Services Bureau (FYSB) at the Administration for Children and Families (ACF), is awarding a total of $797.5 million in American Rescue Plan (ARP) funding to support survivors of domestic violence and sexual assault and their children. The funds will cover COVD-19 testing, vaccines, mobile health units, and other support for domestic violence services programs, as well as increase support for sexual assault service providers and culturally specific services.
https://www.hhs.gov/about/news/2021/10/25/hhs-announces-nearly-800-million-american-rescue-plan-funds-support-domestic-violence-sexual-assault-survivors-their-children.html

9. FDA, NIH, and 15 Private Organizations Join Forces to Increase Effective Gene Therapies for Rare Diseases

The U.S. Food and Drug Administration, the National Institutes of Health, 10 pharmaceutical companies and five non-profit organizations have partnered to accelerate development of gene therapies for the 30 million Americans who suffer from a rare disease. The newly launched Bespoke Gene Therapy Consortium (BGTC), part of the NIH Accelerating Medicines Partnership (AMP) program and project-managed by the Foundation for the National Institutes of Health (FNIH), aims to optimize and streamline the gene therapy development process to help fill the unmet medical needs of people with rare diseases.
https://www.fda.gov/news-events/press-announcements/fda-nih-and-15-private-organizations-join-forces-increase-effective-gene-therapies-rare-diseases

10. Merck Sees Up to $7B in Coming Sales of Coronavirus Pill

Merck & Co. executives forecast between $5 billion and $7 billion in sales of the company's COVID-19 pill through the end of 2022, assuming an expected emergency use authorization from the Food and Drug Administration in December. The sales of molnupiravir, as the experimental, antiviral pill is known, could go higher if additional research shows it can prevent disease in people who have become exposed but not sick, Merck executives said on an earnings call Thursday.
https://www.biopharmadive.com/news/merck-coronavirus-pill-7-billion-sales/609064/

11. Democrats Reach Deal on Lowering Prescription Drug Prices

Democrats reached an agreement on provisions designed to lower the price of some prescription drugs, appearing to resolve one of the final issues in the party's negotiations over their $1.85 trillion healthcare, education and climate-change bill. The agreement, which is backed by the White House, would empower Medicare to negotiate the price of some drugs, penalize drug companies for raising prices faster than the rate of inflation and cap out-of-pocket costs for seniors at $2,000 annually
https://www.wsj.com/articles/democrats-reach-deal-on-prescription-drug-pricing-schumer-says-11635879481?mod=article_inline

12. Once Sidelined, Eli Lilly's COVID-19 Antibody Treatment Is on the Comeback Trail with New $1.3B Supply Agreement

On Tuesday, the company revealed that it has struck a deal with one of its loyal customers, the United States government, which has agreed to purchase 614,000 doses of the therapy for $1.29 billion. The combination of etesevimab and bamlanivimab is a treatment for mild to moderate COVID-19 or for post-exposure prophylaxis in high-risk individuals. Lilly will provide at least 400,000 doses by the end of the year, with the rest guaranteed by the end of January 2022.
https://www.fiercepharma.com/pharma/once-sidelined-eli-lilly-s-covid-19-antibody-treatment-comeback-trail-supply-agreement-u-s

13. Biden Administration to Invest $650M in Rapid Diagnostic Testing in Latest Action to Increase Access to Tests

As part of the Biden-Harris Administration's ongoing commitment to increasing access to COVID-19 testing for Americans and to further strengthen domestic manufacturing of needed tests, the U.S. Department of Health and Human Services (HHS) will invest $650 million from the American Rescue Plan to strengthen manufacturing capacity for quick, high-quality diagnostic testing through rapid point-of-care molecular tests and increase Americans' access to them.
https://www.hhs.gov/about/news/2021/11/10/biden-administration-invest-650-million-rapid-diagnostic-testing-latest-action-increase-access-tests.html

14. J&J, World's Largest Drugmaker, Plans to Split in Two

On Friday, J&J said it will separate its consumer health division, which sells well-known brands like Tylenol, Listerine, and Band-Aids, into a new publicly traded company. Expecting to complete the separation, which is meant to boost the value of the company's main businesses, in the next 18 to 24 months, J&J will retain its prescription drug and medical device units and keep in place its current leadership plan.
https://www.biopharmadive.com/news/johnson-johnson-split-spin-consumer-health-restructuring/609950/

15. The FDA Authorizes COVID Booster Shots for All U.S. Adults

The Food and Drug Administration has given its OK for fully vaccinated Americans who are age 18 and older to receive a COVID-19 booster shot. The FDA on Friday granted emergency use authorization for a third dose of the Pfizer-BioNTech and Moderna vaccines, which had already been available to people 65 and older and to anyone 18 years and older who is at elevated risk of contracting COVID-19. People who got the Pfizer or Moderna immunizations to start would be eligible for a booster six months after their second shot, the FDA said. People who got the Johnson & Johnson vaccine would be eligible for a booster two months after their first shot.
https://www.npr.org/sections/coronavirus-live-updates/2021/11/19/1056832774/the-fda-authorizes-covid-19-booster-shots-for-all-u-s-adults

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