IFPW FOCUS
A Bi-Weekly Pharmaceutical Industry Newsletter
Vol 32 | No. 8
April 11, 2024

South Korea Unveils Cutting-Edge Biotech Initiative

(Source: An article by Jung Won Shin for Scrip Citeline)

South Korea is proceeding with plans to setup a biotech cluster in Osong, like the Kendall Square biotech hub in Boston, MA, US. The cluster was unveiled as part of an initiative announced by South Korean President Yoon Suk Yeol. Leaders in the biopharma industry in Korea are calling for rapid progress and exceptional support.

With Johnson & Johnson set to establish its third Asian JLAB site in the country and Merck KGaA planning its biggest APAC investment in a major bioprocessing center in the country, global big pharma firms now appear to be shifting more of their attention to the Northeast Asian nation.

This new interest may be related to ambitious central government plans to attract global capital and talent by setting up major biotech clusters and providing various incentives as motivation to foster and grow the biopharma industry.

In remarks to a recent discussion on public welfare, President Yoon vowed to progress the planned K-Biosquare cluster in Osong, North Chungcheong Province (Chungcheongbuk-do) and pursue regulatory innovation to create a local version of the Kendall Square – where universities, research institutes, biotech firms and supporting providers including law, financial and accounting companies are all co-located.

During the discussion, Daewoong Pharmaceutical Company Ltd.'s head of manufacturing operations raised the need to speed up the initiative, given that "time is competitiveness" and South Korea is standing in the field amid rapidly changing global biotech competition. He also emphasized that the government needs to provide "exceptional" support to accelerate K-Biosquare.

In addition, the Ministry of Science and ICT announced that it will lay out detailed plans to foster a core labor force in the sector, including support for the establishment of an artificial intelligence (AI) and bioscience talent school by 2027 in the same region.

President Yoon noted a small number of major western countries have dominated the traditional biotech sector, but as the industry moves towards the integration of cutting-edge AI and digital technologies, a "large door of opportunity" is opening for South Korea.

The country currently enjoys a deep and knowledgeable global talent pool and high-quality medical data and the technologies and opportunity to quickly transform into a strong "digital nation".

The President also unveiled the national Cutting-Edge Bio Initiative as part of these ambitions. Under this, the government will sharply raise R&D investment in the digital health sector, which includes AI-based new drug R&D, digital therapeutics, and the creation of a data platform for research use.

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In Brief...

- **Walgreens Boots Alliance (WBA)** reported financial results for its second quarter of 2024 with an increase in sales of 6.3% to US$37.1 billion (5.7% on a constant currency basis) which the company said reflects sales growth across all segments. "We're encouraged by our first quarter of U.S. Healthcare positive adjusted EBITDA and continued topline growth alongside another quarter of strong execution in pharmacy, as we look to re-energize and evolve its impact both at Walgreens and at large," said *Tim Wentworth*, CEO of WBA. He continued, "We remain confident in our goal of achieving US$1 billion in cost savings this year. We are continuing to strategically review our portfolio over the next three months in an effort to ensure it drives growth and delivers value."
- **McKesson's** new program, *Project Oasis* will launch with the intention of bridging healthcare gaps in underserved communities while elevating the important role of community pharmacists. The initiative is led by McKesson's *Global Impact Organization and Community Pharmacy & Health*, and seeks to identify and address these pharmacy deserts, particularly in urban areas where residents face significant challenges in accessing essential pharmacy services. The first activation site will be in Avondale, Ohio, a neighborhood in the Cincinnati area.
- **Cardinal Health** has begun construction of its new 350,000 sf. centralized replenishment center for the distribution of over-the-counter consumer health products in support of its core pharma business. Scheduled to open by the summer of 2025, the center will be the 4th Cardinal Health distribution facility in central Ohio, along with its corporate headquarters in Dublin, Ohio.

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HHS Responds to Industry Counteroffers in IRA Price Negotiations

(Source: An article by by Zoey Beck for FiercePharma)

Medicare drug price negotiations under the Inflation Reduction Act are steadily progressing after drugmakers recently submitted their counteroffers to the government's initial pricing proposals.

Subsequently, U.S. Department of Health and Human Services (HHS) has put forward its own responses to those counteroffers. In addition, the agency invited each company affected by the process to engage in "further discussions," the agency announced in a press release on April 2nd.

The Centers for Medicare & Medicaid Services (CMS) is "proud to be negotiating in good faith with drug manufacturers to lower the prices of some of the most expensive drugs for

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South Korea (cont.)...

The strategic intention is to improve the nation's quality of life and welfare through means including software for the treatment of mental health problems, innovative biologics for intractable diseases, the diagnosis and treatment of diseases of aging, such as dementia, as well as the development of anti-aging technologies.

It is hoped that the project will foster collaboration between industry, academia, research institutes and hospitals, and attract about 200 biotech firms (including those from overseas), create 20,000 jobs and foster five "decacorn" firms (unicorns with valuations of more than US$10 billion) by 2040.

J&J's JLABS program, as its partner for a global accelerator platform project, will become the third site in Asia, after Shanghai and Singapore.

Meanwhile, Merck KGaA plans to invest more than US$324 million into a new bioprocessing center in Daejeon. This will be the German firm's largest life science investment to date in the Asia-Pacific region. The facility will support biopharma process development, clinical research, and commercial manufacturing of biologics, including vaccines, cell and gene therapies, and protein-based therapies.

HHS (cont.)

people with Medicare," CMS Administrator Chiquita Brooks-LaSure said in a statement.

The negotiation process officially kicked off Feb. 1 with the government's first pricing offers.

If the drugmakers and the HHS reach an agreement on a maximum fair price by the end of the negotiation period Aug. 1, the new prices will be published Sept. 1 and take effect starting in 2026.

Johnson & Johnson, Bristol Myers Squibb, Merck & Co., Novartis, Eli Lilly, AstraZeneca, Novo Nordisk and Amgen each have products subject to the negotiations.

Also, President Biden and Sen. Bernie Sanders (I-Vermont) joined forces announcing an effort to lower out-of-pocket drug costs at an event on April 3rd.

The President had already laid out his mission to allow Medicare to negotiate drug prices for "at least 50 drugs" each year and to expand the $2,000 out-of-pocket cap that will apply to Medicare products in 2025 to "all private insurance" programs to benefit "all Americans," he said, as laid out in a White House fact sheet.

That plan was quickly denounced by prominent industry trade group the Pharmaceutical Research and Manufacturers of America (PhRMA), which argued that the government is "rushing to make this bad law worse," it said in a statement.

Japan Kicks Off New Reporting System For "Supply Risk" and "Supply Status"

(Source: A staff article by Pharma Japan)

On April 1st, the Japanese government launched its revamped scheme for drug supply reporting by pharmaceutical companies, which uses a two-fold approach for "supply risks" and "supply statuses".

Under the new plan, there will be two types of reports: "supply risk reports" that companies will issue to the Ministry of Health, Labor and Welfare (MHLW) when they identify potential supply risks, and "supply status reports" they will provide when there are actual shortages, triggering shipment restrictions.

This new scheme was approved by the MHLW's panel on the stable supply of ethical drugs in February of this year. The MHLW sent out notification in late March to announce its specific procedures replacing its December 2020 guidance on the reporting of supply concerns.

According to the new directive, marketing authorization holders will issue supply risk reports to the MHLW when they become aware of the possibility of a shortage happening within the upcoming six months. Products that must be reported include: 1) products without alternative drugs or means of treatment; 2) products with a dominant market share that cannot be completely replaced by alternative drugs to meet all medical needs; 3) products in short supply in all specifications/dosages; and, 4) designated "stable supply medicines." Companies will report not only the expected timings of the shortages, their causes, measures needed to avoid shortages, and expected time of resolution, but also their market share the availability of alterative drugs, as well as the status of their efforts to coordinate with alternative drug manufacturers, scientific societies and medical institutions.

On April 1, the MHLW began announcing the supply status of ethical drugs through its website, which will be updated on a daily basis. According to the MHLW, this covers nearly all listed products.

In Brief (cont.)

- Japanese wholesaler **Alfresa** will host the grand opening ceremony for its newest distribution center on April 18, 2024. The facility will be the largest of Alfresa's facilities.
- **Johnson & Johnson** announced it will buy heart pump maker **Shockwave** in a deal valued at US$13.1 billion. The deal is expected to close by mid-2024.
- **Novo Nordisk's** *GLP-1 semaglutide* medication is under review at the **U.S. Food and Drug Administration (FDA)** to add heart failure to its litany of approved indications. Data presented suggests that the GLP-1 agonist could treat heart failure over and above its weight loss effects alone. The study tested the drug in 616 patients with obesity-related heart failure with preserved ejection fraction (HFpEF) and type 2 diabetes. The dosage used was 2.4 mg injected weekly, the same level approved to treat obesity.
- **Pfizer** announced that its respiratory syncytial virus (RSV) vaccine *Abrysvo* was well-tolerated and generated an immune response in higher risk adults under the age of 60 similar to that in older adults for whom the shot is already approved. The company plans to submit its findings from the trial to seek expanded approval of the vaccine in adults ages 18-59 but did not give a time frame for when it expects the data to be reviewed by regulators. Last year Pfizer launched *Abrysvo* for older adults and for pregnant women to protect their babies from RSV.

(Sources: Company Press Releases, Drug Store News, FiercePharma, Reuters and Scrip Citeline)