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Korean Consortium is Focused on Next-Gen mRNA Vaccines

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

South Korea is moving quickly to develop its own mRNA COVID-19 vaccine and eventually next generation platform technology for use in other diseases, to meet its goal of becoming a global source for vaccines. This strategic consortium of pharmaceutical companies will focus on accelerating development by next year. In the coming years, the aim is to elevate mRNA platform technology so that it can be used to fight other diseases beyond COVID-19.

In a joint ministry statement the national government also highlighted an urgent need to develop and commercialize mRNA vaccines, given that this is expected to change the paradigm of vaccines in the future. As shown over the past 18 months, the advantages include rapid development and manufacture of mRNA vaccines compared to traditional vaccines, along with now-proven superior efficacy and relative safety.

While developers in the U.S. and Europe have succeeded through accumulated research and technologies, relevant South Korean technologies are still in the early stages, prompting the government vow to provide aggressive support.

The consortium is lead by three major domestic pharmaceutical firms – Hanmi Pharmaceutical Co., Ltd., ST Pharm and GC Pharma – and supported by KIMCo, the Korea Innovative Medicines Consortium. KIMCo is a not-for-profit organization established by the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) and supported by 56 individual pharma firms promoting and supporting anti-infective and innovative medicines and global commercialization.

The consortium will build on the strengths of Hanmi, ST Pharma and GC Pharma in active pharmaceutical ingredients (APIs), vaccines and new drug development to obtain relevant technology and establish mass production systems to achieve not only COVID-19 mRNA vaccine self-sufficiency, but also build up a basis for global exports. The goal is to establish independent technology development by 2022 and manufacture 100 million doses of the vaccine within two years, enough for two doses for every South Korean citizen.

By 2023, the consortium aims to establish a mass production

(continued on page 2)

In Brief...

- **Walgreens Boots Alliance** has named three individuals to its executive leadership team. *Tracy Brown* will take over as the new President of Retail Products and Chief Customer Officer of Walgreens. *Danielle Gray* has been named as Executive Vice President and Global Chief Legal Officer, and *Jeff Gruener* will take the position of Sr. Vice President and CFO. "I am pleased to welcome Danielle, Tracey and Jeff to the WBA family," said *Roz Brewer*, CEO of Walgreens Boots Alliance. "They will be instrumental in continuing to build momentum across our business as we further innovate, and work to define the future of health and well-being in communities we serve for many years to come."
- **Takeda**, Japan's biggest drugmaker, will distribute its COVID-19 vaccine, *TAK-019*, in early 2022, pending approval from regulators, according to the company representatives. The terms of the deal with the government are confidential, Takeda said. **Novavax** is licensing and transferring manufacturing technologies to enable Takeda to manufacture the vaccine. The announcement builds on an earlier agreement between Takeda and the government to make some 250 million doses of the Novavax shot.
- **Sinopharm** (China) is developing a homegrown mRNA vaccine for COVID-19, making it one of the first Chinese pharma companies to pursue the technology to combat the

(continued on page 2)

Solutions to Securing the Drug Supply Chain

(Source: A staff article by Forbes Magazine)

In 2013, the Drug Supply Chain Act (DSCSA) was passed to protect the pharmaceutical supply chain in the United States. As recent history had proven, counterfeit or contaminated drugs were a threat to public safety.

According to the World Health Organization (WHO), the counterfeit drug market in the developing world had grown to $30 billion in 2017, causing thousands of deaths. But by that stage, the DSCSA had created something of a safety net, requiring that millions of daily drug shipments – involving thousands of industry trading partners – be traced.

Still, the DSCSA was crafted with a long-term goal in mind, specifically tracking and tracing prescription drugs at the unit level across each stage of the US supply chain.

One of the first companies involved in helping the DSCSA realize its vision was the global pharmaceutical wholesale distributor, AmerisourceBergen. With more than 150 locations across 50 countries, the company efficiently supplies hundreds of

(continued on page 2)

Korean Consortium (cont.)...

system using the platform to produce more than one billion doses for both home and abroad. This will encourage global competitiveness for novel cancer vaccines and other innovative drugs. An initial investment of US$618 million by the three firms will help to progress clinical trials, obtaining core APIs and assist in standing up mass production facilities.

Going forward, the consortium plans to add more participants, including other Korean pharmas, biotechs and research institute relevant to the development and production of mRNA technology and raw materials.

The consortium predicts that western vaccines are unlikely to satisfy all demand and noted multiple considerations such as how effective they are against variants and how long their protection will last, as well as distribution costs if they are administered seasonally.

South Korean mRNA vaccine technologies are seen to be about three years behind those of leading countries. The consortium, along with the South Korean government aims to rapidly close this technology gap. In the interim, relevant ministries will assist to enable vaccine candidates to enter clinical trials, while longer-term official objectives are to encourage basic and proprietary technologies in prediction, diagnosis, treatment and prevention of new infectious diseases.

Safeguarding (cont.)...

thousands of medical sites, pharmacists, and veterinarians.

Upon the DSCSA's passing, the company realized there were no viable software solutions to address the new regulations.

But the dilemma was averted when AmerisourceBergen in partnership with SAP, launched the drive to co-innovate and produce the first enterprise solution to meet the DSCSA's track-and-trace requirements.

Each year, 58,000 unique units of drugs, worth US$2.5 billion, are returned. Generally, the returned items are re-sold in the U.S. But, under the new regulations, the process was at risk.

To comply with the DSCSA's dramatic changes in supply chain management, trading partner authorization was required, validating any member of the supply chain as an authorized associate. Additional requirements included: new product labeling and bar codes with unique identifiers; the ability to identify and quarantine illegitimate products across the supply chain; notification among trading partners and the Food and Drug Administration (FDA) of suspected counterfeit or contaminated products; transaction blocking in the supply chain to ensure that only properly encoded products were distributed; and, unit level product tracing by 2023, consisting of standardized and unique serial numbers embedded in 2D Data Matrix labels.

The track and trace technology implemented by AmerisourceBergen and other leading wholeslaers not only complied with U.S. healthcare rules but established end-to-end visibility within the supply chain — from manufacturer to shipping point to delivery at the healthcare provider or pharmacy.

The solution makes it possible to track the units of drugs returned each year, verifying the product back all the way back to the manufacturer, in accordance with DSCSA regulations, thus effectively securing the drug supply chain.

In Brief (cont.)...

disease. The state-owned pharma group's move comes as concerns over the efficacy of conventional inactivated virus vaccines. Certain studies show that these types of vaccines produce fewer antibodies compared to mRNA vaccines.

- Only a few days after **Eli Lilly's** COVID-19 antibody combo of *bamlanivimab* and *etesevimab* made its return to more than 20 states, U.S. federal officials are resuming distribution nationwide. In a Thursday alert, **U.S. Food and Drug Administration (FDA)** officials said Lilly's drug "can be used in all U.S. states, territories, and jurisdictions" based on data about variants circulating nationwide. Since Eli Lilly's combo is expected to be effective against the delta variant, officials are ready to again endorse the drugs.
- Both **Pfizer** and **Merck** have launched pivotal clinical studies of new experimental oral COVID-19 drugs. Merck is conducting a trial of 1,300 patient to study whether its medicine, *molnupiravir*, can prevent COVID-19 in adults who live with a symptomatic patient with confirmed coronavirus. Pfizer, who is also conducting a trial of 1,140 patients who have received a dose of its therapy candidate, *PF-07321332*, to treat symptomatic patients who have not been hospitalized and are not at high risk of severe illness.
- The U.S. plans to invest US$3 billion in the vaccine supply chain as it continues to work to position itself as a leading supplier of vaccines for the world, according to U.S. White House COVID-19 adviser, *Jeffry Zients*, during a news conference. The funding, which will be distributed in the coming weeks, will focus on manufacturers of the inputs of COVID-19 vaccine production as well as facilities that fill and package vaccine vials. The focus will also encompass lipids, bioreactor bags, tubing, needles, syringes, and personal protective equipment.
- In a sample of over 400 older adults in Argentina, who had recovered from COVID-19, more than 60% displayed some degree of cognitive impairment, a researcher from The **University of Texas Health Science Center** at San Antonio reported July 29 at the *Alzheimer's Association International Conference*. It is not known whether the impairment, such as forgetfulness and language difficulty, will be progressive, said *Gabriel de Erausquin, MD, PhD*, a neurologist with the health science center's Glenn Biggs Institute for Alzheimer's and Neurodegenerative Diseases. The individuals in the study are over 60 years of age and have been assessed once so far. They will be followed for the next three to five years.
- South Korea announced that it plans to start distribution of COVID-19 booster shot beginning in October, following suit with several other countries, including the United States. Initial booster doses will initially go to those with weakened immune systems or deemed to be at high risk of severe illness or death from COVID-19. Others will receive them six months after full vaccination, according to the Korea Disease Control and Prevention Agency.

(Sources: Business Wire, Company press releases, Drug Store News, Financial Times, FiercePharma, Healthcare Dive, Korea Business Review, and World Pharma News)