IFPW FOCUS IFPW

Vol. 27, No. 16 International Federation of Pharmaceutical Wholesalers July 30, 2020

China Advances Two Coronavirus Vaccines Into Phase III Trials

(Source: An Article by Brian Yang for Scrip Intelligence)

Chinese state-owned company Sinopharm Group Co., Ltd.'s subsidiary, China National Biologics Products Group (CNBG), has commenced a Phase III study for its vaccine against the coronavirus in Abu Dhabi via a partnership with locally-based G42 Healthcare and carried out by Abu Dhabi Health Services. The regulatory approval, granted by the United Arab Emirates state, allows as many as 15,000 volunteers to participate in the trial.

The large-scale, late-stage study will be a test for the UAE and the local partner G42, an artificial intelligence and cloud computing firm led by CEO Xiao Peng. G42 has said it will recruit a minimum of 5,000 participants for the study and Sinopharm is likely to seek more from other countries.

Abu Dhabi was chosen for the study because of its largely diverse population. This could show the vaccine's efficacy for potential global use, according to CNBG. In comparison, another Chinese vaccine developer, CanSino Biologics Inc., says it will enroll as many as 40,000 people for its Phase III study, U.S. firm Moderna, Inc. is planning to involve 30,000 individuals in its study for its mRNA-based vaccine. CanSino is in discussions with authorities in Brazil, Chile, Russia and Saudi Arabia.

Similarly, Beijing-based developer Sinovac Biotech Ltd. is also planning to commence a Phase III study for its candidate in Latin American countries including Brazil and Chile, through its partnership with Brazil's Butantan.

Sources within the industry explain that the reasoning behind the decision to conduct studies in the Middle East and Latin America is being driven by multiple factors. First, the governments are generally accepting of Chinese quality standards and they are also willing to work with Beijing to promote the vaccines, Ke Wu, CEO for Chinese company, BravoVax, told Scrip. Wuhan-based BravoVax is also developing a vaccine against the coronavirus.

Apart from the need to conduct the studies in a pandemic-hit area where exposure to the virus is required, the costs of carrying out such work in emerging markets in Latin America is another potential consideration, Wu added.

While the Chinese government's vow to make any successful home-grown vaccines widely accessible for the "global public good," the countries that are collaborating with developers are expected to be among the first in line to receive supplies upon approval.

Both the Sinopharm and SinoVac vaccines are based on the inactivated virus, an established technology where China has a distinct advantage. Given that the vaccines made in China have not been tested outside the country, assessing them in a "friendlier" environment may make the process easier.

China's National Medical Products Administration has initiated five separate audit groups who are tasked with ensuring that these vaccine products are in regulatory compliance. The process, which began on July 20th, is set to conclude by the end of July.

In Brief...

- **Walgreens Boots Alliance** announced that CEO and Executive Vice Chairman, *Stefano Pessina*, will be stepping down as CEO once a new CEO has been selected. At that time, Pessina will assume the role of executive chairman and current executive chairman *James Skinner* will step down. Skinner will remain on the board to ensure a smooth transition. The company said that the leadership shuffle is meant to help drive progress on its strategic priorities and position the business for the future as the healthcare environment continues to change.
- **AstraZeneca** aims to deliver 100 million doses of its coronavirus vaccine to Japan, according to *Pascal Soriot*, AstraZeneca's CEO. The company released its early stage trial data for *AZD1222* vaccine, which showed "robust" immune responses in all patients. The vaccine is being developed in partnership with Oxford University. AstraZeneca is ramping up manufacturing capacity in parallel with clinical trials and aims to make *AZD1222* available as early as September. However, dropping infection rates in the U.K., where ongoing late-stage trials were launched, could delay the results, delaying release of the vaccine.
- **Shanghai Fosun Pharmaceutical Group Co., Ltd.** announced that its subsidiary **Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd.** has received acceptance of its clinical trial application for its licensed coronavirus vaccine

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Tom VanMolkot is Appointed to IFPW's Board of Directors

IFPW is pleased to announce the appointment of Tom VanMolkot to IFPW's Board of Directors, replacing John Davison, who retired from his position as CEO of Zuellig Pharma on July 1st.

Tom is Executive Vice President Distribution & Client Services for Zuellig Pharma Asia Pacific where he oversees Zuellig Pharma's Distribution, Client Development, Clinical Reach and Data Analytics functions across its 13 markets. He also manages key markets in North Asia and Southeast Asia and drives the in-country teams and key personnel across the organization's various Business Units to maximize the value and services delivered to clients and customers in the region. Additionally, Tom leads the regional IT, Operations and Quality and Assurance teams.

Tom's career with Zuellig Pharma spans over 18 years where he has assumed many leadership positions in the company. He brings to the IFPW Board nearly 25 years of experience in the global supply chain and logistics industry. He has also served as an advisory committee member for the IFPW Foundation Board of Trustees. Tom was born and raised in Africa and holds a degree in Economics from the Université Catholique de Louvain (Belgium), and is currently based in Singapore.

Trump Signs Executive Orders to Lower Drug Prices

(Source: An Article by Sandra Levy for Drug Store News)

On July 24th, President Trump issued four executive orders broadly focused on lowering drug prices for Americans.

"The four orders that I am signing today will completely restructure the prescription drug market, in terms of pricing and everything else, to make these medications affordable and accessible for all Americans," Trump said in remarks following the signing of the orders. "The first order will require federal community health centers to pass the giant discounts they receive from drug companies on insulin and EpiPens directly to their patients."

President Trump stated that one of the reasons pharmaceutical drug prices in the United States are so high is "because of the complex mix of payers and negotiators that often separates the consumer from the manufacturer in the drug-purchasing process."

"The result is that the prices patients see at the point-of-sale do not reflect the prices that the patient's insurance companies, and middlemen hired by the insurance companies, actually pay for drugs. Instead, these middlemen negotiate significant discounts off of the list prices, sometimes up to 50% of the cost of the drug," Trump said. "Medicare patients, whose cost-sharing is typically based on list prices, pay more than they should for drugs while the middlemen collect large 'rebate' checks. These rebates are the functional equivalent of kickbacks and erode savings that could otherwise go to the Medicare patients taking those drugs. Yet, currently, federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law."

The Pharmaceutical Care Management Association, which represents the PBM industry, was not enthusiastic about the executive orders, arguing that the executive orders will have an adverse effect on patients and their out-of-pocket costs. Similarly, the Pharmaceutical Research and Manufacturers of America president and CEO, Stephen Ubl, disapproved of the moves.

Beyond restructuring the market in terms of pricing, Trump's orders also permits drug importation from Canada. "We will finally allow the safe and legal importation of prescription drugs from Canada and other countries where the price for the identical drug is incredibly lower," he said.

The Top 20 Drugs by Global Sales in 2019

(Source: An Article by Kyle Blankenship for FiercePharma)

For any drug maker, taking a medication to the billion-dollar sales mark, giving it the designation of a "blockbuster", is a massive achievement in its own right. But for the pharmaceutical industry's bestselling drugs, some of which are blockbusters many times over, the bar is set much higher. Evaluate Pharma, has assembled a list of the top 20 drugs by global sales in 2019, showing pharma's biggest sales drivers.

Things change quickly in pharma, but 2019 was much the same as past years in one notable way. In terms of sales, it is AbbVie's mega-blockbuster *Humira* and everyone else. But with *Humira* biosimilar challengers hitting abroad for the first time in 2019—and U.S. copycats right around the corner in 2023— other top sellers are eyeing their march to the top. In the second tier below *Humira's* US$19.74 billion in sales are a suite of rockstar oncology meds, with five of the top 10 bestselling drugs approved to treat cancer.

Among those is Merck & Co.'s fast-growing *Keytruda*, which is on its way to sales supremacy. *Keytruda's* robust pipeline is so lucrative that Evaluate has pegged the I-O med's sales in 2026 at US$25 billion, which is roughly in line with Wall Street consensus and significantly higher than *Humira's* peak. The other story unfolding is the loss of patent protection, a fate that eventually dooms every bestseller. Of our top 20 drugs, six therapies faced generic or biosimilar challengers for the first time in 2019 or previously saw copycats hit the market. No single drug maker will be as affected by that challenge more than Roche, which saw its three bestselling oncology meds—*Avastin, Herceptin* and *Rituxan*—face U.S. copycats in 2019. But it's not all *Humira* and oncology. Drugs from Gilead, Biogen, Bristol Myers Squibb and others round out the list, and their roads to blockbuster success have all been unique.

Rank	Drug	Rank	Drug
1	Humira	11	Xarelto
2	Keytruda	12	Herceptin
3	Revlimid	13	Prevnar
4	Opdivo	14	Imbruvica
5	Eylea	15	Remicade
6	Eliquis	16	Ibrance
7	Enbrel	17	Biktarvy
8	Avastin	18	Tecifidera
9	Stelara	19	Trulicity
10	Rituxan	20	Genvoya

In Brief (cont.)...

product candidate *BNT162b1*. The company obtained the license from German company BioNTech to exclusively develop and commercialize its vaccine products based on BioNTech's proprietary mRNA technology platform.

- Coronavirus vaccine candidates from **AstraZeneca/ Oxford University, CanSino** and **Pfizer** have all shown to trigger immune responses and have passed initial safety tests. By inducing immune responses, this is an indication that the vaccines show promise in protecting against the coronavirus. Volunteers in a clinical trial were given an experimental vaccine and developed an antibody against a protein the virus uses to break into cells. Participants in the study produced immune cells called T cells that are necessary for long-term immunity.
- **Amazon** is starting a pilot program that will open third-party primary care clinics near several of its warehouse centers and operations facilities nationwide. The partnership with **Crossover Health** is aimed at providing easy access to health care facilities instead of using more expensive emergency or urgent care options. The first facility will open in Las Colinas, Texas and will feature extended hours to accommodate employee schedules and will be open exclusively for Amazon employees and their families. Among the services to be provided are acute, chronic and preventative care, prescription meds, vaccinations, behavioral health, physical therapy and chiropractic care.
- The **U.S. Center for Disease Control (CDC)** has changed its guidance with respect to how long COVID-19 patients should be isolated. According to the new guidelines, patients with mild to moderate COVID-19 symptoms can leave isolation without a negative test after ten days of showing initial symptoms of the virus. Increasing evidence shows that most people are no longer infectious after ten days. Additionally, the CDC is discouraging people from getting a second test.

(Sources: Drug Store News, FiercePharma, NBC News, Pharma Japan, and Press Releases)