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HAPPY NEW YEAR FROM IFPW
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COVID Vaccine Candidates and Approvals Accelerate Around the World

(Sources: An article by Emily Schmall and Sameer Yasir for the New York Times, an article by Sandra Levy for Drug Store News, an article by Andrew McConaghie for Scrip, and an article by Pharma Japan)

As COVID vaccine rollouts continue, countries are expediting approvals at an accelerated pace so that populations can be inoculated quickly and efficiently, particularly those who are in high-risk groups. Likewise, governments are also finalizing deals so that adequate vaccine supplies can be secured.

In Japan, the Ministry of Health, Labor and Welfare (MHLW) revealed its distribution and storage plans for three COVID vaccine frontrunners from Pfizer, Moderna, and AstraZeneca/Oxford University. Included in these agreements are 120 million doses from Pfizer and AstraZeneca and another 50 million doses of the Moderna vaccine. These agreements are, of course, dependent on each candidate's successful development and approval.

The government of India has approved two coronavirus vaccines, including the AstraZeneca vaccine and another developed by Indian manufacturer Bharat Biotech named *Covaxin*. Both received emergency use authorization after examination of both by the Central Drugs Standard Control Organization, India's pharmaceutical regulator. Other vaccines are also being considered for approval by the Indian government and include Russia's Sputnik V and Pfizer's mRNA vaccine, which has already received widespread approval from the United States and Europe.

Officials in India are moving quickly for several reasons, not the least of which is their high infection rate, which is second only to the United States. The outbreak is also believed to be far worse than the official figures indicate. The pandemic has devastated the Indian economy and the unemployment rate is now at a 45 year high. Disruptions in the education system has also led to concern regarding long term impact on India's youth population. Complicating these challenges is finding a distribution solution to get the vaccine to India's 1.3 billion citizens, as well as a public that is questioning the safety and efficacy of these vaccines.

China's National Medical Products Administration announced December 31st that it granted conditional approval for the COVID vaccine developed by Sinopharm Group Co., Ltd.'s state-owned subsidiary China National Biotec Group. Initial results collected from ongoing Phase III clinical trials on the inactivated virus-based vaccine conducted in several countries outside China. These results show that the efficacy of the vaccine protection against COVID is approximately 79.34%, a percentage lower than mRNA-based vaccines developed by Moderna and Pfizer.

Another dark horse vaccine candidate receiving attention is being developed by CureVac and shows potential as another mRNA-based vaccine CVnCoV. CureVac is currently enrolling

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- Global wholesaler and distributor **McKesson Corporation** has begun distribution of Moderna's COVID vaccine and ancillary supply kits to Americans. In August, the company expanded its partnership with the **U.S. Centers for Disease Control and Prevention (U.S. CDC)** to support *Operation Warp Speed*. The first order was filed by the U.S. CDC on December 20th with shipping partners delivery initial vaccine orders at administration sites on Monday, December 21st. *Brian Tyler*, CEO of McKesson, said "In March, our world seemed to change overnight. But with a renewed sense of commitment and intensified focus, we've come together across industries and forged public and private partnerships to help restore and protect the health and well-being of people around the world."
- **Sanofi** has pioneered sustainable finance in the pharmaceutical industry with the signing of its two first sustainability-linked revolving credit facilities. The two

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Walgreens Boots Alliance to Sell Pharmacy Wholesale Operation to AmerisourceBergen.

(Source: An article by Micah Maidenberg for the Wall Street Journal and an article by Cecile Duraut for Bloomberg)

Walgreens Boots Alliance Inc. (WBA) announced that it has agreed to sell the majority of its pharmacy wholesale unit to AmerisourceBergen Corporation (ABC). The move is aimed at helping the drugstore chain better focus on its retail pharmacy business and health offerings. For ABC, it would be gaining one of the largest pharmaceutical wholesalers in Europe.

AmerisourceBergen will pay US$6.5 billion for the WBA wholesale business, Alliance Healthcare, with approximately US$6.275 billion in cash and two million shares of common stock. The planned deal would expand Walgreens' stake in AmerisourceBergen, which makes it the largest shareholder of ABC, according to sources from both companies.

In its latest quarter Walgreens generated US$6 billion in sales from its wholesale unit, which consists of Alliance Healthcare and the stake in AmerisourceBergen. The Alliance unit distributed healthcare products and services to more than 115,000 pharmacies, hospitals and other health providers annually, as of the end of last August. It also operates in 11 countries, mostly in Europe.

With Alliance Healthcare, ABC will strengthen its global reach, while Walgreens will focus on its main pharmacy business. In addition to the transaction, the two companies announced extensions of existing distribution agreements. The companies already maintain close ties, as Walgreens already holds a 30% stake in the ABC.

COVID Vaccine (cont.)...

participants in its Phase IIb/III. Chief Executive Franz-Werner Haas believes that CVnCoV can be a valuable addition in the fight against COVID and, pending favorable results, could receive emergency use authorization in the second quarter of 2021. One of the key advantages of the CureVac candidate is its stability which boasts at least three months storage at a standard refrigeration temperature of +5ºC. What remains to be seen is the efficacy of CVnCoV compared to other vaccines. Results from early trials were not as compelling as had been hoped.

Moderna's vaccine is showing great promise and may be better at preventing severe disease. It may also offer some benefit in preventing asymptomatic infections. However, it is not known how long the vaccine may offer these benefits and would be hard to capitalize on due to supply limitations. Moderna has received emergency use authorization for use in the United States, Canada and Israel as well. For Moderna, emergency use authorization from Israel is an important step towards a global rollout of its vaccine.

Israel has emerged as an early success story among the first countries to roll out vaccinations for their populations, with 1.22 million doses administered. This represents 13% of the country's 9.3 million citizens, putting it ahead of other countries in terms of the coverage achieved across the population. Currently Israel is running out of doses and is waiting for six million doses to be delivered.

Moderna has most recently received emergency use authorization from the European Union. Additional authorizations are under review in Singapore, Switzerland and the United Kingdom. By far the most important of these is approval from the EU, with whom Moderna has a contract for 160 million vaccine doses. The European Medicines Agency recommended approval of the Moderna vaccine on the 7th of January after a short delay. First doses are being prepared from its manufacturing partners in Switzerland.

Also noteworthy, AstraZeneca/Oxford University received its first emergency approval from the government of the United Kingdom. Subsequent approval is close behind with Argentina already approving the AstraZeneca vaccine. El Salvador has already given approval for emergency use authorization and Mexico is expected to follow suit shortly. In October, both Argentina and Mexico teamed up with AstraZeneca and the Carlos Slim Foundation to distribute 150 million doses of the vaccine at no profit during the pandemic. This includes most of Latin America (excluding Brazil who has not yet approved the AstraZeneca vaccine.) Brazil, who is experiencing a particularly brutal COVID outbreak, is expected to approve the AstraZeneca vaccine in mid-January.

In Brief (cont.)...

facilities are part of Sanofi's strategy to secure its long-term financing sources, including a new €4 billion (US$4.92 billion) revolving credit facility expiring December of 2025 with two extension options of one year each) and an amendment of the €4 billion revolving credit facility expiring in December 2021with the addition of two extension options of one year each. Both incorporate an adjustment mechanism that links the cost of the facilities to the achievement of annual targets for two selected sustainable KPIs: contribution to Polio eradication and carbon footprint reduction.

- The **U.S. Congress** has authorized US$4 billion to support the **GAVI's** *Vaccine Equity Plan* and COVAX facility through its COVID Relief legislation. GAVI launched the COVAX facility in partnership with the **World Health Organization** with the aim of immunizing at least 20% of the people in all countries, prioritizing those at highest risk, regardless of income or development levels. It aims to distribute at least 2 billion doses by the end of 2021, including to 92 low- and middle-income countries that cannot afford to pay on their own.
- Although air travel is down markedly from years past, American airports had their busiest day of the pandemic on January 2nd with nearly 1.2 million passengers passing through security checkpoints. Officials are concerned that a post-holiday COVID spike could see the greatest infection numbers to date. Also concerning is the new variant of the virus, which is spreading to multiple regions around the world. In addition to high air travel numbers, tens of millions of people were expected to leave their homes and travel by car.
- Pharmaceutical Manufacturer **Pfizer** has unveiled the redesign of their iconic logo, setting aside its "blue pill" logo that has been its moniker for 70 years for a logo that signals Pfizer's "shift from commerce to science." The new logo debuted in video ads and features a two-tone blue double helix spiral which will be prominently displayed in its "Science Will Win" campaign. Pfizer CEO, *Albert Bourla*, said" Pfizer is no longer in the business of just treating diseases. We're curing and preventing them." The new logo is the culmination of 18 months of work with input from patients and doctors around the world.
- The third interim data on Russia's *Sputnik V* vaccine's Phase III trial in Russian has shown that the adenovirus vector jabs were 91.4% effective at preventing COVID-19. The results were announced by the vaccine's co-developer **Russian Direct Investment Fund (RDIF)** on Monday and was the last results to be announced before completion of the trial in May at which time a final analysis to determine the safety and efficacy would be conducted. The third interim analysis was carried out among 22,714 volunteers, with three-fourths of them receiving the vaccine and the remainder receiving the placebo.
- Romania's largest medical service provider, **MedLife**, has reached an agreement to acquire 75% of the pharmaceutical distribution company **Pharmachem**. This is MedLife's first acquisition in the pharma sector and its largest takeover in 2020. Pharmachem has 16 years of activity and operates a countrywide warehouse network.
- U.S. officials are considering administering half doses of the Moderna vaccine. Evidence seems to indicate that half doses can be given without compromising immunity. The **U.S. Food and Drug Administration** has not approved this approach and other government officials are advising against the decreased dosages.

(Sources: Company Press Releases, Drug Store News, FierceBiotech, FiercePharma, Romania Insider, Scrip Intelligence and Wall Street Journal)