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Shots in Arms – An Update on New Vaccines, Variants and Rollouts

(Sources: Staff articles by The Economist, Scrip Intelligence and World Pharma News, and an article by Alexander Smith for NBC News)

While COVID and its variants continue to ravage populations around the world, several bright spots have emerged surrounding vaccines and therapeutic treatments. Recent announcements from clinical trials of two vaccine candidates from Novavax and Janssen within the span of 24 hours are encouraging, but also emphasize that these new virus variants are making the task of vaccinating much more complicated than initially anticipated.

American firm Novavax tested its vaccine in Britain and South Africa, where two variants are also present. Results announced in January showed an efficacy rate of nearly 90% when two doses were administered 21 days apart. In South Africa, the rate was lower at 60% (and down to 49% when HIV positive participants were included.) The lower efficacy rate is worrisome to scientists, as it indicates that the virus has already mutated in a way that makes the vaccine less effective. The British trials of the Novavax jab covered a time period when the British variant, B.1.1.7 (which has sent the country back into lockdown) was already shown to be widespread locally. The trial in South Africa took place when that country's variant, B.1.351, was also rampant.

The results of trials involving the vaccine by Johnson & Johnson's subsidiary, Janssen, showed a similar pattern. The Janssen vaccine was tested in the U.S., South Africa and Latin America and involved a one-shot regimen, setting it apart from other vaccines. While efficacy rates were similar to the Novavax vaccine, it is tricky to compare the Janssen jab with other vaccines that involve two shots and have generally been evaluated against cases that produce even mild symptoms. Further complicating results is the fact that other vaccines were tested earlier in the pandemic when the incidence of variants were lower and prevalence of infections were different.

Overall, the news is good for Janssen. Across all three regions the vaccine significantly cut moderate to severe cases by approximately 66% after 28 days post-vaccination. The company also stressed benefits (citing data from its Phase III Ensemble trial) stating that the vaccine was 85% effective at preventing severe disease across all regions after day 49 with no cases in vaccinated participants, and 100% effective at preventing hospitalization and death, with no reported cases of death or patients requiring medical intervention 28 days post-vaccination.

Several companies, including Pfizer/BioNTech and Moderna, are already working on modified versions of their vaccines to target variants, much like the flu vaccine is tweaked every year. The difference is that flu viruses have been tracked for decades while COVID-19 variants have been dealt with as they surface. Noteworthy are results from a Pfizer/BioNTech study that showed their vaccine elicits anitibodies that neutralize the U.K variant spike protein. Additionally, the U.S. and other countries are setting up variant surveillance processes, but these variants may outpace

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- **Walgreens Boots Alliance (WBA)** announced that *Rosalind Brewer* has been appointed CEO of WBA effective March 15, 2021. Additionally, she will join WBA's board of directors upon assuming the role. She replaces *Stefano Pessina* who will transition to the role of Executive Chairman of the Board of WBA, replacing current executive chairman *James Skinner.* Brewer brings with her 35 years as a consumer and retail industry veteran, and has served as COO of Starbucks and President/CEO of Sam's Club. She is also the only black woman to head a Fortune 500 company. Separately, Walgreens has successfully administered one million vaccines in the U.S. in one month. Vaccinations have been administered to vulnerable populations in accordance with state and jurisdiction distribution plans.
- **McKesson Corporation** reported financial results for the third quarter of 2021, with revenues of US$62.6 billion reflecting a 6% increase year-over-year. The company recorded a pre-tax charge of US$8.1 billion related to opioid litigation resulting in a third quarter loss per share of US$39.03. Additonally McKesson's Board of Directors also authorized an additional US$2.0 billion share repurchase program. "McKesson continued to demonstrate its operational excellence and extensive healthcare supply chain expertise, as we began the distribution of COVID-19 vaccine doses to the

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South Korea Unveils National Vaccine Plan

(Source: A staff article by Scrip Intelligence)

The Korea Disease Control and Prevention Agency (KDCA) has unveiled its national COVID-19 vaccination plan, with a staged launch beginning in February. The goal is to vaccinate at least 70% of the population and generate herd immunity by November.

The plan was finalized after experts and the medical community took into consideration overseas cases and the efficacy and safety of available vaccines. First inoculations will be administered to front line medical staff involved in treatment of COVID-19 patients, followed by nursing hospital patients and staff, then medical staff at general hospitals and those related to COVID-19 response work such as paramedics, quarantine officers and epidemiological investigators. Individuals will be given a choice of which vaccine they want to receive.

Beginning in the second quarter, individuals aged 65 and over and those in eldercare facilities will be next in line. After those groups in the second half of 2021, the remaining citizens will be targeted for vaccination depending on when supplies are available and how the program progresses in the first half of the year.

The government has entered into agreements with the COVAX facility and individual pharmaceutical manufacturers including AstraZeneca, Janssen Pharmaceuticals, Pfizer/BioNTech and Moderna to provide vaccinations for 56 million

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these efforts in the coming months.

Still, it is overwhelmingly positive news that the Novavax and Janssen vaccines are almost completely effective against the worst cases of COVID-19. Also of significant importance is the fact that both vaccines can be stored at regular refrigeration temperatures for months, which makes them widely distributable. The challenge will be determining which vaccines should be used in what areas of the world based on each vaccine's efficacy against the variants.

Meanwhile vaccine rollouts are slow in many countries around the world, with poorer countries being particularly vulnerable. Wealthier countries are buying up vaccine doses by the hundreds of millions. Europe is experiencing widespread division and disagreement over limited vaccine stocks, while Africa, South America and Latin America have turned to vaccines produced by China and Russia to boost supplies. As for the U.S., while it is best positioned to immunize its citizens with the 1.2 billion doses already ordered, it lags significantly behind other countries, including Israel, the United Arab Emirates, the United Kingdom and Bahrain, in shots delivered per capita.

Part of the issue is that supplies have been scaled back by drugmakers trying to keep up with demand, sometimes committing to more doses than can be delivered. Managing expectations has been a big challenge. Bureaucratic infighting appears to have impeded the EU rollout, which has been particularly slow and dysfunctional. Doctors in Madrid and Paris have been forced to pause inoculations because vaccine stocks have run dry.

Adding to the problem, the EU and AstraZeneca are in disagreement after the British-Swedish pharma giant said it would have to scale back deliveries because of a manufacturing issue. The EU has insisted that the drugmaker keep its word. In a drastic step, the EU is now seeking to block exports of any vaccines from companies that have not fulfilled the EU orders.

"We reject the logic of first-come, first-served," EU Health Commissioner Stella Kyriakides said at a news conference Wednesday. "That may work in a butcher's shop but not in contracts and not in our advanced purchase agreements."

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people in total, or 108% of the total population. The government is also in the process of trying to secure vaccines from Novavax for an additional 20 million people for efforts to avoid possible uncertainties with vaccine supplies.

The first vaccines will be supplied by AstraZeneca and are scheduled to arrive in country in stages beginning in the first quarter. The Moderna vaccine will arrive in the second quarter and the Pfizer vaccine in the third quarter. Timing for vaccines supplied by the COVAX facility will also be finalized with timing for arrival sometime in the first quarter.

The individual agreements with each company will go through a review and approval process overseen by a separate dedicated team at the drug ministry after being discussed at external expert advisory meetings. The government will also consider bringing in COVAX facility supplies through a special import process in line with the WHO's emergency use approval status.

Due to different storage and distribution conditions, the government, private sector and military will join together to devise a safe distribution and storage system. Preparations are currently being made with SK Bioscience appointed to establish and run the system and secure the ultra-low temperature freezers. The process in its entirety will be internet-based to monitor and maintain appropriate temperatures and track deliveries in real time. The military will manage any unexpected challenges or crises.

Efforts to prevent the occurrence of adverse side effects include an examination prior to innoculation and a wait time for 15 to 30 minutes post-innoculation before recipients are discharged from the vaccination facility. Additionally, active monitoring will be initiated for prompt response to any adverse reactions.

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entire U.S. in the third quarter," said Brian Tyler, McKesson's CEO.

- Indianapolis-based **Eli Lilly,** whose antibody treatment *bamlanivimab* was the first antibody treatment authorized by the **U.S. Food and Drug Administration** for use in COVID patients, released Phase III study data showing that the drug therapy prevents symptomatic infections related to COVID-19 and cut the risk of developing these infections by 57% among residents and staff in long-term care facilities. The trial was conducted by the **National Institutes of Allergy and Infectious Diseases (NIAID)**, a unit of the **U.S. National Institutes of Health**. Talks of an additional emergency use authorization as a preventative treatment are expected to follow.
- Both **Amazon** and **Walmart** have indicated to the new Biden Administration they stand ready to assist in the vaccine rollout. Walmart has been training thousands of pharmacists and pharmacy techs, building a new digital scheduling tool to make appointments easy, and partnering with state and federal agencies. Amazon has offered their full assistance with the national effort to distribute vaccine supplies, Amazon stated in a letter to President Biden.
- The **U.S. Food and Drug Administration** has approved a sixth dose that could be pulled from vials of the **Pfizer/BioNTech** vaccine, rather than the original 5 doses. The shift to 6 doses will require a special syringe needed to extract the shot, which could be problematic. Pfizer is working with the U.S. government to pair the appropriate syringes with the vaccine shipments, as well as count doses accordingly.
- **Takeda Pharmaceutical** (Japan) has launched a Phase I/II trial for **Moderna's** mRNA-based COVID-19 vaccine in Japan, with the first subject receiving initial dose on January 21st. The two-dose vaccine will be investigated by Takeda under the code name *TAK-919*. The study will gauge safety, efficacy and immunogenicity of the vaccine versus placebo in 200 healthy adult volunteers with follow-up for one year to be conducted after the second dose. The government of Japan has already inked a 50 million dose deal with Moderna beginning the first half of 2021, enough for 25 million individuals. Takeda hopes to have EUA approval in place by June of 2021.
- **Sanofi** announced that it will fill and package 100 million doses of **Pfizer/BioNtech's** COVID-19 vaccine for the EU in 2021, demonstrating the pharmaceutical industry's willingness to work together to meet unprecedented demand for the vaccines. While an unusual arrangement, it was discussed among industry leaders early in the pandemic as a way to expand capacity on a global scale. Sanofi will not be manufacturing the actual vaccine since they do not currently manufacture the novel mRNA technology platform on which the Pfizer vaccine is built.

Sources: (Company Press Releases, Drug Store News, Fierce Pharma, Pharma Japan and Scrip Intelligence)