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COVID Vaccine Candidates Shine Brightly On the Horizon

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As the last quarter of 2020 ushers in a number of COVID-19 vaccine candidates with impressive Phase III trial results and possible approval – either through government approval process or emergency use authorizations – it is critical to look at each vaccine and the pros and cons that each presents. The frontrunners include candidates from Pfizer, Moderna, AstraZeneca and the Russian vaccine *"Sputnik V"*. The following is a rundown of commonalities and differences in each, and how they could best be used.

Most noteworthy is the never-before-seen speed with which these vaccine candidates have been developed. The eight-month journey to this point has cut the previous time for development of a viable vaccine by as much as two-thirds.

The Pfizer/ BioNtech BNT162b2 vaccine. The companies announced their first interim analysis from its Phase III trials very impressive efficacy rates of 95%. Perhaps more important is that the efficacy rate in the over 65 age group was 94% - a hugely significant result, as older patients have a less robust immune response and are most vulnerable to SARS-CoV-2. Pfizer and BioNtech also revealed much more detailed data, showing that its efficacy was consistent across age, gender, race and ethnicity demographics. Thus far, no serious concerns have been reported by the Data Monitoring Committee.

The Pfizer/BioNTech vaccine is the first to receive approval through an emergency use authorization (EUA) from the U.K. with distribution beginning the week of December 8th. Additionally, the two-month milestone required for an EUA from the U.S. Food and Drug Administration has been met. The U.S. FDA will meet on December 10th regarding the EUA,with a decision expected soon after.

While the overwhelmingly positive results show great promise, it is still not known how long the vaccine will protect against the virus. Trial participants will continue to be monitored with the hope this question will be answered in time. Also, to achieve immunity, the vaccine will require two doses within a certain time frame.

U.K-bound vaccines will be transported from Pfizer's manufacturing facility in Belgium. Already, in anticipation of the U.S. EUA approval, Pfizer has already flown its first shipment of the vaccine into the United States. United Airlines was involved in the special coordination of a charter flight to Chicago's O'Hare International Airport. Since the Pfizer vaccine requires ultra-cold chain technology (-70ºC) to maintain long-term stability, engineers devised special temperature-controlled units to store the vaccine. While the U.S. federal government has designated McKesson Corporation as the official distributor of the vaccine for the United States, Pfizer has opted to go on its own and distribute its vaccine directly.

Pfizer aims to have 50 million doses ready by the end of 2020, and 1.3 billion doses available in 2021. It is also working on a

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In Brief...

- Asian healthcare services provider **Zuellig Pharma** plans to significantly expand its cold storage warehouse capacity in key regional markets over the next 12 months. The move comes as the company prepares for the anticipated storage and distribution demands for COVID-19 vaccines. The construction of a new US$6 million 6,300 square meter warehouse in Cambodia is already underway and is expected to be fully operational by Q3 of 2021. Zuellig is also actively investing to expand its warehouse and distribution facilities and plans to build a new distribution center in Taiwan in 2024.
- According to the **World Health Organization**, Africa is not ready for COVID-19 vaccination distribution, which would constitute the continent's largest-ever immunization drive. All 47 African nations have received the WHO's *Readiness Access Tool* which provides a roadmap for countries to plan for COVID-19 vaccine introduction and is intended to be used by Ministries of Health for guide preparations. The tool covers 10 key areas, including planning and coordination, resources, and funding.
- The **U.S. Food and Drug Administration** has granted emergency use authorization (EUA) for **Regeneron Pharmaceuticals'** antibody cocktail *casirivimab* and *imdevimab* administered together. The drug cocktail is authorized for the treatment of mild to moderate COVID-19 in adults, as well as pediatric patients at least 12 years of age and weighing at least 40 kg who have received positive COVID-19 test results. Clinical evidence shows that these monoclonal antibodies have the greatest benefit when administered early after diagnosis and in patients who have not yet developed their own immune response, or who have a high viral load.
- **Alliance Healthcare UK** and **Boots UK** have donated 500,000 2mg *Almus Dexamethasone* tablets to the UK's **National Health Service (NHS)** in a joint commitment to the NHS and UK patients in support of the fight against COVID-19. The decision came when UK experts announced the benefits of *Dexamethasone* in June following a recovery trial. They found that the low-dose steroid treatment can reduce fatalities by up to one third in hospitalized patients with severe respiratory complications of COVID-19.

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COVID Vaccines (cont.)...

powdered version of its vaccine that is stable at room temperature, which could be available sometime in 2021.

Moderna's mRNA-1273. Moderna's final data analysis indicates that its vaccine is 94.1% effective in preventing COVID-19 among Phase III trial participants, and 100% effective against severe COVID-19. Moderna is also pursuing EUA from the U.S. FDA.

The Phase III study of the *mRNA-1273* vaccine included 196 positive case candidates. Known as the COVE study, more than 30,000 participants in the U.S. were enrolled, and was conducted in collaboration with the National Institute of Allergy and Infectious Diseases (part of the National Institutes of Health) and the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services.

Efficacy was consistent across age, race and ethnicity, and gender demographics. The 196 COVID-19 cases included 33 older adults (ages 65+) and 42 participants identifying as being from diverse communities.

"This positive primary analysis confirms the ability of our vaccine to prevent COVID-19 disease with a 94.1% efficacy and importantly the ability to prevent severe COVID-19 disease. We believe that our vaccine will provide a new and powerful tool that can change the course of this pandemic and prevent severe disease, hospitalizations and death," said Stéphane Bancel, Moderna CEO.

The company also said it remains on track to manufacture 500 million to 1 billion doses globally in 2021. Moderna is working with the U.S. Centers for Disease Control, Operation Warp Speed and McKesson as well as global stakeholders. By the end of 2020, the company expects to have 20 million doses ready to go and available in the United States. The company has also signed an agreement with the EU for 160 million doses.

A significant differentiator between Moderna's and Pfizer's vaccine candidates is that according to Moderna, their vaccine is stable at regular freezer storage temperature of -20°C for up to six months and can last in a refrigerator after thawing for up to 30 days. Moderna hopes that a mass immunization program led by community pharmacies in every country will help to ensure a smooth roll-out worldwide.

AstraZeneca and Johnson & Johnson candidates on the vaccine horizon. While both companies have vaccine candidates that show promise, they have not reached the point were an EUA is yet a consideration. AstraZeneca (in partnership with Oxford University) is developing its *AZD122* vaccine, Johnson & Johnson continues to develop its candidate *Ad26.COV2-S*. AstraZeneca's candidate has an extremely low non-profit price per dose and has received the highest volume of pre-orders globally (over 3 billion doses.) Johnson & Johnson comes in at a non-profit level price of around US$10, with a significant advantage of being a single dose vaccine. Both candidates require standard refrigeration and should have Phase III data readouts by as early as December 2020 or January 2021. While these two candidates may not achieve an efficacy score of 90% or better, if they reach into the 70-80% range they will prove viable alternatives because of their attributes, not the least of which are financial.

Russian Vaccine Sputnik V. Perhaps the true dark horse in the vaccine race is the Russian vaccine named *"Sputnik V"* which promises the best of both worlds – a near perfect efficacy and a price of US$10, putting it at the low end in price. Russia plans to launch its vaccine in the international market in January of 2021 and hopes to have 500 million doses available. The vaccine, which was financed by the state-owned Russian Direct Investment Fund (RDIF) is aimed at providing a lower cost vaccine for worldwide consumption to undercut the Pfizer and Moderna candidates while competing on efficacy of 92%.

Sputnik V was the first COVID-19 vaccine to receive approval and received EUA from the Russian government in August of 2020. It was based solely on a Phase I/II study of 76 patients. While the Johnson & Johnson and AstraZeneca candidates use single adrenovirus platforms, *Sputnik V* uses two distinct adrenovirus vectors. The Moderna and Pfizer candidates both use the more-established messenger RNA platforms.

The RDIF said it has received requests for more than 1.2 billion doses of the vaccine from more than 50 countries. The vaccine supplies for the global market will be produced by international partners in India, Brazil, China, South Korea and other countries.

Sputnik V's existing formulations must be kept at -18°C or below when in storage or transportation, which could be a barrier to some regions of the world. Currently RDIF and partners have launched production of a lyophilized (freeze-dried) formulation that can be stored at +2°C to +8°C, allowing for easier transportation and storage in some international markets.

In Brief (cont.)...

- **Walgreens** has won the "Health and Wellness" category in the **U.S. Chamber of Commerce Foundation** *2020 Citizens Awards*. The annual awards highlight how businesses are helping solve today's greatest challenges and spearheading the transformation to a strong, healthy and sustainable future. Walgreens was recognized for *Get a Shot. Give a Shot.*, the company's eight-year collaboration with the United Nations Foundation, which has helped provide more than 60 million lifesaving vaccines to women and children in some of the world's poorest regions. For every immunization given at a Walgreens store or clinic or Duane Reade store – up to a limit each year - Walgreens donates the value of an immunization to the **UN Foundation's** *Shot@Life* program.
- **McKesson Corporation** announced *Dr. Kelvin A. Baggett* has been appointed to the newly created role of chief impact officer, effective November 30, 2020. As chief impact officer, Dr. Baggett will have global responsibility for McKesson's strategy and execution related to Diversity, Equity and Inclusion (DEI), sustainability and Environmental, Social, and Governance (ESG) strategy, community relations, social impact and philanthropy through the McKesson Foundation.
- The anti-inflammatory drug *colchicine* is set to be investigated in the UK's RECOVERY trial, which is testing treatments for patients hospitalized with COVID-19. *Colchicine* has been included in the trial as it has a range of anti-inflammatory effects and is often used to treat gout and other inflammatory conditions. Severe COVID-19 often presents with inflammation resulting in lung damage, the need for mechanical ventilation and death. The decision to add *colchicine* was made by researchers from the **University of Oxford** and a trial steering committee in conjunction with the UK's chief medical officer, following a recommendation by the *UK COVID'19 Therapeutics Advisory Panel*. Researchers are expecting at least 2,500 patients within the RECOVERY trial to be randomly allocated to receive *colchicine* plus standard-of-care.

(Sources: Drug Store News, FierceBiotech, FiercePharma Pharma Times, World Pharma News and Scrip Intelligence)