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Japan Grants Emergency Use Approval for Additional COVID-19 Vaccine Candidates

(Sources: An article by Ian Haydock for Scrip Intelligence and an article by Japan Today)

The Japanese government has granted emergency use approvals for two more COVID-19 vaccines, expanding what has been to this point a limited arsenal against the pandemic.

An expert advisory panel has given positive recommendations for the Moderna/Takeda Pharmaceuticals vaccine as well as the candidate developed by AstraZenecaPLC and University of Oxford. The vaccines were granted special approval by Japan's Ministry of Health, Labour and Welfare under its Pharmaceuticals and Medical Devices Act covering emergency use following approval applications submitted in early March and early February, respectively.

The new approvals are added to one given to the Pfizer/BioNTech mRNA vaccine which was approved for emergency use on February 14th and recently also received approval in use for those 12 to 15 years of age. (The green light has also been given to the Pfizer vaccine for an extended maximum storage period at temperatures between 2° and 8° C to one month from five days.) Following early administration to priority recipients such as healthcare workers, the Pfizer/BioNTech vaccine is just now being made available to the public, but only those over the age of 65. The government's goal is to have those in 65+ age group (approximately 36 million) inoculated by the end of July and ramp up the number of shots to one million a day nationwide. The new approvals should be a critical step in reaching this goal.

Thus far, vaccines have reached 3% of Japanese citizens (including healthcare workers) with their first doses. In the U.S. and U.K., approximately 30-40% of their populations have received their full two-dose courses of the vaccines. The delay in Japan is due to local clinical trials conducted to confirm the safety and efficacy in Japanese patients, regardless of emergency designation.

The reported cases of total infections and deaths in Japan remains comparatively low at approximately 698,000 and 12,000, respectively. Delays in vaccine availability have been the subject of public scrutiny in recent weeks, particularly given that other populations are now reopening.

The AstraZeneca/Oxford vaccine may not be used in the public campaign for now, given the adequate contracted supplies for the other two approved mRNA vaccines. In total, the Japanese government has signed deals for 194 million doses of the Pfizer vaccine and 50 million doses of the Moderna/Takeda vaccine. Additionally, 120 million doses of the AstraZeneca vaccine have been contracted. This total more than enough to administer two doses to its roughly 126 million population.

The Moderna mRNA vaccine (coded *TAK-919* by Takeda) was based on positive clinical data from Takeda's local placebo-controlled Phase I/II clinical study which showed an immune response consistent with Moderna's U.S. Phase III COVE trials

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In Brief...

- **IQVIA** announced the expansion of *IQVIA Biotech*, a tailored approach to delivering integrated clinical and commercial solutions for biotech and emerging biopharma companies in Japan and Asia. The solution involves lean operating procedures and scientific specialization, and is powered by IQVIA's technology-enabled services designed to assist innovative companies reach their drug development and commercialization milestones, the company said in a press release.
- **Walgreens Boots Alliance (WBA)** has completed the sale of its **Alliance Healthcare** business unit to **AmerisourceBergen (ABC)** for US$6.5 billion. "We are excited to complete the acquisition and extend a warm welcome to the talented team at Alliance Healthcare, "ABC chairman, president and CEO *Steven Collis* said. "The acquisition of Alliance Helathcare expands our reach and solutions in pharmaceutical distribution and adds to AmerisourceBergen's breadth and depth of global manufacturer services. With alliance Healthcare, we will advance our ability to provide innovate and global healthcare solutions and further our purpose of being united in our responsibility to create healthier future. "Completion of this transaction represents a significant step forward in our transformation and will fuel investments to grow WBA's core retail pharmacy and healthcare businesses, WBA CEO *Rosalind Brewer* said. "Through these and other investments, WBA looks to bring even more innovative healthcare offerings to our customers and patients, as we further accelerate our strategic priorities."
- **Johnson & Johnson** is working to assist in restarting **Emergent's** Baltimore manufacturing facility after contamination problems involving J&J's COVID-19 vaccines caused the facility to be shut down. J&J says the contamination issues have been resolved paving the way for a restart and potential release of millions of Emergent-made vaccine doses.
- **McKesson Corporation** will combine **RelayHealth, McKesson Prescription Automation**, **CoverMyMeds** and **RxCrossroads by McKesson** under one brand using the CoverMyMeds umbrella. The unification is part of McKesson's ongoing investment in the CoverMyMeds brand and aims to improve the experience for patients, customers, and employees. The company expects accelerated growth for the brand in 2021.
- The **Federation of Japan Wholesalers Association (JPWA)** announced that *Ken Suzuki* will return to the helm of

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Japan (cont.)...

in the 200 study participants. The participants were aged 20 and older and received two 0.5mL doses 28 days apart in the treatment arm.

Interim analysis also showed binding antibody and neutralizing antibody titers to be elevated 28 days after the second dose in 100% of vaccine recipients, with no significant safety concerns reported. There will be a 12-month follow-up after the second dose. Additionally, Takeda has stated its intention to publish additional data in a peer-reviewed journal.

Takeda plans to immediately begin distribution of batches that were already imported into the country from Belgium at the end of April in anticipation of the approval. It expects to distribute more than 50 million doses contracted under its October 2020 agreement with Moderna and the Japanese Ministry of Health in the first half of 2021. Current plans call for the Moderna product to be used at new, large-volume government-run injection sites being set up in Tokyo and Osaka which will be staff by primarily military medical personnel. Similar sites are being set up by Prefectural and local goverments that will also make use of the Moderna vaccine.

Additionally, Takeda has entered into a collaboration to develop, manufacture and commercialize within the country Novavax Inc.'s COVID-19 candidate once approval is given.

Approved vaccines are available free of charge to recipients under Japan's national COVID-19 immunization program.

Positive Results for COVID-19 Monoclonal Antibody Treatments Show Promise

(Sources: A press release by the U.S. Food and Drug Administration, an article by Angus Liu for FiercePharma, and an article by Scrip Intelligence)

Good news is on the horizon with several new treatments for COVID-19 passing major milestones. These treatments show incredible promise in fighting the virus which, to date, has claimed the lives of approximately 3.5 million people worldwide.

The U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy *sotrovimab* by GlaxoSmithKline and Vir Biotechnology. *Sotrovimab* is for mild-to-moderate cases of COVID-19. Use of the drug is limited to patients who are not hospitalized but are at high risk of progressing to severe disease.

The antibody proved its worth in a Phase III trial. Interim analysis of the "Comet-Ice" study found *sotrovimab* reduced the number of patients who died or needed hospitalization by 85% over placebo. The two companies are now evaluating the trial data and plan to file the drug for a full FDA approval in the second half of the year. The antibody drug also received backing from the European Medicines Agency, which opens the potential for emergency adoptions in EU member states ahead of a formal green light.

"With the authorization of this monoclonal antibody treatment, we are providing another option to help keep high-risk patients with COVID-19 out of the hospital," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "It is important to expand the arsenal of monoclonal antibody therapies that are expected to retain activity against the circulating variants of COVID-19 in the U.S."

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. *Sotrovimab* is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2 and is designed to block the virus' attachment and entry into human cells. Based on the FDA's review of the totality of the scientific evidence available, the agency determined that it is reasonable to believe that *sotrovimab* may be effective in treating adults and certain pediatric patients with mild-to-moderate COVID-19.

Despite the strong trial showing, the drug's commercial value remains in question. The new go-ahead comes as roughly 40% of the U.S. population has been fully vaccinated and as earlier-to-market antibody cocktails by Regeneron and Lilly reportedly go unused because of low demand.

Still, Adrienne Shapiro, M.D., Ph.D., of Fred Hutchinson Cancer Research Center, an investigator in the Comet-Ice trial, believes having additional options is necessary. "While preventive measures, including vaccines, can reduce the total number of cases, *sotrovimab* is an important treatment option for those who become ill with COVID-19 and are at high risk—allowing them to avoid hospitalization or worse," she said in a statement.

Regeneron's antibody cocktail *REGEN-COV (casirivimab/imdevimab)* Phase III trial results showed a significant reduction in the risk of hospitalization or death, shortened symptom duration and reduced viral load in non-hospitalized patients with COVID-19. The study included 4,567 high-risk outpatients with the virus who received two doses of the cocktail – one 2,400 mg dose and one 1,200mg dose – and is under evaluation by the FDA. It is being used as a complement to the widespread vaccination strategy. If approved, Regeneron would be able to provide a significant amount of additional product.

Additionally, Regeneron and Lilly have signed supply deals for their respective antibodies with the U.S. federal government, both covering potentially 1 million-plus doses of their COVID-19 treatment products. GSK and Vir have yet to sign a contract with the U.S. government and will have to sell *sotrovimab* on their own. Recognizing that government contracts are "a defined route" for patients to access COVID treatments, GSK has been in ongoing conversations with governments around the world, including in the U.S., a company spokesperson said in a statement. For now, it's working through existing commercial channels.

In Brief (cont.)...

the organization as its Chairman. Mr. Suzuki served for three prior terms and is returning after a two-year hiatus. Mr. Suzuki is also the current Chairman of IFPW, serving on the IFPW board since 2018.

- COVID-19 vaccine manufacturer **Moderna** has initiated the rolling submission process with the **U.S. Food and Drug Administration** for a Biologics License Application (BLA) for the licensure of its mRNA vaccine for individuals 18 years of age and older. The company will continue to submit data to support the BLA on a rolling basis over the coming weeks with a request for priority review. Additionally, Moderna tapped **Samsung Biologics** for commercial fill-finish duties for its mRNA-based COVID-19 vaccine. The companies plan to start delivering doses from the CDMO's Incheon, South Korea, facilities for countries other than the U.S. in the third quarter. The news came shortly after Moderna said it would set up a commercial subsidiary in South Korea later this year.

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