

COVAX Facility Efforts Garner Significant Worldwide Support

(Source: Press Release by GAVI, the vaccine alliance)

Sixty-four higher income economies have now joined GAVI, the vaccine alliance's COVAX Facility, with an additional 38 economies expected to sign in the coming days. These self-financing economies, which include 29 from Europe participating as part of an agreement with the European Commission, join 92 lower income economies eligible for financial support through the GAVI COVAX Advance Market Commitment (GAVI COVAX AMC). These 156 economies represent 64% of the global population who are now committed to or eligible to receive vaccines through the COVAX Facility.

By pooling financial and scientific resources, participating economies will be able to insure themselves against the failure of any individual vaccine candidate and secure successful vaccines in a cost-effective and targeted way.

With the commitment agreements secured, the COVAX Facility will now start signing formal agreements with vaccine manufacturers and developers, who are partners in the COVAX effort, to secure the doses needed to end the acute phase of the pandemic by the end of 2021. This is in addition to an ongoing effort to raise funding for both R&D and for the procurement of vaccines for lower-income countries via the Gavi COVAX AMC.

"COVAX is now in business. Governments from every continent have chosen to work together, not only to secure vaccines for their own populations, but also to help ensure that vaccines are available to the most vulnerable everywhere," said Dr Seth Berkley, CEO of GAVI, the vaccine alliance. "With the commitments we're announcing today for the COVAX Facility, as well as the historic partnership we are forging with industry, we now stand a far better chance of ending the acute phase of this pandemic once safe, effective vaccines become available."

The COVAX Facility is part of COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, which is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), GAVI, and the World Health Organization (WHO) working in partnership with developed and developing country vaccine manufacturers, UNICEF, the World Bank, civil society organizations and others.

The allocation of licensed and approved vaccines will be guided by an Allocation Framework released by the WHO following the principle of fair and equitable access, ensuring no participating economy will be left behind. Policies determining the prioritization of vaccine rollout within economies will be guided by recommendations from the WHO Strategic Advisory Group of Experts on Immunization (SAGE), which recently released a Values Framework laying the groundwork for subsequent guidance on target populations and policies on vaccine use.

"COVID-19 is an unprecedented global crisis that demands an unprecedented global response," said WHO Director-General,

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- ◆ The **European Commission, Sanofi and GlaxoSmithKline** have signed an Advanced Purchase Agreement to supply up to 300 million doses of a COVID-19 vaccine once it is approved. The final agreement confirms the announcement made on July 31 by both companies.

- ◆ The **Russian Direct Investment Fund (RDIF)** partnered with **Dr. Reddy's** to supply Russia's *Sputnik V* vaccine in India. RDIF maintains that the vaccine will provide a "safe and scientifically validated" option for India in the battle against COVID-19.

- ◆ Japan's ethical drug sales fell 4.9% in July year-over-year (less one business day) on a wholesaler shipment basis, according to a report released by **Crecon Research & Consulting**. The drop is attributed to patients avoiding medical institutions amid the COVID-19 outbreak and a slump in sales of originator drugs following generic launches in June.

- ◆ The **U.S. Department of Health and Human Services** will allow pharmacies to administer COVID-19 vaccines. State-licensed pharmacists will be authorized to order and administer the vaccinations to patients three years and older, and state-licensed pharmacy interns working under a pharmacist's supervision will also administer the vaccine to the same age group, subject to certain requirements. This follows efforts by the **American Pharmacists Association (APhA)** and the **National Association of Chain Drug Store's (NACDS)**

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IFPW Holds Webinar on Stockpiling and COVID Vaccine Distribution Strategies

On September 23rd, IFPW hosted its second webinar of the year, focusing on pharmaceutical stockpiling and possible strategies being considered once an approved COVID-19 vaccine reaches the market.

The webinar, in partnership with IQVIA, featured Doug Long, Vice President of Industry Relations for IQVIA, as well as IQVIA's Vice President of Strategic Partners, Per Troein. Mr. Long spoke gave a concise and timely presentation on the impact of COVID-19 on the pharmaceutical supply chain, and Mr. Troein followed up with insights and perspectives on stockpiling as "insurance" for the world's drug supply.

IFPW Executive Vice President, Chris Goetz, and Vice President of Member Engagement, George Bray also gave an overview of results from a survey conducted by IFPW on the global vaccine distribution landscape. IFPW members were interviewed to collect information on how countries around the world are dealing with cold chain supply requirements, how the vaccine will be distributed, perceptions by country populations on efficacy and safety of the vaccine and when the vaccine might be available.

Following IFPW's presentation of survey results, industry panelists, including Shawn Seamans of McKesson Corporation,

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COVAX Facility (cont.)...

Dr. Tedros Adhanom Ghebreyesus. "Vaccine nationalism will only perpetuate the disease and prolong the global recovery. Working together through the COVAX Facility is not charity, it's in every country's own best interests to control the pandemic and accelerate the global economic recovery."

The commitment of fully self-financing economies - which began on September 15th with a public commitment by Japan - will now unlock vital funding and the security of demand needed to scale up manufacturing and secure the doses needed for the facility. CEPI is leading COVAX vaccine research and development work, which aims to develop at least three safe and effective vaccines that can be made available to economies participating in the COVAX Facility.

Approximately US\$700 million in sovereign funds have been raised, including philanthropic and private sector donations against the initial target of US\$2 billion in seed funding needed by the end of 2020.

Pfizer Moves Forward with a Leaner R&D Business Model for 2020-2025

(Source: An article by Jessica Merrill for Scrip)

At a two-day virtual research and development conference held 14-15 September, Pfizer Inc. unveiled a new research and development goal of "25 by 2025" promising investors that the company is on track to launch 25 new drugs by 2025, driving Pfizer's growth through the next five years and beyond as the company reaches its next big patent cliff.

Many of the new drugs are expected to launch in late 2023 or after. Among the near-term opportunities, *tanezumab* (pending U.S. Food and Drug Administration (FDA) approval for osteoarthritis pain) has a complicated risk/benefit profile and is partnered with Eli Lilly & Company. Also on the horizon is Pfizer's 20-valent pneumococcal vaccine due to be filed with the FDA in October, but will largely replace the company's current blockbuster 13-valent *Prevnar*.

Management outlined how Pfizer expects to reach a previously-disclosed goal to achieve a compound annual growth rate of at least 6% and double-digit earnings per share growth from 2020-2025. The company also showcased products that will hopefully fill a potential US\$18 billion – US\$20 billion gap beginning in 2026, due to exclusivity loss for blockbuster brands like *Eliquis* (*apixaban*), *Xeljanz* (*tofacitinib*) and *Ibrance* (*Palbociclib*).

Pfizer's current pipeline will be able to at least replace the lost revenues from patent expirations. CEO Albert Bourla reiterated his interest in bringing in mid-stage assets that are in Phase II development, or Phase III-ready.

Pfizer's R&D engine has gone through somewhat of a transformation over the last decade that began in 2010 under then-CEO Ian Read. This transformation has accelerated over the last 18 months under Bourla's leadership.

"The increased R&D productivity as well as the depth and breadth of our pipeline gave us the confidence to move so quickly over the past year to transform into the new Pfizer," he said. "The new Pfizer will be very different. It will combine the agility and innovative spirit of a biotech with the scale of a big pharma."

COVID-19 has given Pfizer an opportunity to showcase this nimbler reincarnation, with the company now being a frontrunner in the race to bring a vaccine for COVID-19 to market – potentially within one year since the outbreak began. None of the company's

long-range financial forecasts include a COVID-19 vaccine or treatment, however. Company guidance will be updated if the products are proven to work in clinical trials. There were no material updates on the COVID-19 vaccine, developed in collaboration with BioNTech which is in Phase III development and has enrolled to the trial's 30,000 patients; the enrollment goal recently was increased to 44,000. About 12,000 patients have received a second dose, the firm said. Pfizer reiterated the expectation that data will be available in late October with no safety issues at this time.

Worldwide R&D president Mikael Dolsten outlined how the company's slimmer pipeline is already demonstrating better success rates. The pipeline now includes 54 new molecular entities with broader modalities and in five targeted therapeutic areas – oncology, inflammation/immunology, vaccines, rare diseases and internal medicine.

"We are confident that we are on the right road and have set an ambitious goal to put up to 25 breakthroughs in the hands of patients by 2025," he said. "Of those, 70% have passed Phase I clinical testing and 35% are in Phase III, registration or recently approved. This pipeline could deliver US\$35 billion-US\$40 billion in annual revenue-based on each product's peak sales."

IFPW Webinar (cont.)...

Heather Zenk of AmerisourceBergen, John Kallend of Walgreens Boots Alliance and Victor Soh of Merck, gave their professional insights into how their organizations are dealing with the fluid situation surrounding the vaccine, its distribution, cold chain challenges and timelines. Participants were given the opportunity to pose questions to the panelists at the end of the session.

There were 145 registrants for the webinar, which was also recorded for on-demand viewing. **If you would like information on how to view the recorded webinar, please contact Christina Tucker at c.tucker@ifpw.com.**

A follow-up webinar is planned for mid-November 2020. IFPW thanks its speakers and attendees for their valuable participation.

In Brief (cont.)...

advocating for such measures.

- ♦ The governments of India and Pakistan have ramped up production of the coronavirus drug *remdesivir* in partnership with Gilead Sciences. Thus far, 800,000 doses of *remdesivir* have been delivered since the start of production in June.

- ♦ **Eli Lilly and Company** and **Amgen** announced a global antibody manufacturing collaboration to significantly increase the supply capacity available for Lilly's potential COVID-19 therapies. The two companies will be able to scale up production of several potential neutralizing antibodies currently being studied for the prevention and/or treatment of coronavirus.

- ♦ **Walmart** has teamed with drone technology provider **Zipline** to make for on-demand deliveries of health and wellness items, and potentially expand to general merchandise. In its newest drone delivery pilot, Walmart will make trial deliveries near its headquarters in northwest Arkansas using Zipline's proprietary technology, enabling on-demand delivery in under an hour. The retailer expects to commence the pilot in early 2021, servicing a 50-mile radius with expansion to other areas if successful.

(Sources: Company Press Releases, Drug Store News, Financial Times, Pharma Japan, and Scrip)