

COVID-19 Pandemic – One Year and Ten Vaccines Later

(Source: A staff article by Scrip Intelligence)

It has been a long and difficult year on Planet Earth. Very long. To date, more than 120 million people worldwide have been infected by the virus, and over 2.6 million people have died due to COVID-19.

As the world reflects back on 11 March 2020 when the World Health Organization declared the SARS-CoV2 virus a global pandemic, it is promising that millions of people have had a least one vaccination against COVID-19 and more are now fully vaccinated. Immunizations are performing as intended by reducing deaths for at-risk groups (as shown in dropping infection rates) in those countries that are working fervently to vaccinate their citizens.

By and large these vaccinations have been administered in a small number of developed nations, leaving a significant gap in the majority of the world's 7.6 billion people who still require inoculation. This requires the pharmaceutical sector, governments, and non-governmental organizations to collaborate and support ramped up efforts for vaccine manufacturing and distribution.

While the news regarding vaccinations is overwhelmingly positive, further vaccine authorizations are also required, along with the development of booster shots and "tweaked" vaccines to meet the challenge of the emergence of variants of COVID-19, which have emerged in the UK and South Africa. Several of the vaccines have proven effective against these variants, which is promising.

Some countries like Israel have been very successful in moving to vaccinate individuals as soon as vaccines received emergency use authorization (EUA). Israel's Ministry of Health (MoH) launched a massive campaign to distribute vaccinations as quickly as possible as infection rates surged and the country was once again locked down on January 8th (which has since been lifted.) To date, the MoH has vaccinated 6.4 million people, approximately 71% of their total population aged 16 and older. The MoH also announced that the Pfizer BioNTech vaccine has demonstrated real-world evidence that it dramatically lowers the incidence rates of COVID-19 in fully vaccinated individuals. The new data builds upon and confirms previously released data from the MoH regarding the Pfizer/BioNTech vaccine's effectiveness. Latest analysis shows that two weeks after the second dose of the vaccine is administered, protection is even more effective in preventing symptomatic infections, and critical hospitalization and death. This information is invaluable to other countries as they advance their own vaccination campaigns.

It is also particularly promising that while Pfizer and Moderna have begun pediatric trials for children 12 years and older, the Serum Institute of India and Bharat Biotech have plans to begin testing its indigenous vaccines in children under the age of 12. These trials will be the first in this age group.

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In Brief...

- ◆ U.S. wholesaler and distributor **Cardinal Health** is divesting itself from **Cordis**, its business focused on manufacturing cardiovascular devices. Cardinal has struck a deal with **Hellman & Friedman**, who will pay US\$1 billion, including assumption of certain liabilities and Cardinal's retention of certain working capital accounts. The deal is expected to close in the first half of Cardinal's fiscal 2022, subject to customary closing conditions and regulatory clearances. Cardinal Health acquired Cordis from Johnson & Johnson in 2015.

- ◆ **Eli Lilly** released trial data on its COVID-19 antibody combo (*bamlanivimab* and *etesevimab*) showing an 87% reduction in hospitalization and death versus placebo. The antibody combo drug also holds authorization from the **U.S. Food and Drug Administration** for patients at high risk of developing severe COVID-19. The new trial data further reinforces the FDA's authorization.

- ◆ The **European Commission** will propose an EU-wide digital certificate providing proof of a COVID-19 vaccination that could allow Europeans to travel more freely over the summer. The plan is for a "digital green pass" will provide proof that a person has been vaccinated, the test results of those not yet vaccinated, and information on recovery for people who have already contracted COVID-19. The aim of the program is to encourage cooperation with international organization to ensure its system also works beyond the EU. This will allow for EU citizens to move safely in the EU or abroad, for both work and tourism. Separately, the European Commission also endorsed **Johnson & Johnson's** "one and done" COVID-19 vaccine for use in EU countries. This will be the first one-dose option to win approval in the EU. Delivery of the first shipment of the J&J vaccine are expected in the second half of April.

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One Year Later (cont.)...

The COVAX program (a coalition involving the Coalition for Epidemic Preparedness Innovations, Gavi the Vaccine Alliance and the World Health Organization) is continuing efforts to ensure equitable distribution of COVID-19 vaccines that have received WHO's emergency use listing (EUL). In conjunction with key delivery partner UNICEF, it was recently announced that two versions of the AstraZeneca/Oxford vaccine (one produced by AstraZeneca and SKBioscience and the other produced by the Serum Institute of India) are now available for global rollout through the COVAX facility. Next steps will involve final Q1/Q2 allocations to COVAX participants.

The following combines statistics and information on the vaccines that have received authorization or are in phase 3 trials.

Company	Vaccine	1st EUA	EUAs	2021 Doses Forecast	Phase 3 Efficacy
Pfizer/BioNTech	Comirnaty (BNT162b2) (mRNA)	12/2/2020	US/EU/UK	2bn	95%
Moderna	MRNA-1273 (mRNA)	12/18/2020	US/EU/UK	700m-1bn	94%
Johnson & Johnson	Ad26.COV2.S (adenovirus)	2/27/2021	US	1bn	66%
Sinopharm (China)	Covid-19 vaccine	8/11/2020	China/Brazil	1.4bn	79%
Russia Direct Inv. Fund	Sputnik V (adenovirus)	8/11/2020	Russia/UAE/Hungary	1.4bn	92%
AstraZeneca/Oxford	AZ COVID-19 vaccine	12/30/2020	UK/EU/India/Brazil	3bn	62-90%
Bharat Biotech	Covaxin (BB152)	1/3/2021	India/Brazil	700m	81%
Sinovac	CoronaVac (inactivated)	2/6/2021	China/Brazil/Indonesia/Turkey	1bn	51%
CanSino Biologics	Convidicea	2/25/2021	China/Mexico	500m	66%
Wuhan Inst./Sinopharm	19 vaccine (inactivated)	2/25/2021	China	100m	73%
Phase 3 Pending					
Novavax	NVX-CoV2373 (protein)		US/UK/EU Rolling Review	1bn	89%
CureVac	(mRNA)			50m	Q2
AstraZeneca (US Study)	AZD1222 (adenovirus)			(see AZ/Ox entry)	Q2

Top 10 Drugs Losing Exclusivity in 2021

(Source: An article by Eric Sagonowsky for FiercePharma)

As drugmakers remain laser-focused on vaccines and therapeutics in response to the COVID-19 pandemic, many of their biggest sellers are losing patent exclusivity in 2021. Not all of the products with this challenge are guaranteed to face generic competition. Some may be saved from patent protection loss due to developments in the courts, regulatory setback and unforeseen events. But some are already facing generic rivals and biosimilars.

While this year's list features only one blockbuster, Bristol Myers Squibb's blood cancer drug *Revlimid* will face limited generics sometime after March of 2022 under a patent settlement between BMS and Dr.Reddy's Laboratories. BMS added the drug to its portfolio when it merged with Celgene in 2020. Likewise, AbbVie's immunology blockbuster *Humira* will not be forced to deal with biosimilar launches in 2021, it will be faced with challengers in 2023.

Some pharma manufacturers are managing to keep hold of their biggest hits. Novartis still enjoys market exclusivity for its big sellers *Gilenya* (used in the treatment of multiple sclerosis) and *Sandostatin LAR*, which is used to treat metastatic carcinoid

tumors. Regeneron's macular degeneration drug *Eylea* could face competition from biosimilars in years to come, but it is still not clear when. AstraZeneca just scored a patent win on *Symbicort* that could keep copycats at bay until 2023.

The list below is based on information from numerous sources, including lists of potential generic launches of OptumRx, GoodRx, GreyB. and Corporate Pharmacy Services, plus numerous company filings, conference calls with industry analysts, FDA records and more.

Top 10 Drugs Losing Exclusivity in 2021:

1. *Lucentis*
2. *Bystolic*
3. *Vascepa*
4. *Northera*
5. *Narcan*
6. *Brovana*
7. *Sutent*
8. *Saphris*
9. *Amitiza*
10. *Feraheme*

In Brief (cont.)...

◆ The government of India will manufacture **Johnson & Johnson's** single-dose COVID-19 vaccine as part of the first Quad Summit vaccine initiative. The project will be financed by Quad members Japan and the U.S., while Australia will use its logistics capabilities to ship the vaccines to Southeast Asia and Pacific countries. In the first-ever Quad summit between the U.S., Japan, Australia and India, the participating countries will use their current initiatives to provide vaccines to dozens of other countries.

◆ An experimental COVID-19 drug is showing promise to be a kind of *Tamiflu* for the COVID-19 pandemic, as demonstrated in a preliminary study. The pill, in development under partnership between **Ridgeback Biotherapeutics LP** and **Merck**, significantly reduced infectious virus in subjects in a mid-stage study after five days of treatment. Further studies of the antiviral are under way, and if effective, it would be the first oral treatment in a growing arsenal of therapeutics for COVID-19.

◆ Under the U.S. Production Act, **Merck** has received funding of US\$268.8 million (including US\$105 million initial investment) from the U.S. government to manufacture **Johnson & Johnson's** single-dose COVID-19 vaccine and other therapeutics at two of its U.S. production plants. The **U.S. Department of Health and Human Services** stated that retrofitting of certain U.S. Merck facilities is being done under the agreement with The **U.S. Biomedical Advanced Research and Development Authority (BARDA)** to provide large-scale manufacturing.

◆ Scientists at the **Nanyang Technological University** in Singapore have created a compound that could reduce overactivation of the human immune response that causes the body to injure itself. The compound, called *ASO-1*, may be an effective treatment against rheumatoid arthritis, type 1 diabetes and even severe COVID-19 infections. With respect to COVID-19 infection, the immune system can signal the body to ramp up protein production to dangerous levels, leading to damage to the body's own cells. The findings were published in February in the scientific journal *ImmunoHorizons*.

(Sources: Company Press Releases, FiercePharma, FierceBiotech, Drug Store News, Scrip Intelligence and World Pharma News)