COVID-19 Fact Sheet – Vaccines & Treatments

Background information for media briefing

NB: All facts that are not directly cited are from Airfinity (8 April) or directly from represented companies

COVID-19 vaccines

State of COVID-19 approvals to date and candidates in clinical trials

- 10 vaccines have received WHO EUL approval[1], 271 in pre-clinical, 147 in clinical, 9 discontinued, and 6 rejected. According to WHO, 196 in preclinical and 153 in clinical[2].
- 11 preclinical candidates were announced this week, including two Omicron-specific candidates. The candidate Merah Putih from Indonesia progressed to phase II. Sanofi/GSK Vaccine completion of Phase III Q2 2023.
- Pfizer and Moderna are testing bivalent Omicron and wild-type vaccines in response to Omicron.
- Both Pfizer and Moderna went from virus sequencing to clinical candidate in approximately 60 days.
- Moderna is working on both a combined Flu/COVID and a combined Flu/COVID/RSV vaccine.

State of COVID-19 vaccine production and absorption to date

- 13.7 billion doses delivered to date in total[3], and 11 billion administered.
- COVAX have delivered 1.39 billion doses to 145 countries. 82.16% of COVAX deliveries by end of February came from AZ, Pfizer, J&J, Moderna.
- Of the over 13 billion doses delivered, 2.25 billion doses are being held in stock, of which 1.035 billion doses are in low- and lower-middle income countries (LMIC). Available stock of COVID-19 vaccines in Europe is reaching 350 million doses.
- The manufacturing scale-up from zero to over 13 billion doses in 16 months since the first vaccine was given emergency approval has been achieved thanks to 372 partnerships, of which 88% (329) include technology transfer or fill & finish. 51 manufacturing and production agreements were made in developing countries (LICs and LMICs).
- Since mid-2021, global vaccine production has exceeded global vaccine demand (vaccinations) and this gap has continuously risen, peaking at ~20% at the end of 2021 (~1.7 billion doses).
- On 4 April, SSI and Bharat Biotech halted COVID-19 vaccine production, which will impact production forecasting[4][5].

COVID-19 vaccine production and demand in 2022 and 2023

- More than 7.98 billion doses could be produced in 2022.

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[1] https://covid19.trackvaccines.org/agency/who/
[2] https://www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape
[3] https://www.unicef.org/supply/covid-19-vaccine-market-dashboard
[4] https://www.biospace.com/article/covid-update-india-s-top-vaccine-makers-halt-covid-19-vaccine-production-and-more/#:~:text=India's%20Two%20Vaccine%20Makers%20Halt,stopped%20manufacturing%20COVID%2D19%20vaccines
[5] https://www.business-standard.com/article/companies/covid-vaccine-firms-halt-production-as-demand-slips-focus-on-non-covid-vax-122040400024_1.html

- Pfizer/BioNTech is expected to account for over 30% of the 9 billion COVID-19 vaccine doses that could be produced in 2022. IFPMA member companies are forecasted to produce at least 53 percent of vaccines in 2022 (32% Pfizer, 10% AstraZeneca, 8% Moderna, 3% J&J).
- Global vaccinations are slowing and may be trending towards a middle-bound demand scenario of ~6 billion doses in 2022. Some leading COVID-19 vaccine manufacturers, including AstraZeneca, Sinovac, Sinopharm and Moderna, have started to experience a plateau in production over this week. The Serum Institute of India Ltd., the country's main supplier that produced 2 billion Covid shots last year, halted manufacturing in December after a lack of orders.
- Orders for 2023 based on demand might go down from the peak of annual production in 2021 at 11 billion, to 7.98 billion in 2022, where global vaccine production in 2022 might exceed demand (lower bound demand 4.3bn, middle bound demand 6bn, upper bound demand 7.78bn). In 2023, global vaccine output may be lower still with estimates for vaccines orders ranging from 2.2 to 4.4 billion, putting the focus on country readiness to ensure vaccines become vaccinations.

COVID-19 Treatments

Overview of available treatments and those in clinical trials

- There are 18 different treatments approved for the treatment of COVID-19 across the U.K, U.S. and E.U. (See Annex)
- There have been over 5500 publications and 4500 newly registered clinical trials for COVID-19 treatment since the start of the pandemic.
- Airfinity estimates 1,827 treatment candidates being investigated as COVID-19 treatments or prophylaxis, 1,016 of which are in clinical trials.

Company agreements on IP or access

- Pfizer to supply 4 million Paxlovid courses to UNICEF in 2022 and 36 manufacturers have been granted sublicences for Paxlovid through the MPP, for distribution to 100+ LMIC incl. Generic manufacturer locations include India, China, Bangladesh, South Korea, Pakistan, Serbia, Israel, Jordan, Mexico, Dominican Republic, Vietnam. Generic manufacturers are expected to export to broader market in late 2022-early 2023.
- Roche is providing a significant portion of Actemra/RoActemra intravenous (IV) supply at cost to WHO and ACT-A partners to distribute in line with public health needs
- Roche is overcoming industry-wide supply challenges as the pandemic has evolved, including dedicating their largest manufacturing facilities exclusively to producing COVID-19 medicines and working with partners to transfer technologies to maximize production. Roche's Tocilizumab is being manufactured by Novartis (API, Singapore), Chugai (complete treatment, Japan), Cipla (Distribution, India), Hetero (complete treatment, India), Genentech (complete treatment, US). Roche recently announced Tocilizumab production has tripled from 2021 to 2022.
- Lilly has utilized the full force of its expertise to develop the first monoclonal antibody authorized for Emergency Use (EUA) by the U.S. Food and Drug Administration (FDA) – bamlanivimab, followed by the authorization of bamlanivimab with etesevimab and, most recently, bebtelovimab.[6]
- Lilly donated approximately 100,000 doses of bamlanivimab alone or bamlanivimab with etesevimab to nine low- to lower-middle-income countries (LMIC).

[6] https://investor.lilly.com/news-releases/news-release-details/lillys-bebtelovimab-receives-emergency-use-authorization

- Lilly announced access and affordability principles for monoclonal antibodies: treatment will be allocated based on unmet medical needs globally; patients should have no out-of-pocket costs for our antibody treatments, wherever possible; and that government pricing will be tiered based on a country's ability to pay [7]
- In addition, Baricitinib, an oral JAK inhibitor already widely available around the world was approved for emergency use in 15 countries.
- Lilly entered into royalty-free, limited, non-exclusive voluntary licensing agreement with Lupin, Cipla, Sunpharma, Natco Pharma for manufacturing and selling of Lilly's treatment Baricitinib in India.
- Lilly is accelerating Baricitinib's availability in India following receipt of permission for restricted emergency use as a COVID-19 therapy via donations and licensing agreements[8]
- To further underscore Moderna's commitment to LMICs, and as part of the Company's continued support to achieving global health equity, Moderna will not enforce its patents for COVID-19 vaccines against manufacturers in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries.

For more information on company activities – please check the IFPMA COVID-19 Hub - IFPMA-

Testing

Overall market

- As of mid-September 2021, there have been more than 220 million confirmed cases of COVID-19 and nearly 4.7 million deaths from the virus. Every continent except Antarctica has been affected.
- There is a marked diversity of testing capacity for COVID-19 around the world.[9]
    - Sub-Saharan countries perform less than 1 COVID-19 test per day per 10,000 people.
    - Other countries, such as EU countries, US, Australia, Canada, UK, perform between 10 and 200 daily COVID-19 tests per 10,000 people.
    - Since the start of the pandemic, Austria performed almost 20 tests per person, Denmark over 10 per person, the UK and Greece performed over 7,000 tests per 1,000 people. Niger, Yemen, Chad, Sudan, Madagascar, Burkina Faso, Central African Republic, performed less than 20 tests per 1,000 people.

Roche

- In 2021, more than 27 billion tests were conducted with Roche products. This includes more than 320 million tests to diagnose SARS-CoV-2 infections or measure related antibodies.
- More than 1.2 billion COVID-19 tests shipped since the beginning of the pandemic. This figure includes a total of 16 products: PCR-, rapid-, self- and antibody tests (Status Jan 2022).
- Over the past two years, Roche has invested in production capacity and significantly ramped-up COVID-19 test supply across 3 continents, with investments over 600m CHF, over 1000 new employees hired, and 90 new manufacturing lines.
- Since the pandemic outbreak, Roche has more than doubled the installed base for the high-throughput instruments (cobas 6800/8800) that run the lab-based PCR tests. In 2021, 1772 cobas 6800/8800 systems were installed.

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[7] CEO Dave Ricks on Our Principles of COVID-19 Antibody Therapy Pricing and Access | Eli Lilly and Company

[8] https://investor.lilly.com/news-releases/news-release-details/lilly-accelerating-baricitinibs-availability-india-following

[9] https://ourworldindata.org/grapher/daily-tests-per-thousand-people-smoothed-7-day; https://ourworldindata.org/grapher/full-list-cumulative-total-tests-per-thousand-map; https://ourworldindata.org/coronavirus-testing

An enabling environment, with pathogen sharing and fully functioning regulatory authorities, supports COVID-19 responses

- **Pathogens:**
  - More than 10 million Covid-19 sequences shared on GISAID as of 5 April[10]. In the wake of omicron being detected in South Africa, GISAID, in just one week in December 2021[11], processed more data than they had to process in the entire year 2020.
  - December 2021 marked the first month during which over one million hCoV-19 genomes have been submitted, processed, and released in GISAID's EpiCoV. GISAID has since added over one million genomes monthly.
- **Regulatory:** Fewer than 30% of the world's regulatory authorities are considered fully functioning and operational, e.g. 140 countries. This represents a major regulatory barrier for vaccines and treatments.[12]

[10] https://www.gisaid.org/

[11] 311,774 genome sequence between 10-Jan to 31-Dec 2020 (356 days); 310,635 genome sequence between 02-Dec to 09-Dec 2021 (7 days) *all times UTC*

[12] https://www.who.int/news/item/30-03-2022-egypt-and-nigeria-medicines-regulators-achieve-high-maturity-level-in-who-classification-and-who-launches-list-of-regulatory-authorities-that-meet-international-standards

Annex

Approved COVID-19 treatments

I. Remdesivir (Gilead) – Antiviral – U.S./U.K./E.U.
II. Molnupiravir (Merck) – Antiviral – U.K./U.S./E.U.
III. Paxlovid (Pfizer) – Antiviral – U.K./U.S./E.U.
IV. Convalescent Plasma – Antibody (Passive immunotherapy) – U.S.
V. Ly-CoV555 (Eli Lilly) – Antibody (Passive Immunotherapy) – E.U./U.S.
VI. Ly-CoV Combo (Eli Lilly) – Antibody (Passive Immunotherapy) – U.S./E.U.
VII. Ly-CoV1404 (Eli Lilly) – Antibody (Passive Immunotherapy) – U.S.
VIII. REGEN-COV (Regeneron) – Antibody (Passive Immunotherapy) – U.K./U.S./E.U.
IX. Sotrovimab (GSK/Vir) – Antibody (Passive Immunotherapy) – U.K./U.S./E.U.
X. CT-P59 (Celltrion) – Antibody (Passive Immunotherapy) – E.U.
XI. AZD7442 (Astra Zeneca) – Antibody (Passive Immunotherapy) – U.K./U.S./E.U.
XII. Dexamethasone – Steroid – U.K./U.S./E.U. Hydrocortisone – Steroid – U.K./U.S./E.U.
XIII. Methylprednisolone – Steroid – U.K./U.S./E.U.
XIV. Hydrocortisone – Steroid – U.K./U.S./E.U.
XV. Baricitinib (Eli Lilly) – Anti-inflammatory or immunomodulator – U.S.
XVI. Anakinra – Anti-inflammatory or immunomodulator – E.U.
XVII. Sarilumab (Sanofi) – Antibody (Antiinflammatory) – U.K.
XVIII. Tocilizumab (Roche) – Antibody (Antiinflammatory) – U.S./U.K

Overview of treatments recommendations