OPPI

Organisation of Pharmaceutical Producers of India

Vaccines and Therapies from OPPI Member Companies to support the country in its fight against COVID-19

VACCINES

AstraZeneca

AstraZeneca has partnered with Serum Institute of India, the world's largest vaccine manufacturer, for manufacturing vaccine AZD1222 named "Covishield" in India. Subsequently, Serum Institute of India obtained Emergency Use Authorisation from Indian regulators for Covishield in January, 2021.
The Serum Institute of India is currently producing over 60 million doses of the vaccine a month at its Pune facility. In the meantime, AstraZeneca is working with its global partners to continue building manufacturing capacity of up to three billion doses of the vaccine globally in 2021 on a rolling basis.[1]

Developed out of a global Oxford-AstraZeneca collaboration, the vaccine has shown 70.4 per cent efficacy in international clinical trials. The vaccine is made from a weakened version of a common cold virus (known as an adenovirus) of chimpanzees, and modified to look more like coronavirus sans causing COVID illness. Covishield is administered in two doses between four and 12 weeks apart. Once injected into the human body, the vaccine triggers the immune system to produce antibodies that can attack coronavirus infections.

astrazeneca.in @AstraZenecaIn

Johnson & Johnson

Johnson & Johnson is collaborating with Indian vaccine maker Biological E. Limited for manufacturing its single-dose Janssen COVID-19 vaccine candidate. Under the agreement, Johnson & Johnson is enabling the technology transfer of its vaccine to Biological E.

In April 2021, Johnson & Johnson submitted an application to the Drugs Controller General (India) to conduct a bridging clinical trial in India for its single-dose COVID-19 vaccine, the same single-dose vaccine the US Food and Drug Administration (USFDA) had in February 2021 approved for emergency use. [2]

Johnson & Johnson announced topline data from its global Phase 3 ENSEMBLE study clinical trial on January 29, 2021, which found that the Janssen COVID-19 vaccine candidate met all primary and key secondary endpoints. The global study demonstrated that the vaccine was 66.1 percent effective in preventing moderate to severe/critical disease and 85 percent effective in preventing severe/critical disease across all regions studied, 28 days post-vaccination. The vaccine showed protection against COVID-19 related hospitalization and death, beginning 28 days after vaccination.

The Janssen COVID-19 vaccine leverages the AdVac® vaccine platform, proprietary technology that was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.

jnj.in @JNJNews

Pfizer

The Pfizer-BioNTech COVID-19 mRNA vaccine was the first successful vaccine (with an efficacy of around 95 per cent) to be developed globally. Pfizer has received an Emergency Use Authorisation or temporary authorisation in more than 50 countries worldwide.[3]

In India, Pfizer was one of the first to approach Indian regulators seeking Emergency Use Authorisation for its Pfizer-BioNTech mRNA vaccine BNT162b2 in December 2020. Since then, the company continues to be in discussions with the government and remains committed to make its vaccine available for deployment in India's immunization programme. It is also extending support to state governments to set up and operationalize oxygen and ICU beds in the worst affected states of India and donating essential medicines that have been included in India's COVID-19 treatment protocol. [4]

During the first phase of the pandemic, Pfizer stepped in to support government efforts by providing equipment, protective gear and essential medicines. All this while working towards equitable and affordable access for its COVID-19 vaccine for people around the world including in India. [5]

pfizerindia.com @pfizer

Therapies from OPPI Member Companies to support the country in its fight against COVID-19

THERAPIES

GILEAD

In May 2020, Gilead has signed non-exclusive voluntary licensing agreements with 7 generic pharmaceutical manufacturers in India to ensure higher supply of its antiviral drug remdesivir. The drug that treats COVID-19 by producing inhibiting a particular enzyme necessary for the virus to replicate itself has been reported to reduce the hospital stay and help patients recover faster.

The agreements allow the companies – Cipla Ltd.; Dr. Reddy's Laboratories Ltd.; Eva Pharma; Ferozsons Laboratories; Hetero Labs Ltd.; Jubilant Lifesciences; Mylan; Syngene, a Biocon company; and Zydus Cadila Healthcare Ltd. – to manufacture remdesivir for distribution in 127 low-income and lower-middle income countries, as well as several upper-middle-

and high-income countries that face significant obstacles to healthcare access.

Under the licensing agreements, the companies have the right to receive the technology for the manufacturing process of remdesivir.These licenses currently remain royalty-free, reflecting Gilead's existing commitment to enabling broad patient access to remdesivir. The licenses are royalty-free until the World Health Organization declares the end of the Public Health Emergency of International Concern regarding COVID-19, or until a pharmaceutical product other than remdesivir or a vaccine is approved to treat or prevent COVID-19, whichever is earlier.[6]

On April 26, the company announced its support for its voluntary licensing partners including technical assistance, support for the addition of new local manufacturing facilities and the donation of active pharmaceutical ingredient (API) to rapidly scale up production of remdesivir. In addition, Gilead has also donated 450,000 vials of Veklury®, its remdesivir brand produced in the US, to help address the immediate needs of Indian patients.

gilead.com @GileadSciences

MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ USA), has entered into non-exclusive voluntary licensing agreements for its investigational oral antiviral drug *molnupiravir* with six established Indian generics manufacturers.

The company has signed agreements with Cipla Limited, Dr. Reddy's Laboratories Limited, Emcure Pharmaceuticals Limited, Hetero Labs Limited, Sun Pharmaceutical Industries Limited and Viatris, six generic manufacturers with World Health Organization (WHO) Pre-Qualified Manufacturing facilities and experience as major suppliers to global and key Low and Middle Income Countries (LMIC) procurers. Under the agreements, MSD will provide licenses to these manufacturers to supply *molnupiravir* to India and more than 100 LMICs.[7]

Molnupiravir is an investigational oral antiviral agent currently being studied in Phase 3 trials for the treatment of non-hospitalized patients with confirmed COVID-19.[8]

MSD is developing molnupiravir in collaboration with Ridgeback Biotherapeutics. MSD has entered into these agreements to accelerate availability of molnupiravir in India and in other low- and middle-income countries following approvals or emergency authorization by local regulatory agencies.

msdindia.in @MSDInvents

Roche India has donated INR 40+ crores worth of Tocilizumab (Brand: Actemra) to India. Fifty thousand vials of Tocilizumab (Brand: Actemra) 80 mg are being donated to the Ministry of Health and Family Welfare (MoHFW), Government of India to help patients during the pandemic. The supplies reached India on 11 May 2021 and will be handed over to the MoHFW in the next few days. Roche significantly increased its supplies of Tocilizumab (Roche brand Actemra) to meet the immediate emergency demand.[9]

The company also working urgently to increase manufacturing capacity and supply by ramping up its production network, as well as actively collaborating with external partners to maximize production of Actemra wherever possible with the goal of increasing its availability. This should enable Roche to meet future demand in a fluid and hard to predict environment.

Roche India has received a EUA for its investigational Antibody Cocktail - Casirivimab and Imdevimab. This EUA enables the company to import the globally manufactured product batches to India, which will be marketed as well as distributed in India through a strategic partnership with Cipla Limited. It is used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age or older, weighing at least 40 kg) who are confirmed to be infected with SARS-COV2 and who are at high risk of developing severe COVID-19 disease. It could significantly help these high-risk patients before their condition worsens. This will also help in easing the pressure on the Indian healthcare systems.

rocheindia.com @Roche

On April 30, Subject Expert Committee (SEC) of the Drug Controller General (India) granted Emergency Use Authorisation to permit manufacture of Baricitinib, a drug patented by Eli Lilly. CDSCO, based on SEC recommendation, has granted NATCO the permission to manufacture Baricitinib, both as a formulation and API, in India.

The SEC had recommended the grant of permission to manufacture and market the drug for restricted use in emergency situation. The committee allowed use of "Baricitinib, in combination with Remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)."

The permission granted is for the aforesaid indication and subject to conditions inter alia that the product is for use in hospital/institution set up only; and that NATCO shall conduct Phase IV and submit protocol for the same within 15 days of the approval.

Among people hospitalized with COVID-19, a combination of baricitinib and remdesivir reduces the median time to recovery compared with remdesivir plus placebo, according to trial results published December 11 in the New England Journal of Medicine.

Eli Lilly and Company (Lilly) has issued royalty-free, non-exclusive voluntary licenses to Indian generic firms Cipla Ltd, Lupin Ltd and Sun Pharmaceutical Industries Ltd manufacture to sell low cost versions of its new COVID-19 drug Baricitinib in India.

Dr Reddy's Laboratories said it has inked a licensing pact with Eli Lilly and Company to produce Baricitinib in the country for treatment of COVID-19. This partnership comes at a critical juncture in the fight against the pandemic in India, and adds to the company's existing range of COVID-19 therapeutics covering the full spectrum from mild to moderate and severe conditions of the disease, and a vaccine, Dr Reddy's noted.

Eli Lilly announced that it had issued an additional royalty-free, non-exclusive voluntary license to Natco Pharma to manufacture and distribute Baricitinib in the country. The rheumatoid arthritis drug is used in treating COVID-19 patients. The drug has to be used as co-treatment with Remdesivir as per approval granted by the CDSCO/DCGI for Emergency Use Authorisation.[10]

lillyindia.co.in @LillyPad

1. Serum Institute of India obtains emergency use authorisation in India for AstraZeneca's COVID-19 vaccine, Astrazeneca Website, 6 January 2021
2. Statement on Johnson & Johnson's Collaboration in India with Biological E to Expand Manufacturing Capabilities For its COVID-19 Vaccine Candidate, Janssen India August 13, 2020
3. Pfizer seeks emergency use authorisation for its COVID-19 vaccine in India, The Hindu, December 6, 2020
4. Pfizer drops India vaccine application after regulator seeks local trial, Reuters, February 5, 2021
5. Pfizer offers vaccine to Indian govt at not-for-profit price, Hindustan Times, April 23
6. Gilead has signed non-exclusive voluntary licensing agreements with generic pharmaceutical manufacturers to further expand supply of remdesivir
7. MSD Pharma signs pact with 5 Indian firms to make investigational covid-19 drug
8. MSD ties up with 5 Indian pharma majors for supply of oral COVID-19 drug Molnupiravir
9. Roche donates 50,000 tocilizumab vials to India Roche donates 50,000 tocilizumab vials to India
10. Lilly accelerating baricitinib's availability in India following receipt of permission for restricted emergency use as a COVID-19 therapy via donations and licensing agreements