



## **Roche receives Emergency Use Authorisation in India for its investigational Antibody Cocktail (Casirivimab and Imdevimab) used in the treatment of Covid-19**

- *Casirivimab and Imdevimab is indicated for the treatment of mild to moderate Covid-19 in high-risk patients*
- *Partners with Cipla for pan-India distribution*
- *At a global level, Roche and its partner Regeneron are collaborating to jointly address increasing demand.*

**Mumbai, 5 May 2021:** Roche India today announced that the Central Drugs Standards Control Organisation (CDSCO) has provided an Emergency Use Authorisation (EUA) for Roche's antibody cocktail (Casirivimab and Imdevimab) in India. This approval was based on the data that have been filed for the EUA in the United States, and the scientific opinion of the Committee for Medicinal Products for Human Use (CHMP) in the European Union. This Emergency Use Authorisation will now enable Roche to import the globally manufactured product batches to India and will be marketed as well as distributed in India through a strategic partnership with Cipla Limited.

The antibody cocktail (Casirivimab and Imdevimab) is to be administered 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. On March 23 2021, Roche announced that a large phase III global trial (n=4,567) in high-risk non-hospitalised COVID-19 patients ("outpatients") met its primary endpoint, showing that Casirivimab and imdevimab significantly reduced the risk of hospitalisation or death by 70% compared to placebo. Casirivimab and imdevimab also significantly shortened the duration of symptoms by four days.

'With the increasing number of Covid-19 infections in India, Roche is committed to doing everything we can to minimise hospitalisations and ease pressure on healthcare systems. This is where neutralising antibody cocktails like casirivimab and imdevimab can play a role in the fight against COVID-19 and in treatment of high risk patients before their condition worsens. We are thankful to the CDSCO for granting an EUA for casirivimab and imdevimab. This outpatient treatment for COVID-19 will be complementary to the ongoing vaccination drive and support our fight against the pandemic in India', said **Mr. V. Simpson Emmanuel, Managing Director, Roche Pharma India.**

Commenting on the partnership, **Umang Vohra, MD & Global CEO Cipla** said, "We are deeply committed to exploring all possible treatment options and being at the forefront in our fight against COVID-19. This partnership with Roche is a significant step in enabling access to promising treatments in furtherance to our purpose of 'Caring for Life'.

Cipla will market and distribute the product in India by leveraging its solid distribution strengths across the country. The drug will be available through leading hospitals and Covid treatment centers.

**About the product:** Casirivimab and Imdevimab are human immunoglobulin G-1 (IgG1) monoclonal antibodies produced by recombinant DNA technology. The production process for this biologic medicine is very complex and Roche as one of the largest biologics manufacturers in the world was selected by its partner Regeneron to expand worldwide production capacity. Roche will do everything to ensure an equitable distribution across the globe, however initial local demand may far exceed the supplies the company will be able to provide.

**Mechanism of action:**

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. Casirivimab and imdevimab are monoclonal antibodies that are specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.

Thanks to its specific engineering of two neutralising antibodies which bind to different parts of the virus spike, the Casirivimab and imdevimab cocktail remains efficacious against widest spread variants and reduces the risk of losing its neutralisation potency against new emerging variants.

**Dosage:** Casirivimab and Imdevimab is approved at a combined dose of 1200 mg (600 mg of each drug) administered by intravenous infusion or subcutaneous route. It has to be stored at 2 °C to 8 °C.

-Ends-

**\* High risk is defined as:**

- Age ≥60 years
- Obesity
- Cardiovascular disease, including hypertension
- Chronic lung disease, including asthma
- Type 1 or type 2 diabetes mellitus
- Chronic kidney disease, including those on dialysis
- Chronic liver disease
- Immunosuppressed, based on investigator's assessment. Examples include: cancer treatment, bone marrow or organ transplantation, immune deficiencies, HIV (if poorly controlled or evidence of AIDS),
- Sickle cell anemia, thalassemia, and prolonged use of immune-weakening medications.

**About Roche Products (India) Pvt. Ltd.**

Roche Products (India) Private Limited was incorporated in 1994 as a wholly owned subsidiary of the Roche Group, headquartered in Basel, Switzerland. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system.

For more than 60 years, Roche has been committed to making a difference to the lives of people in India. Today, Roche is the leader in oncology treatment in India; apart from cancer, Roche's has innovative medicines in other therapy areas too: transplantation, rheumatoid arthritis (RA), and chronic kidney disease (CKD)-related anaemia. Roche believes in making the latest and most innovative medicines accessible to patients in India in the fastest possible time.

For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, Roche is investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer. For more information on Roche Pharma India, visit [www.rocheindia.com](http://www.rocheindia.com).

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