

5th May 2021

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35A Boulevard Joseph II,
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Sub: Press Release - Roche receives Emergency Use Authorisation in India for its investigational Antibody Cocktail (Casirivimab and Imdevimab) used in the treatment of Covid-19

Dear Sir/Madam,

Please find enclosed press release dated 5th May 2021 for the captioned subject.

This is for your information and records.

Kindly acknowledge the receipt.

Thanking you,

Yours faithfully,
For Cipla Limited

Rajendra Chopra
Company Secretary

Prepared by: Mandar Kurghode

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 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.

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.

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.

About Cipla:

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 46 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT March' 21), 3rd largest in the pharma private market in South Africa (IQVIA MAT March' 21), and is among the most dispensed generic players in the U.S. For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit www.cipla.com, or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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