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Roche's Antibody Cocktail (Casirivimab and Imdevimab) is now available in India, Cipla to market it pan-India

 Casirivimab and Imdevimab is indicated for restricted use in emergency situation for the treatment of mild to moderate COVID-19 in patients who are at high risk* of severe COVID-19

Mumbai, 24 May 2021: Roche India and Cipla Limited (BSE: 500087; NSE: CIPLA EQ, referred to as "Cipla") today announced that the first batch of the Antibody Cocktail (Casirivimab and Imdevimab) is now available in India while a second batch will be made available by mid-June. In total they can potentially benefit 200,000 patients as each of the 100,000 packs that will be available in India offers treatment for two patients. Cipla will distribute the product by leveraging its strong distribution strengths across the country. The drug will be available through leading hospitals and COVID treatment centers. The Central Drugs Standards Control Organisation (CDSCO) had recently provided an Emergency Use Authorisation (EUA) for the antibody cocktail (Casirivimab and Imdevimab) in India. It has also received a EUA in the US and several EU countries.

"Roche is deeply committed to support the ongoing efforts to combat the COVID-19 pandemic, mitigate the deadly second wave and save lives. We are optimistic that the availability of Antibody Cocktail (Casirivimab and Imdevimab) in India can help in minimizing hospitalisation, ease the burden on healthcare systems and play a key role in treatment of high risk patients before their condition worsens," said V. Simpson Emmanuel, Managing Director and CEO, Roche Pharma India.

Commenting on the launch, **Umang Vohra**, **MD & Global CEO Cipla** said, "We are guided by our strong sense of responsibility to address unmet patient need and look forward to leveraging our solid marketing and distribution strengths in India to provide broader, equitable access to this innovative treatment option in the country".

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 and do not require oxygen. It has been shown to help these high-risk patients before their condition worsens, reducing the risk of hospitalisation and fatality by 70% and shortening the duration of symptoms by four days¹.

About the antibody cocktail

- The antibody cocktail (Casirivimab and Imdevimab) is a medical product that can be procured subject to a medical prescription by a registered medical practitioner
- Casirivimab and Imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat an infusion reaction, such as anaphylaxis
- The intravenous administration takes about 20 to 30 minutes. For the subcutaneous route, four syringes of 2.5 ml (2 each of Casirivimab & Imdevimab) need to be administered concurrently at four different sites on the abdomen or thigh

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• Patients should be monitored during the infusion and observed for least one hour after the completion of the infusion and 15--30 minutes after the subcutaneous injection

Each pack of Antibody Cocktail (Casirivimab and Imdevimab) contains one vial of Casirivimab and one vial of Imdevimab totaling 2400 mg of the antibody cocktail (one vial of Casirivimab (1200 mg) and one vial of Imdevimab (1200 mg)). Each pack can treat two patients as the dosage per patient is a combined dose of 1200 mg (600 mg of Casirivimab and 600 mg of Imdevimab) administered by intravenous infusion or subcutaneous route. The vials need to be stored at 2°C to 8°C. If opened for the first patients' dose, a vial can be used for the second patients' dose within 48 hours if stored at 2°C to 8°C.

How can one get the product?

Antibody cocktail drug (Casirivimab and Imdevimab) will be available through Cipla's distribution network across the country. Healthcare institutions, both private and public can place an enquiry by reaching out to their nearest Cipla distributor.

Price of the Product:

The price for each patient dose [a combined dose of 1200 mg (600 mg of Casirivimab and 600 mg of Imdevimab)] will be INR 59,750 inclusive of all taxes. The maximum retail price for the multidose pack (each pack can treat two patients) is INR 119,500 inclusive of all taxes.

Mechanism of action:

Casirivimab and Imdevimab are human immunoglobulin G-1 (IgG1) monoclonal antibodies produced by recombinant DNA technology in the lab. Monoclonal antibodies are 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.

-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.

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1<u>https://investor.regeneron.com/news-releases/news-release-details/phase-3-trial-shows-regen-covtm-casirivimab-imdevimab-antibody</u>

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 <u>www.rocheindia.com</u>.

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 <u>www.cipla.com</u>, or click on Twitter, Facebook, LinkedIn.

For further information, please contact:

ROCHE:

S. Rajan Chief Corporate Affairs and Communications Officer Mobile: +91 9930109372 | Email: rajan.s@roche.com Christina Dsouza SPAG Mobile: +91 97690 27774 | Email:





CIPLA:

Corporate Communications Heena Kanal Email: <u>CorpComm@cipla.com</u> Investor Relations Naveen Bansal E-Mail: <u>Investor.Relations@cipla.com</u>