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CDSCO approves Roche's antibody cocktail to treat COVID-19

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Casirivimab and Imdevimab is indicated for the treatment of mild to moderate Covid-19 in high-risk patients

Roche India has 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.

The antibody cocktail (Casirivimab and Imdevimab) is to be administered for the treatment of mild to moderate coronavirus 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.

"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 V. Simpson Emmanuel, Managing Director, Roche Pharma India.