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DCGI approves Biocon's drug Itolizumab to fight COVID-19

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Itolizumab will be manufactured and formulated as an intravenous injection at Biocon's bio-manufacturing facility at Biocon Park

Biocon Ltd., an innovation-led global biopharmaceuticals company, announced that it has received the Drugs Controller General of India's (DCGI) approval to market Itolizumab Injection 25mg/5mL solution for emergency use in India for the treatment of cytokine release syndrome (CRS) in moderate to severe ARDS (acute respiratory distress syndrome) patients due to COVID-19.

Itolizumab is the first novel biologic therapy to be approved anywhere in the world for treating patients with moderate to severe COVID-19 complications. Biocon has repurposed Itolizumab, an anti-CD6 IgG1 monoclonal antibody launched in India in 2013 as ALZUMAb? for treating chronic plaque psoriasis, for the treatment of CRS in moderate to severe ARDS patients due to COVID-19.

Itolizumab will be manufactured and formulated as an intravenous injection at Biocon's bio-manufacturing facility at Biocon Park, Bengaluru.

The approval of Itolizumab, from the DCGI is based on the results from the successful conclusion of a randomized, controlled clinical trial at multiple hospitals in Mumbai and New Delhi.

The study focused on the safety and efficacy of Itolizumab in preventing CRS in moderate to severe ARDS patients due to COVID-19. The primary endpoints for reduction in mortality rate were met and other key secondary endpoints for efficacy and biomarkers were also achieved.