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Biocon presents Clinical results for DCGI approval of Itolizumab for COVID-19

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The results of Biocon's clinical trial support the hypothesis that Itolizumab's novel immune-modulating mechanism of action is effective in addressing the severe 'cytokine storm' experienced by COVID-19 patients.

India's Biocon Ltd., an innovation-led global biopharmaceuticals company, on 13 July 2020 presented key insights into the results of the pivotal study that demonstrated its novel biologic, Itolizumab, significantly reduced mortality in moderate to severe ARDS (acute respiratory distress syndrome) patients hospitalized with COVID-19, in India. This led to the Drug Controller General of India (DCGI) approving this novel biologic therapy for restricted emergency use in India.

"Itolizumab is a 'Made in India,' 'Innovated in India,' first-in-class anti-CD6 monoclonal antibody, which has a seven-year proven track record of safety as doctors in India have been prescribing this biologic therapy to treat acute psoriasis. As Itolizumab has been approved in India and given that we are in the middle of a medical emergency, the regulator has approved Biocon's product for emergency use based on compelling data from a pivotal clinical trial involving a cohort of 30 patients. The two-arm, randomized study met both the primary and secondary endpoints, with the Itolizumab arm demonstrating a statistically significant advantage over the control arm, culminating in the drug's approval for restricted emergency use by the DCGI. The study results show that Itolizumab's unique mechanism of action can bring down mortality in moderate to severe ARDS patients due to COVID-19." says Kiran Mazumdar-Shaw, Executive Chairperson, Biocon.

A multi-centric, open label, two-arm randomized pivotal clinical trial was conducted in 30 eligible patients at four hospitals across Mumbai and New Delhi. Twenty patients were randomized to receive Itolizumab plus best supportive care, while 10 patients received best supportive care alone in the control arm. The primary endpoint was mortality at the end of one month.

At the end of the treatment period, Itolizumab demonstrated statistically significant advantage over the control arm in one-month mortality rate. All 20 patients on drug arm who were administered Itolizumab recovered fully and were discharged from hospital. Whereas three out of ten patients in the control arm with best standard of care died. Key efficacy parameters of lung function such as PaO2 and SpO2 (oxygen saturation) improvement without increasing FiO2 (oxygen flow) also showed statistically significant advantage for the Itolizumab arm over the control arm. All patients on the Itolizumab arm were weaned off oxygen by Day 30, and none needed ventilator support unlike the control arm.

Key secondary endpoints of clinical markers of inflammation such as IL-6, TNF-?, serum ferritin, d-dimer, LDH and CRP showed clinically significant suppression post Itolizumab dosing and correlated well with clinical improvement in symptoms and chest X-ray images.

Itolizumab when administered to patients with moderate to severe ARDS due to COVID-19 effectively controlled hyper-activation of the immune system in response to the SARS-CoV-2 virus and prevented morbidity and mortality related to the ‘cytokine storm’. Older patients and those with co-morbidities like diabetes and hypertension, who were treated with Itolizumab, recovered well.

At the end of the trial, 79% of severely ill patients were discharged from the ICU after 14 days of treatment, while moderately ill patients showed a reduction in the rate of disease progression. Itolizumab was overall well tolerated and found to be safe with infusion reactions manageable with slowing infusion rate.