

## **Biocon Biologics Committed to Innovative Solutions to Transform Patients' Lives**

### **The Innovation**

Itolizumab is an approved and in-market drug that has been available in India under the trade name ALZUMAb® for the treatment of chronic plaque psoriasis since 2013 and has been used safely in thousands of patients.

As the COVID-19 pandemic swept through India, Biocon responded to the need of the hour and repurposed its novel biologic ALZUMAb® (Itolizumab), for COVID-19 patients. It is a 'first-in-class,' anti-CD-6 IgG1 monoclonal antibody, which has shown promising results in treating cytokine release syndrome (CRS) in COVID-19 patients experiencing acute respiratory distress syndrome (ARDS).

After receiving permission from the Drugs Controller General of India (DCGI) in April 2020, we conducted a multi-centre, open label, two-arm, randomised Phase 2 clinical trial in 30 eligible patients, to study the efficacy and safety of Itolizumab in COVID-19 complications.

Twenty patients received Itolizumab plus best supportive care in the test arm, while 10 patients received best supportive care alone in the control arm. At the end of the treatment period, Itolizumab demonstrated statistically significant advantage over the control arm in one-month mortality rate. Key efficacy parameters of lung function such as PaO<sub>2</sub> and SpO<sub>2</sub> (oxygen saturation) improvement without increasing FiO<sub>2</sub> (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.

Itolizumab was overall well tolerated and found to be safe and the drug received restricted emergency use authorization from the DCGI based on results of the Phase II randomized control trial in July 2020.

A clinical trial in 10 Cuban hospitals by our partner there showed timely administration of Itolizumab, guided by biomarkers, can interrupt the hyperinflammatory cascade and might prevent morbidity and mortality related to CRS in COVID-19 patients.

### **The Approach**

Itolizumab's unique mechanism of action of immunomodulation involves binding to the CD6 receptor and blocking the activation of T lymphocytes, which in turn suppresses the pro-inflammatory cytokines, thus reducing inflammation.

COVID-19 patients who develop serious complications experience a 'cytokine storm,' which leads to excessive inflammation, organ failure and death. Itolizumab reduces cytokine storm and the deadly inflammatory response.

To bring Itolizumab to patients we used all appropriate evidence types and built on the existing evidence base using proven best practices in response to the need to save lives during this critical public health emergency as a result of COVID-19.

### **Benefits**

Hospitalized patients who progress rapidly to severe ARDS, organ damage, and coagulation disorders due to systemic hyper-inflammation currently have no approved treatments. Biocon Biologics is proud to present a repurposed Itolizumab to address an area of unmet need and provide doctors with a safe, effective treatment option that has contributed to reducing the mortality rate in our country.

Biocon Biologics' repurposed novel biologic drug has contributed to successfully treating over 1,500 patients in India.

### **The Future**

As a part of our commitment to the DCGI, we have commenced enrolment for a 300-patient, Phase IV clinical study across 15 centres in India in order to generate a larger body of scientific evidence to support the safety, efficacy and usefulness of Itolizumab in prevention and treatment of CRS in COVID-19 patients with moderate to severe ARDS.