COVID-19 - Govt gives nod for Emergency Use to Itolizumab

By TIOL News Service

NEW DELHI, JULY 11, 2020 - **Itolizumab** (rDNA origin), a monoclonal antibody which was already approved for severe chronic plaque psoriasis, has now been granted Restricted Emergency Use authorisation by the Drugs Controller General of India (DCGI) based on clinical trials data.

M/s Biocon has been manufacturing and marketing this drug for the treatment of patients with moderate to severe chronic plaque psoriasis since 2013 under brand name Alzumab. This indigenous drug has now been repurposed for COVID-19.

M/s Biocon has presented the Phase II clinical trial results generated in COVID-19 patients to DCGI. The results of these trials were deliberated in the Subject Expert Committee of DCGI's office.

Details of primary endpoint of mortality, other key endpoints of lung function such as improvement in PaO2 and O2 saturation were presented. Key inflammatory markers IL-6, TNFa etc., were presented to have reduced significantly with the drug thereby preventing hyper- inflammation in COVID-19 patients.

After detailed deliberation and taking into account the recommendations of the Committee, DCGI has decided to grant permission to market the drug under Restricted Emergency Use of the drug for the treatment of Cytokine Release Syndrome Â (CRS) in moderate to severe Acute Respiratory Distress Syndrome (ARDS) patients due to COVID-19, subject to some conditions like informed consent of patients, a risk management plan, to be used in hospital set up only etc.

The average cost of treatment with this indigenous drug i.e Itolizumab is also lesser than comparable drugs which are part of the â€œInvestigational Therapiesâ€• indicated in the Clinical Management Protocol for COVID-19 of the Ministry of Health and Family Welfare