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Initial response to Covid drug Itolizumab ‘extremely encouraging’, says Biocon

ANIL URS

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Biocon, which is under criticism from several quarters for fast-tracking its Itolizumab drug to treat coronavirus patients, said that such a step was necessary as the initial response to the drug was extremely encouraging.

“The drug had already received necessary approvals. So, we went ahead with it as it has already saved lives during the clinical trials in treating Covid-19 patients,” said a spokesperson for the company. Each vial costs ₹8,000 and the full course will cost ₹32,000.

DCGI approval

The company received the Drugs Controller General of India’s (DCGI) approval to market Itolizumab (ALZUMAb) injection 25mg/5mL solution for

emergency use in India for treating cytokine release syndrome in moderate-to-severe ARDS (acute respiratory distress syndrome) patients.

“Until the vaccine comes out, we need life-saving drugs. I think what we are doing across the world is either repurpose the drugs to treat this pandemic. When we started on this journey of developing the drug or repurposing the Itolizumab for Covid-19, it was based on a very strong hypothesis that it was related to cytokine storm or cytokine syndrome as we call it in medical terms.

“This was identified as the leading cause of deaths by the end of March 2020,” said Kiran Mazumdar-Shaw, Executive Chairperson, Biocon.

Active Covid infections

As per the Union Ministry of

Health and Family Welfare Statistics, India currently has more than 283,400 documented active coronavirus infections and more than 22,100 deaths.

Krishna Kumar, a professor with IIT Madras, who has been involved with such trials, told BusinessLine that Simon’s two-stage test is a well-established drug trial algorithm for the phase II trial. The number involved in carrying out the trials being small is not the criteria, but whether it is statistically significant or not is the criteria in a stage II trial.

Mazumdar-Shaw said this drug was basically developed in India for treating psoriasis as it is an autoimmune condition that sees a large release of cytokine, and the ability of Itolizumab that regulates cytokine made it compelling to develop it for psoriasis.