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Zydus Cadila receives DCGI approval for Ph 3 trial of biological therapy in COVID-19 patients

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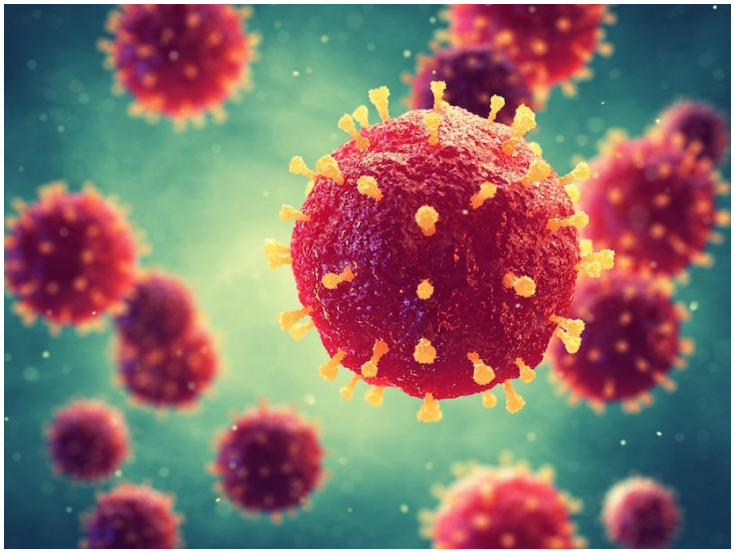

Zydus Cadila announced that it had received an approval from the Drugs Controller General of India (DCGI) to start the Phase 3 clinical trial in COVID-19 patients with its biological therapy, Pegylated Interferon alpha-2b, 'PegiHepTM'.

The trials which will commence in December will be conducted on 250 patients across 20-25 centres in India. In the Phase II clinical trials study established the early safety, efficacy and tolerability of PegiHep TM and has indicated that Pegylated Interferon alpha-2b having statistical clinical beneficial impact on the patient suffering from moderate COVID-19 disease by reducing their viral load helping in better disease management such as reduced duration of oxygen support.

Moreover, a single dose therapy will improve compliance and also make it highly affordable for patients. Pegylated Interferon alpha-2b, 'PegiHepTM is an approved drug and is being re-purposed for the treatment of COVID-19.

Speaking on the development, Dr Sharvil Patel, Managing Director, Cadila Healthcare Ltd, said, "We are encouraged by the results of Phase II study of Pegylated Interferon alpha 2-b which has shown the potential to reduce virus titres when given earlier in the disease."

In the Phase 2 clinical trial which was open-label, randomised, comparator controlled study, involving 40 adult patients with moderate COVID-19 disease, 95 per cent subjects in the test arm who received a single dose of PegiHepTM along with the Standard Of Care (SOC), became virus free as assessed by RT-PCR on day 14 and showed a statistically significant clinical improvement over the patients in the reference arm, who received only the standard of care and where only 68 per cent patients showed an improvement in clinical symptoms and became RT-PCR negative.

In the test arm 16 subjects were RT-PCR negative as early as day seven of treatment which was an improvement over the reference arm. Clinical improvement was assessed using a seven point ordinal scale where the patients were assessed on multiple criteria such as requirement and duration of hospitalisation, ventilation, supplemental oxygen etc.

Zydus Cadila is also conducting a similar Phase 2 trial in Mexico. The Company is also working with the US FDA to open an Investigational New Drug (IND) application for Pegylated Interferon alpha-2b in order to initiate appropriate clinical trials in US.