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Zydus receives approval from DCGI to commence Phase III clinical trials with Pegylated Interferon alpha-2b in India

- *Pegylated Interferon alpha – 2b significantly increased viral reduction and reduced the need for supplemental oxygen in moderate COVID-19 patients*

Ahmedabad, India, December 04, 2020

Zydus Cadila, today 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, 'PegiHep™'. 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 ™ 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, 'PegiHep™ 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. Our efforts are to look at possible treatment options to fight COVID-19 which are safe, can be administered easily and also reduce the disease burden."

In the Phase 2 clinical trial which was open-label, randomized, comparator controlled study, involving 40 adult patients with moderate COVID-19 disease, 95% subjects in the test arm who received a single dose of PegiHep™ 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% 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 7 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 hospitalization, ventilation, supplemental oxygen etc.

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

About Zydus' Pegylated Interferon Alpha-2b

Pegylated Interferon alpha-2b is not a new therapy. The product was first approved internationally in 2001 and is also included in WHO's Essential Medicines List. Zydus Cadila's Pegylated Interferon alpha-2b, PegiHep™, was originally approved for Hepatitis C and was launched in the Indian market in 2011. Since then safe and efficacious drug use for this product has been demonstrated in thousands of patients. Given that type I interferons including Interferon alpha have been implicated as crucial in the protection against SARS-CoV-2 in the recent publications in the leading journal Science (Hadjadj et al, Bastard et al and Zhang et al), the findings in Zydus Cadila's Phase 2 study are not surprising. In this study, a single dose of PegiHep at 1 mcg/kg body weight was tested to find out whether the drug could be repurposed for treating moderate COVID-19 patients. In 19 out of 20 patients, a single 1 mcg/kg dose of the drug demonstrated viral clearance as assessed by RT-PCR and a significant improvement in clinical symptoms.

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