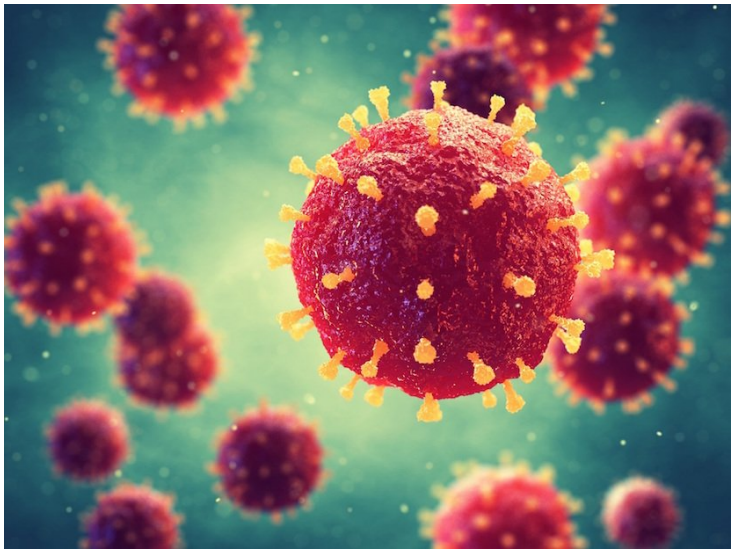
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Zydus reports increased viral reduction with PegiHep in COVID-19 patients

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The company will now commence Phase III clinical trials



Zydus Cadila has announced that it has successfully completed a Phase 2 clinical trial in CoVID-19 patients with its biological therapy, Pegylated Interferon alpha-2b, 'PegiHepTM'.

In this 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 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% 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. The study established the early safety, efficacy and tolerability of PegiHepTM in moderate COVID-19 patients.

The study so far has indicated that Pegylated Interferon alpha-2b could have a 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 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, PegiHepTM, was originally approved for Hepatitis C and was launched in the Indian market in 2011.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Cadila Healthcare Ltd., said, "We continue to look at possible treatment options that are safe and efficacious in the treatment and management of COVID 19. Pegylated Interferon alpha-2b has shown the potential to reduce virus titres when given earlier in the disease and we will like to explore this biological option further. We are hopeful of reinforcing our treatment options to fight COVID 19."

Based upon the results from its Phase 2 study, Zydus Cadila now plans to conduct a Phase 3 clinical trial in India. The Company 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.