

## **Zydus receives approval from COFEPRIS to conduct clinical trials in Mexico with Pegylated Interferon alpha-2b to treat novel Coronavirus**

- *Trials to commence in July with dosing in patients*
- *Trials in India are already underway with Pegylated Interferon alpha-2b*
- *Interferon alpha emerges as one of the treatment options for COVID 19; In vitro and in vivo studies suggest positive effects on COVID-19 Patients*
- *Recent research shows that Interferon alpha significantly reduces novel Coronavirus titers in vitro. A clinical study in China shows shortened duration of viral shedding in patients*

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Ahmedabad, July 17, 2020

Zydus Cadila, today announced that it had received approval from the Mexican regulatory authority COFEPRIS to conduct clinical trials with its biological therapy, Pegylated Interferon alpha-2b, 'PegiHep™'. This will be an open-label, randomized, comparator controlled study of Pegylated IFN alpha-2b to evaluate safety, efficacy and tolerability in patients with COVID-19. Clinical and regulatory development of Pegylated Interferon alpha-2b in COVID-19 is being executed in Mexico by Avant Santé Research Center S.A. de C.V., a leading Contract Research Organization (CRO) headquartered in Monterrey, Mexico.

Zydus had earlier approached the DCGI to investigate the role of Pegylated Interferon alpha-2b for COVID 19 and the clinical trials are now underway. The Company is also working with USFDA to open an Investigational New Drug (IND) application for Pegylated Interferon alpha-2b.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Cadila Healthcare Ltd., said, "Our endeavour is to continue looking for pathways for a safe and efficacious treatment to combat COVID 19. Pegylated Interferon alpha has the potential to reduce virus titres when given earlier in the disease. The focus is on reducing the viral load and generating virus eliminating specific immune response."

The treatment option emerged after the publication of two recent peer reviewed research articles. The first one by Ogando et al (Journal of General Virology, June 2020) at Leiden University Medical Center, Netherlands showed an evidence of a direct anti-viral effect of Pegylated Interferon alpha against novel Coronavirus. The study demonstrated that Pegylated Interferon was able to completely neutralize SARS-CoV-2 virus in vitro. The second by Zhou et al (Frontiers in Immunology, May 2020) from a group of universities in China, Australia and Canada retrospectively analysed 77 moderate COVID-19 subjects in Wuhan and observed that those who received Interferon alpha-2b showed a significant reduction in the duration of virus shedding period and even in levels of the inflammatory cytokine, IL-6.

### **How Interferon Alpha 2b works**

When the human body contracts an infection due to a viral attack, it produces a group of molecules called Type 1 interferons as a first line of defence. Interferon alpha is one such Type 1 Interferon molecule, that not only slows down the viral replication but also helps activate the two arms of our immune system – Innate, for immediate killing of the virus and Adaptive, for long lasting immunity. To make it more effective, the molecule is coupled with polyethylene glycol to produce a new molecule called, Pegylated Interferon alpha, that has the same functionality as Interferon alpha but remains in the body longer and therefore requires only once-a-week injection, thus providing a much better efficacy profile.

Zydus has been commercially manufacturing Pegylated Interferon alpha-2b under the brand name, PegiHep™, since 2011 for the treatment of Hepatitis B and C with 1.5 lac doses being administered. PegiHep™ is not yet licensed or approved for the treatment of COVID-19.

**About Avant Santé**

Avant Santé Research Center S.A. de C.V. through its integrated clinical and regulatory development infrastructure enables drug discovery and drug development companies for the early access to patient and the market. Avant Santé employs nearly 300 people who is dedicated to their vision of fostering health and safety. [www.avantsante.com](http://www.avantsante.com)

**About Zydus**

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs nearly 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. [www.zyduscadila.com](http://www.zyduscadila.com)

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