

Zydus explores the biologicals route to treat novel Coronavirus with long-acting Interferon alpha-2b

- *Interferon alpha can potentially emerge as one of the treatment options for COVID 19; In vitro and in vivo studies suggest positive effects on COVID-19 Patients*
- *Recent research conducted in the US shows that Interferon alpha significantly reduces novel Coronavirus titers in vitro. A clinical study in China shows shortened duration of viral shedding in patients*
- *Zydus approaches Department of Biotechnology, Government of India to investigate the role of Pegylated Interferon alpha-2b for COVID 19. Ready to undertake clinical trials.*
- *The Company is also working with USFDA to open an Investigational New Drug (IND) filing for Pegylated Interferon alpha-2b and explores possibility for “Compassionate Use Program”*

Ahmedabad, India, April 20, 2020

Zydus Cadila, today announced that its biological therapy Pegylated Interferon alpha-2b, ‘PegiHepTM’ can emerge as one of the pathways to treat COVID 19. The treatment has emerged after the publication of two non-peer reviewed research articles at bioRxiv and medRxiv, the COVID-19 pre-print servers hosted by Cold Spring Harbor Laboratory. The first one by the University of Texas Medical Branch, Galveston, showed an evidence of a direct anti-viral effect of Interferon alpha against novel Coronavirus in vitro. The study demonstrated around 10,000 fold reduction in virus titre in cells that were pre-treated with Interferon alpha 48 hours earlier. The second by 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. This suggests that if a long-acting molecule like Pegylated Interferon alpha is given early on in the infection, the patient suffering from COVID 19 will have a significant benefit as the viral load is reduced, lesser IL-6 is produced and virus eliminating specific immune response is generated.

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 defense. 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.

Interferon alpha-2b has been used in the treatment of COVID-19 in China and Cuba and is a part of treatment guidelines of the Chinese Government. 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.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Cadila Healthcare Ltd., said, “At this juncture, as the healthcare fraternity the world over, is exploring options for a safe and efficacious treatment to combat COVID 19, Pegylated Interferon alpha emerges as one such possibility with it’s potential to reduce virus titres when given earlier in the disease and offering better clinical outcomes. We are working with the U.S. Food and Drug Administration (FDA) and have opened an investigational new drug (IND) filing for Pegylated Interferon alpha-2b for the treatment of COVID-19. We are also working with the Department of Biotechnology to investigate the role of Pegylated Interferon alpha-2b for COVID 19 and are planning to undertake clinical trials for this.”

Additionally, Zydus is already manufacturing Hydroxychloroquine which has been found to be effective in treating patients suffering from COVID 19. The group is also working on an accelerated vaccine development programme which is currently in the animal testing stage and if the results are successful it should enter clinical studies in second quarter of this financial year.

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
