April 23, 2021

Listing Department **Code: *532 321***
**BSE LIMITED**
P J Towers, Dalal Street, Fort,
Mumbai – 400 001

Listing Department **Code: *CADILAHC***
**NATIONAL STOCK EXCHANGE OF INDIA LIMITED**
Exchange Plaza, Bandra Kurla Complex,
Bandra (E),
Mumbai – 400 051

**Re.:** Press Release

Dear Sir/Madam,

Please find enclosed a copy of press release dated April 23, 2021 titled "**Zydus receives Emergency Use Approval from DCGI for the use of Pegylated Interferon alpha-2b, 'Virafin' in treating moderate COVID-19 infection in adults**".

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Thanking you,

Yours faithfully,
For, **CADILA HEALTHCARE LIMITED**

**DHAVAL N. SONI**
**COMPANY SECRETARY**

**Encl.:** As above

Zydus dedicated to life

Press Release Press Release Press Release Press Release Press Release Press Release Press Release Press Release

# Zydus receives Emergency Use Approval from DCGI for the use of Pegylated Interferon alpha-2b, 'Virafin' in treating moderate COVID-19 infection in adults

- *A single dose of the antiviral Virafin administered subcutaneously early on shows significant clinical and virological improvement in moderate COVID-19 adult patients*
- *91.15% of patients treated with PegIFN were RT PCR negative by day 7.*
- *The treatment significantly reduces the hours of supplemental oxygen in the patients*

*Ahmedabad, India, 23 April, 2021*

Zydus Cadila today announced that the company has received Restricted Emergency Use Approval from the Drug Controller General of India (DCGI) for the use of 'Virafin', Pegylated Interferon alpha-2b (PegIFN) in treating moderate COVID-19 infection in adults. A single dose subcutaneous regimen of the antiviral Virafin will make the treatment more convenient for the patients. When administered early on during COVID, Virafin will help patients recover faster and avoid much of the complications. Virafin will be available on the prescription of medical specialist for use in hospital/institutional setup.

In the multicentric trial conducted in 20-25 centers across India, Virafin had shown lesser need for supplemental oxygen, clearly indicating that it was able to control respiratory distress and failure which has been one of the major challenges in treating COVID-19. The drug has also shown efficacy against other viral infections.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Cadila Healthcare Limited said "The fact that we are able to offer a therapy which significantly reduces viral load when given early on can help in better disease management. It comes at a much-needed time for patients and we will continue to provide them access to critical therapies in this battle against COVID-19."

In its Phase III clinical trials, the therapy had shown better clinical improvement in the patients suffering from COVID-19. During the trials, a higher proportion of patients administered with PegIFN arm were RT PCR negative by day 7. The drug ensures faster viral clearance and has several add-on advantages compared to other anti-viral agents.

Type I interferons are body's first line of defense against many viral infections and Pegylated Interferon alpha-2b has been used to treat these infections successfully. Interferon alpha has also been implicated as crucial in the protection against SARS-CoV-2 in the recent publications in the leading journal Science. Furthermore, aging reduces the body's ability to produce Interferon Alpha

For further information please contact :
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in response to viral infections and may be associated with the higher mortality observed with COVID-19 in elderly patients. Virafin when given early on during infection can replace this deficiency and aid a faster recovery process.

Zydus acknowledges the support of BIRAC, in the development of Virafin for the treatment of COVID-19.

**Phase III clinical trial data**

The Phase III trials demonstrated that a higher proportion of patients in the PegIFN arm showed a two point statistically significant clinical improvement (WHO 7-point ORDINAL SCALE) on day 8 as compared to the Standard of Care (SOC arm) (80.36% vs 68.18%).

Clinically the hours of supplemental oxygen required was significantly lesser in the PegIFN arm and as well as the time to resolution of signs and symptoms as compared to the SOC arm (5 days vs 6 days).

The findings are in line with recently reported importance of early IFN treatment in the treatment of COVID-19 (*Lu et al, Signal Transduction and Targeted Therapy (2021) 6:107)*- a Nature publication.

Earlier the Phase II clinical trials study established the early safety, efficacy and tolerability of Virafin and indicated that Pegylated Interferon alpha-2b had significant statistical clinical 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.

The results of the Phase II trial have been published in *International Journal of Infectious Diseases [Efficacy and safety of pegylated interferon alfa-2b in moderate COVID-19: A phase II, randomized, controlled, open-label study, Anuja Pandit, et al., VOL 105, 516-521, APRIL 01, 2021*.]

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