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Cipla launches Cipremi for COVID-19 treatment

23 June 2020 | News

Cipla will be commercialising remdesivir through its own facilities and partnered sites



Mumbai based Cipla Limited has announced the launch of remdesivir under its brand name CIPREMI. The U.S. FDA issued an Emergency Use Authorization (EUA) to Gilead Sciences Inc. for emergency use of remdesivir for the treatment of hospitalized 2019 coronavirus disease (COVID-19) patients.

It is the only U.S. FDA approved Emergency Use Authorisation (EUA) treatment for adult and paediatric patients hospitalized with suspected or laboratory confirmed COVID-19 infection. In May, Gilead Sciences Inc. extended a voluntary non-exclusive license to Cipla to manufacture and market Cipla's generic version of remedisvir called CIPREMI.

Cipla has been granted regulatory approval by the Drug Controller General of India (DCGI) for restricted emergency use in the country as part of the accelerated approval process considering the urgent and unmet medical need. As part of a risk management plan, Cipla will provide training on use of the drug, informed patient consent documents, conduct post marketing surveillance as well as conduct a Phase IV clinical trial on Indian patients.

According to a preliminary report from the ACTT-1 (Adaptive COVID-19 Treatment Trial 1) study1, a randomized clinical trial conducted with remdesivir in 1063 patients over 60 centres across U.S., Europe and Asia demonstrated a faster time to clinical recovery in hospitalised patients as compared to placebo. Most of these patients were on oxygen therapy of which some were receiving high flow oxygen or non-invasive ventilation, and some were on a mechanical ventilator. The mortality rates in the study were 7.1% in those given remdesivir and 11.9% in those who were given placebo.

As part of its efforts to enable speedy and equitable access to this treatment and in anticipation of demand, Cipla will be commercialising remdesivir through its own facilities and partnered sites. The drug will be supplied through Government and open market channels, to ensure equitable distribution.

Commenting on the launch, Mr. Umang Vohra (MD and Global CEO, Cipla Limited) said, "Cipla appreciates the strong partnership with Gilead to bring remdesivir to patients in India. We have been deeply invested in exploring all possible avenues to save millions of lives impacted by COVID-19 pandemic, and this launch is a significant milestone in that direction. We will continue to collaborate with all stakeholders in the healthcare ecosystem towards providing access to such promising treatments in furtherance with our belief that no patient should be denied access to life-saving treatments."