

Zydus receives Orphan Drug Designation from US FDA for ZY-19489, a novel compound to treat malaria

- *ZY19489 is a novel anti-malarial compound active against all current clinical strains of P. falciparum and P. vivax, including drug resistant strains.*
- *The Orphan Drug Designation provides up to seven years of marketing exclusivity in the USA*
- *According to the US CDC, about 2,000 cases of malaria are diagnosed in the United States each year*
- *The vast majority of cases in the United States are found in travellers returning from countries where malaria transmission occurs*

Ahmedabad, India, December 16, 2021

Zydus Cadila, a research-driven, global healthcare provider, today announced that its antimalarial compound ZY19489 (MMV253), currently in development together with Medicines for Malaria Venture (MMV), a leading product development partnership (PDP) in antimalarial drug research, has received Orphan Drug Designation from the USFDA.

Orphan drug designation provides eligibility for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval.

The Phase I study of ZY19489 has demonstrated long half-life and potential for a single-dose cure for malaria [Reg'n Number [ACTRN12619000127101](#)]. In a separate malaria challenge trial, potent antimalarial activity has been demonstrated following single-dose oral administration of ZY19489 [Reg'n Number [ACTRN12619001215112](#)].

Speaking on the development, Pankaj R. Patel, Chairman, Zydus Group said, "As a global community facing threats from rapidly mutating malaria strains and the rise in artemisinin resistance cases, we have to be prepared with novel therapeutic drugs. ZY-19489 is a potential single dose radical cure for P. falciparum and P. vivax malaria which is a major global health risk today."

"ZY19489 is a potent, first in class molecule, originally discovered and elaborated in India" said Dr. Timothy Wells, Chief Scientific Officer, MMV. "It has tremendous potential as part of a new generation of treatments and is fully active against drug resistant strains of malaria which are increasingly a concern."

Artemisinin resistance is seen as a mounting challenge to the global fight against malaria. ZY19489 is being developed to provide an effective alternative to the current front-line antimalarial drugs for the treatment of P. falciparum and P. vivax malaria, as artemisinin-based combination therapies (ACTs) are under threat of resistance.

As per the [World Malaria Report 2021](#), there were an estimated 241 million cases of malaria worldwide and the estimated number of malaria deaths stood at 627,000 in 2020. A major health concern, it is estimated that a child dies from malaria every minute. About 96% of malaria deaths globally were in 29 countries. India accounted for about 82% of all malaria deaths in the WHO South-East Asia Region.

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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 over 23,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

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