

Zydus receives Orphan Drug Designation from US FDA for malaria drug

16 December 2021 | News

ZY19489 is a novel anti-malarial compound active against all current clinical strains of *P. falciparum* and *P. vivax*, including drug resistant strains



Ahmedabad-based Zydus Cadila has 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 US FDA.

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 a long half-life and potential for a single-dose cure for malaria. In a separate malaria challenge trial, potent antimalarial activity has been demonstrated following single-dose oral administration of ZY19489.

Pankaj R Patel, Chairman, Zydus Group said, “ ZY-19489 is a potential single-dose radical cure for *P. falciparum* and *P. vivax* malaria which is a major global health risk today.”