

Zydu announces completion of Phase-I trials of ZY19489—A single dose cure for Malaria in collaboration with MMV

- Phase I healthy volunteers study demonstrated long half-life and potential for a single-dose cure for malaria
- Potent antimalarial activity demonstrated in malaria challenge trial following single-dose oral administration of ZY19489
- ZY19489 is a fast-acting and effective drug against both *Plasmodium falciparum* and *P. vivax* strains of malarial parasites

Ahmedabad, India, February 4, 2021

Zydu Cadila, a research-driven, global healthcare provider, today announced that its antimalarial compound ZY19489 (MMV253) in development with Swiss-based product development partnership Medicines for Malaria Venture (MMV) has now completed Phase I clinical evaluation [Reg'n Number [ACTRN12619000127101](#)]. In the first in humans study conducted in Australia, escalating doses of 25 to 1500 mg were administered to healthy human volunteers. Emerging pharmacokinetic (PK) and safety data were evaluated by a safety data review committee.

In addition, a malaria challenge trial involving the *P. falciparum* volunteer infection study (VIS) model was also conducted in Australia to determine the safety and tolerability and to characterize the antimalarial activity of a single-dose oral administration of ZY-19489 in healthy adult volunteers [Reg'n Number [ACTRN12619001215112](#)]. No serious or severe drug-related adverse events were observed.

ZY19489 has the potential to be a single-dose cure for *P. falciparum* and *P. vivax* malaria due to its novel mechanism of action, rapid parasites killing activity across all intra-erythrocytic malaria stages, low resistance potential and long half-life.

Speaking on the development, Pankaj R. Patel, Chairman, Zydu Group said, "Malaria continues to be a scourge globally. ZY19489 has the potential to become a next-generation anti-malarial drug that would not only address resistance to existing drugs, but might also provide a single-dose cure for malaria. In collaboration with MMV, we look forward to developing an effective treatment option for *P. falciparum* and *P. vivax* malaria which is a major global health risk today."

"MMV is delighted to know that our partnership with Zydu Cadila has borne fruit," said Dr. Timothy Wells, Chief Scientific Officer, MMV. "To achieve the malaria elimination goals, the malaria community urgently needs new, effective, easy-to-administer antimalarials that can counter resistance. ZY19489 (MMV253) seems to meet all the required characteristics. If successful, this potent compound could be an important tool in

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the global antimalarial toolkit. MMV looks forward to our continued partnership with Zydus Cadila as we collaborate on progressing this compound through the research pipeline.”

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 2020, in 2019 there were an estimated 229 million cases of malaria worldwide and the estimated number of malaria deaths stood at 409,000.

Nineteen countries in sub-Saharan Africa and India carried almost 85% of the global malaria burden. Globally, 53% of the *P. vivax* burden is in the WHO South-East Asia Region, with the majority being in India (47%). *P. vivax* is the predominant parasite in the WHO Region of the Americas, representing 75% of malaria cases. [<https://www.who.int/news-room/feature-stories/detail/world-malaria-report-2019>].

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 25,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com