

Zydus receives approval from DCGI to initiate Phase III trials of Zintrodiazine, a novel anti-malarial candidate

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

Ahmedabad, India, April 25, 2026

Zydus Lifesciences Limited (“Zydus”), an innovation-led global lifesciences company, announced that it has received permission to conduct two Phase III clinical trials of Zintrodiazine in patients with uncomplicated malaria due to *Plasmodium falciparum* (*P. falciparum*) and uncomplicated *Plasmodium vivax* malaria in India.

The first Phase III and second Phase III trials will be multi-centre, randomised, assessor-blind, active-comparator studies to determine the efficacy, safety and tolerability of orally administered Zintrodiazine in patients with uncomplicated malaria due to *P. falciparum* and uncomplicated *P. vivax* malaria.

The first Phase III clinical trial will be conducted in 651 patients with uncomplicated malaria due to *P. falciparum* with the primary objective of evaluating the efficacy of Zintrodiazine as measured by PCR-adjusted adequate clinical and parasitological response (ACPR). The second Phase III clinical trial will be conducted in 390 patients with the primary objective of evaluating the efficacy of Zintrodiazine as measured by ACPR with uncomplicated malaria due to *P. vivax* mono-infection. Secondary endpoints in both clinical trials will include the incidence of recrudescence – *the return of malaria symptoms and parasites in the blood because the original infection was not fully cleared*, new infections, parasite clearance time and fever clearance time.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Limited, said, “Our journey of innovation has always been about advancing science to address unmet healthcare needs. Malaria remains a significant health concern affecting people of all ages. The approval to begin Phase III trials for Zintrodiazine marks a critical milestone in the fight against malaria. With increasing resistance to current therapies, we are committed to developing an effective treatment to address this challenge.”



**PRESS
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Last year alone over 1,80,000 people were diagnosed with malaria in India. In 2016, Medicines for Malaria Venture (MMV) and Zydus announced a collaboration to develop a Zintrodiazine-containing drug combination with the aim of providing an effective alternative to the current artemisinin-based combination therapies (ACTs), which are under threat of resistance.

Artemisinin resistance is seen as an enormous challenge to the global fight against malaria. The WHO's World Malaria Report 2025 report mentions that partial resistance to artemisinin derivatives – the backbone of malaria treatments after failures of chloroquine and sulfadoxine - pyrimethamine – has now been confirmed or suspected in at least 8 countries in Africa. Zintrodiazine is being developed as part of a combination therapy to provide an effective alternative to the current front-line antimalarial drugs for the treatment of *P. falciparum* and *P. vivax* malaria.

About Zydus Lifesciences Ltd.

Zydus Lifesciences Ltd., with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 29,000 people worldwide, including 1,500 scientists engaged in R&D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. Over the last decade, Zydus has introduced several innovative, first-in-class products in the market to address unmet healthcare needs with vaccines, therapeutics, biologicals, and New Chemical Entities. For more details, visit www.zyduslife.com.

About MMV

MMV is a not-for-profit product development partnership working to discover, develop and deliver medicines to treat, prevent and eliminate malaria. Since 1999, over 1.48 billion people have benefited from our co-developed medicines. With over 600,000 malaria deaths every year, we unite partners to close remaining antimalarial access and innovation gaps. For more information, visit www.mmv.org.

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