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Malaysia, Thailand set to start global clinical trial for Serum Institute of India's dengue treatment

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Phase III clinical trial is expected to begin early next year



The Serum Institute of India (SII) and the non-profit medical research organisation Drugs for Neglected Diseases initiative (DNDi) have signed a licensing agreement covering clinical testing and future access for an SII-developed monoclonal antibody treatment (formerly known as VIS513) against dengue.

With this agreement finalised, a Phase III clinical trial led by DNDi is expected to begin in the first quarter of 2027 across Malaysia, Thailand, and Brazil, all home to leading public health institutions that are members of the Dengue Alliance, a global partnership of dengue-endemic countries working to develop effective and accessible treatments. 1,000 participants are expected to join the study across the three countries.

Monoclonal antibodies are currently among the most advanced dengue treatment candidates. SII has developed and optimised the current formulation of its treatment and conducted pre-clinical studies and Phase I and II clinical trials that delivered promising safety and efficacy results. It is currently leading a pivotal Phase III clinical trial in India.

For the Phase III trial conducted by DNDi in Malaysia, Thailand and Brazil, SII will supply study medicines and manage their refrigerated transportation to clinical trial sites.

Led by DNDi, the trial in Malaysia, Thailand, and Brazil will be conducted with financial support from the European Commission’s Directorate-General for Health Emergency Preparedness and Response Authority (DG HERA) in partnership with the French Development Agency (AFD). Last November, DG HERA announced it will invest EUR 20 million to advance the development of two new dengue medicines.