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Serum Institute of India partners with DNDi to advance development of new dengue treatment

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To accelerate the clinical development of a monoclonal antibody treatment for dengue

Pune-based Serum Institute of India (SII), part of Cyrus Poonawalla Group, the world's largest vaccine manufacturer, and the not-for-profit medical research organization Drugs for Neglected Diseases initiative (DNDi) have signed a Memorandum of Understanding (MoU) to accelerate the clinical development of a monoclonal antibody treatment for dengue that will be affordable and accessible in low- and middle-income countries (LMICs).

Through this collaboration, both SII and DNDi will develop a work plan to implement R&D, additional Phase III clinical trials, and access activities, along with a joint strategy to raise necessary funds and resources.

Additionally, a joint project team will be formed to advance clinical trials, with the goal of registering and deploying the dengue monoclonal antibody in India and other dengue-endemic countries, provided the studies confirm its safety and efficacy.

SII has already conducted pre-clinical studies and Phase I and II clinical trials that show the candidate (formerly VIS513) is safe and effective. Currently, SII is leading the pivotal Phase III clinical trial in India for licensure. SII and DNDi will now work together to conduct additional Phase III trials in other dengue-endemic countries, including Brazil.

DNDi will act as the lead partner for these Phase III clinical trials, including trial leadership, sponsorship, and implementation in Brazil and potentially other endemic countries in Southeast Asia. DNDi and SII will lead strategic engagement efforts with the Dengue Alliance, relevant industry stakeholders, and policymakers in low- and middle-income countries.

For the DNDi-led trial in Brazil and other countries, SII will provide development background and technical support. Furthermore, SII will be responsible for the manufacture, development, and provision of clinical supplies of the monoclonal antibody candidate. The company will define and execute the regulatory strategy in India and will lead the commercialization of the product in the country.

Image caption- (L-R) Dr André Siquiera, Head of Dengue at DNDi and Sunder Lata A Kavitkar, Company Secretary, Serum Institute of India