BioSpectrum the business of Bio & Health Sciences

ICMR and Panacea Biotec initiate Ph 3 trial of first dengue vaccine in India

14 August 2024 | News

Marks a critical advancement in our fight against dengue

The Indian Council of Medical Research (ICMR) and New Delhi-based biotech company Panacea Biotec have announced the initiation of the first-ever Phase 3 clinical trial for a dengue vaccine in India.

This landmark trial will evaluate the efficacy of India's indigenous tetravalent dengue vaccine, DengiAll, developed by Panacea Biotec. The first participant in this trial was vaccinated at Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS), Rohtak.

Currently, there is no antiviral treatment or licensed vaccine against dengue in India. The development of an effective vaccine is complex due to the need to achieve good efficacy for all four serotypes. In India, all four serotypes of Dengue virus are known to circulate or co-circulate in many regions.

The tetravalent dengue vaccine strain (TV003/TV005), originally developed by the National Institutes of Health (NIH), USA, has shown promising results in preclinical and clinical trials worldwide. Panacea Biotec, one of three Indian companies to receive the strain, is at the most advanced stage of development. The company has worked extensively on these strains to develop a full-fledged vaccine formulation and holds a process patent for this work. Phase 1 and 2 clinical trials of the Indian vaccine formulation were completed in 2018-19, yielding promising results.

In collaboration with ICMR, Panacea Biotec will conduct the Phase 3 clinical trial across 19 sites in 18 States and Union Territories of India, involving more than 10,335 healthy adult participants. The trial, primarily funded by ICMR with partial support from Panacea Biotec, is set to follow up with participants for two years.