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ASIA EDITION

Takeda’s Dengue vaccine candidate reveals protection in children

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Results demonstrated overall vaccine efficacy of 80.2% (12-month follow-up after second dose) against virologically confirmed dengue

Japan based Takeda Pharmaceutical Company Limited has announced that results from the primary endpoint analysis of the ongoing pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial of its dengue vaccine candidate (TAK-003) were published in the New England Journal of Medicine.

Takeda’s dengue vaccine candidate was generally well tolerated, and no important safety risks have been observed to date. The observed safety profile was consistent with results reported in previous studies of TAK-003. The TIDES trial will continue to assess safety and efficacy in study subjects for a total of four and a half years.

“The results of this first analysis are very encouraging, indicating that the vaccine could potentially provide important public health benefits against dengue fever and hospitalization,” said Humberto Reynales, M.D., Ph.D., a lead author of the New England Journal of Medicine paper. “It will be important to further analyze the trial results over time in order to assess the long-term efficacy and safety of the vaccine. If longer follow-up data confirm this initial observation, we are looking at a significant step forward in the global fight against dengue.”

“According to the World Health Organization, dengue represents one of the ten biggest global health threats, and it is critical that we have access to a safe and effective vaccine candidate that can reduce the devastating impact dengue fever has in endemic regions,” said In-Kyu Yoon, M.D., Senior Advisor, International Vaccine Institute. “Historically, vaccine development against dengue has been challenging, especially for people who haven’t previously been exposed to dengue, and these results demonstrate protection from dengue fever, including among many participants without prior dengue.”

While in the process of publishing the primary endpoint data, Takeda received additional data from the ongoing TIDES trial, which adds six months of follow-up and provides formal assessment of the secondary efficacy endpoints. Both the primary endpoint analysis and formal assessment of secondary endpoints will be presented at the American Society of Tropical Medicine and Hygiene (ASTMH) 68th Annual Meeting, November 20-24, 2019, in National Harbor, Md., and submitted to a

peer-reviewed journal.

“We are excited to share this long-anticipated data from our TIDES trial, which is evaluating the performance of our dengue vaccine candidate in a diverse set of countries across Asia and Latin America, and in a study population that intentionally includes a large proportion of children who had never been exposed to dengue,” said Rajeev Venkayya, M.D., President of the Global Vaccine Business Unit at Takeda. “While more data is needed to fully understand the safety and efficacy profile of TAK-003, these findings strongly suggest that it could help address the massive global burden of dengue in all populations. We look forward to sharing more data in the coming weeks, and engaging health authorities and the scientific, public health and medical communities on these findings, priorities for future evidence generation, and ways we can work together to maximize the reach and impact of this vaccine upon licensure.”

The Phase 3 TIDES trial is ongoing, and longer-term data will be important in determining the efficacy and safety profile, particularly in baseline seronegative participants with dengue serotype 3 virus. Takeda is engaging global health experts to provide insights into the burden of dengue in endemic regions and analyses of results from the trial. Takeda’s dengue vaccine candidate is not currently licensed anywhere in the world.