ABOUT DENGUE AND TAKEDA’S DENGUE VACCINE CANDIDATE (TAK-003)
Takeda is developing a live, attenuated tetravalent dengue vaccine candidate (TAK-003) to help address unmet needs in dengue prevention. We are committed to developing a dengue vaccine that is safe for and protects those at risk of symptomatic dengue caused by any of the four virus types, regardless of whether they have previously been exposed to dengue.

TAK-003 is designed to protect against all four types of the dengue virus, and activate multiple arms of the immune system including antibodies and immune cells. This is because TAK-003 is based on a live-attenuated dengue serotype 2 virus (DENV-2), which provides the genetic ‘backbone’ for all four vaccine viruses.4,5

Because TAK-003 is based on an attenuated form of the dengue virus itself, it exposes the individual to a number of components of the virus that could be important in protection against future infection with dengue virus. Data from ongoing Phase 3 trials will determine vaccine efficacy and safety against all four virus serotypes, in both seronegative and seropositive individuals.

Dengue is caused by four distinct, but closely related, dengue virus serotypes (DENV-1, 2, 3 and 4).1

Each serotype can cause debilitating dengue fever, also called “breakbone fever,” or more severe, life-threatening disease forms in endemic areas.1

Infection with one dengue serotype confers life-long protection against re-infection with the same serotype, but only short-term protection against the other three serotypes.

Sequential infections with different serotypes can potentially increase the risk of developing severe dengue disease.1 However, less than 5% of secondary infections lead to severe dengue.

Dengue virus can infect people of all ages and is a leading cause of serious illness among children in some countries in Latin America and Asia.1

Approximately 3.9 billion people around the globe – half of the world’s population – are at risk of dengue.1 Dengue is now endemic in more than 120 countries and causes an estimated 390 million infections and more than 20,000 deaths each year.2,3

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In clinical trials to date, Takeda’s dengue vaccine candidate (TAK-003) has been shown to be generally safe, well-tolerated and to activate immune responses against all four dengue serotypes.6,7,8

The Phase 1 and Phase 2 clinical trial program for TAK-003 is comprised of eight studies in children and/or adults.6,7,8

The data generated from these studies supported progression into a Phase 3 study based on the overall safety and reactogenicity profile, as well as the induction of neutralizing antibody responses against all four dengue virus serotypes across age groups and in both seropositive and seronegative individuals. 6,7,8

Safety data from an 18-month interim analysis of the ongoing Phase 2 DEN-204 trial also showed that TAK-003 was associated with reduced incidence of dengue in children and adolescents, supporting the decision to continue the Phase 3 study. 9

While there have been no major safety concerns to date, we’re actively monitoring for safety on an ongoing basis, both at Takeda and through an independent Data Monitoring Committee.

Phase 3 studies will build on these findings to determine whether the vaccine safely helps prevent symptomatic dengue in children and adolescents.5,6,7,8,10

Enrollment and vaccination is complete in the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES), which is evaluating the efficacy, safety and immunogenicity of TAK-003 in 20,100 healthy children in eight dengue endemic countries.11

TIDES is investigating the safety and efficacy of two doses of TAK-003, administered three months apart. Based on Phase 2 data to date, this regimen achieved a high rate of immune response to all four dengue serotypes regardless of previous dengue exposure.9

Initial results of the Phase 3 TIDES trial are expected in early 2019.