TAK-003
Clinical Development Program Overview

Takeda's investigational live-attenuated Tetravalent Dengue Vaccine Candidate, TAK-003, is being studied in both healthy children and adults, in dengue endemic and non-endemic countries. The clinical development program includes five ongoing Phase 3 trials.

DEN-304 is a Phase 3, randomized, double-blind, placebo-controlled trial to demonstrate lot-to-lot consistency of 3 lots of a Tetravalent Dengue Vaccine Candidate (TAK-003) in healthy adults in a non-endemic country for dengue.[1] (NCT03423173)

DEN-305 is a Phase 3, randomized, observer-blind, placebo-controlled trial to assess the immunogenicity and safety of a Tetravalent Dengue Vaccine Candidate (TAK-003) and a Yellow Fever YF-17D Vaccine administered concomitantly and sequentially in healthy subjects aged 18 to 60 years in a non-endemic country.[2] (NCT03342898)

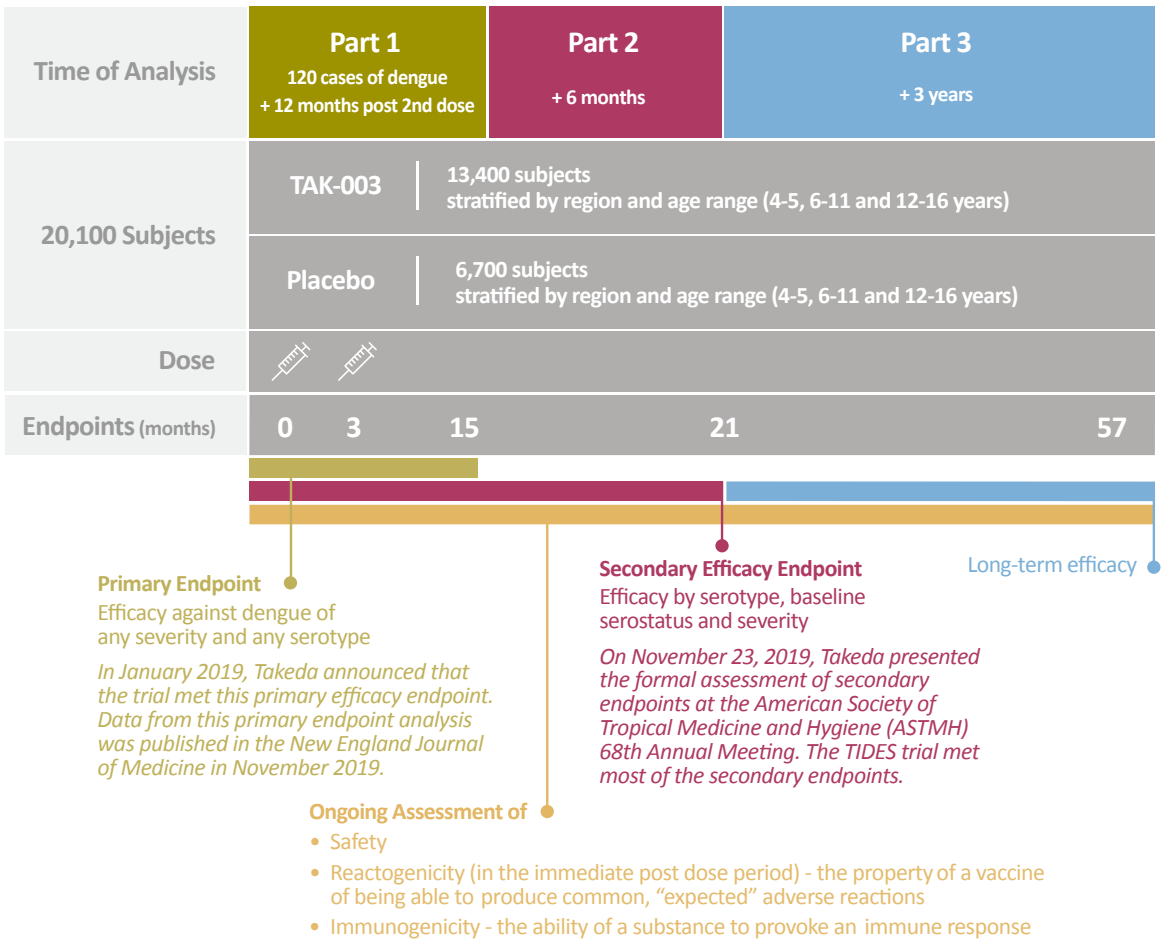
DEN-314 is a Phase 3, randomized, observer blind trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous Tetravalent Dengue Vaccine Candidate (TAK-003) and an intramuscular Hepatitis A Virus (inactivated) Vaccine in healthy subjects aged 18 to 60 years in a non-endemic country for dengue.[4] (NCT03525119)

DEN-301 is a Phase 3, double-blind, randomized, placebo-controlled trial to evaluate the efficacy, safety and immunogenicity of a Tetravalent Dengue Vaccine Candidate (TAK-003) administered subcutaneously in healthy children aged 4 - 16 years old.[3] (NCT02747927)

DEN-315 is a Phase 3 randomized, double-blind, placebo-controlled trial to describe the immunogenicity and safety of subcutaneous administration of a Tetravalent Dengue Vaccine Candidate (TAK-003) in healthy adolescent subjects in a non-endemic area for dengue.[5] (NCT03341637)

DEN-301 is Takeda's largest interventional clinical trial to date.

The trial, also known as the Tetravalent Immunization against Dengue Efficacy Study (TIDES), will evaluate the efficacy and safety of Tetravalent Dengue Vaccine Candidate (TAK-003) in a 2 dose schedule in preventing symptomatic dengue fever of any severity and due to any of the four dengue virus serotypes in both dengue exposed and naïve individuals, ages 4-16 years old, over the duration of the trial (57 months).[3]



References

1. ClinicalTrials.gov. Lot-to-lot Consistency of 3 Lots of Tetravalent Dengue Vaccine (TDV) in Non-endemic Country(Ies) for Dengue. 2018. Retrieved March 2019. https://clinicaltrials.gov/ct2/show/NCT03423173?term=Takeda&cond=%22Dengue%22&phase=2&rank=4
2. ClinicalTrials.gov. Immunogenicity and Safety of Tetravalent Dengue Vaccine (TDV) Administered With a Yellow Fever Vaccine in Adults. 2018. Retrieved March 2019. https://clinicaltrials.gov/ct2/show/NCT03342898?term=Takeda&cond=%22Dengue%22&phase=2&rank=2
3. ClinicalTrials.gov. Efficacy, Safety and Immunogenicity of Takeda's Tetravalent Dengue Vaccine (TDV) in Healthy Children (TIDES). 2018. Retrieved March 2019. https://clinicaltrials.gov/ct2/show/NCT02747927?term=den-301&rank=1
4. ClinicalTrials.gov. Immunogenicity and Safety of Tetravalent Dengue Vaccine (TDV) Co-administered With an Hepatitis A Virus Vaccine. 2018. Retrieved March 2019. https://clinicaltrials.gov/ct2/show/NCT03525119?term=Takeda&cond=%22Dengue%22&phase=2&rank=5
5. ClinicalTrials.gov. Immunogenicity and Safety of Tetravalent Dengue Vaccine (TDV) in Adolescents in Non-Endemic Area(s). 2018. Retrieved March 2019. https://clinicaltrials.gov/ct2/show/NCT03341637?term=Takeda&cond=%22Dengue%22&phase=2&rank=3