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. Its clinical development program consists of five 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)

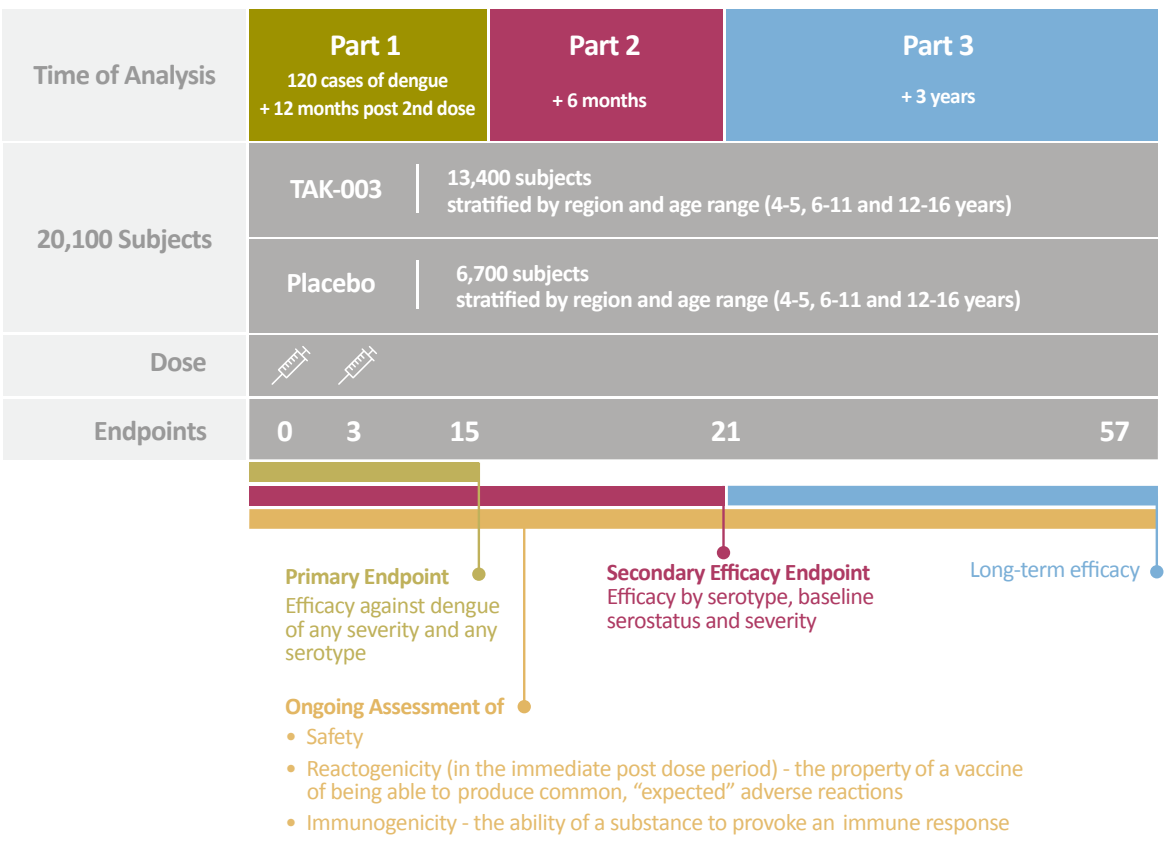
DEN-314 is a Phase 3, randomized, observer blind trial to investigate the immunogenicity and safety of the co-administration of a subcutaneous Tetravalent Dengue Vaccine Candidate (TAK-003) and an intramuscular Hepatitis A Virus (inactivated) Vaccine in healthy subjects aged 18 to 60 years in a non-endemic 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 look to evaluate the efficacy and long-term side effects of 2 doses of Tetravalent Dengue Vaccine Candidate (TAK-003) in preventing symptomatic dengue fever of any severity and due to any of the four dengue virus serotypes in 4 to 16 year old participants.[3]



References

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