

A Study of TAK-755 in Participants With Congenital Thrombotic Thrombocytopenic Purpura

NCT04683003

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	77 participants

Key Eligibility Criteria

Inclusion (37)

- Participants who have completed TAK-755 Phase 3 pivotal Study 281102 (NCT03393975) in the prophylactic cohort and who meet all of the following criteria are eligible for this study:
 - Participants or legally authorized representative has provided signed informed consent ≥ 18 years of age and/or assent form < 18 years of age.
 - Participant 0 to 70 years of age at the time of screening of the 281102 (NCT03393975) study.
 - Participant has been diagnosed with severe congenital ADAMTS-13 deficiency.
 - Participant does not display any severe thrombotic thrombocytopenic purpura (TTP) signs (platelet count $< 100,000$ / microliter (mL) and elevation of lactate dehydrogenase (LDH) greater than ($>$) $2 \times$ ULN at screening (prophylactic cohort only).
- ... and 32 more (see full listing online)

Exclusion (23)

- Participants who have completed TAK-755 Phase 3 pivotal study (281102) (NCT03393975) and naïve participants and non-naïve on-demand cohort participants and participants from an Expanded Access Program or participants in Study 281102 (NCT03393975) who had an allergic reaction to standard-of-care prophylactic treatment. The following criteria also applies to participants who completed study 281101 (NCT02216084), but did not participate in 281102 (NCT03393975).
 - Participant has been diagnosed with any other TTP-like disorder (microangiopathic hemolytic anemia), including immune-mediated TTP.
 - Known life-threatening hypersensitivity reaction, including anaphylaxis, to the parent molecule ADAMTS-13, hamster protein, or other constituents of TAK-755.
 - Participant has a presence of a functional ADAMTS-13 inhibitor at screening.
 - Participant has a medical history of a genetic or acquired immune deficiency that would interfere with the assessment of product immunogenicity, including participants who are human immunodeficiency virus-positive with an absolute cluster of differentiation 4 (CD4) count < 200 / cubic millimeter (mm^3) or who are receiving chronic immunosuppressive drugs.
- ... and 18 more (see full listing online)

Locations (27 total)

Childrens Healthcare of Atlanta, Atlanta, Georgia, United States
Roswell Park Comprehensive Cancer Center, Buffalo, New York, United States
Duke University Medical Center, Durham, North Carolina, United States
... and 24 more locations

<https://clinicaltrials.gov/study/NCT04683003>

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