Safety Study in Subjects ≥12 Years of Age With Hereditary Angioedema Switching to Garadacimab

NCT06806657

Status	RECRUITING
Phase	Phase 4
Sponsor	CSL Behring
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (8)

- • Aged \>= 12 years at the time of providing written informed consent / assent.
- • Have a history of response to on-demand HAE treatment for the treatment of acute HAE attacks.
- • Documented laboratory diagnosis in medical records of C1-esterase inhibitor hereditary angioedema (HAE-C1INH) type 1 or type 2:
- æDocumented clinical history consistent with HAE (subcutaneous or mucosal, nonpruritic swelling episodes without accompanying urticaria),
- æC1-esterase inhibitor (C1INH) antigen concentration or functional activity less than (\<) 50% of normal as documented in the participant's medical record, or

... and 3 more (see full listing online)

Exclusion (3)

- • Concomitant diagnosis of another form of angioedema, such as idiopathic or acquired angioedema or recurrent angioedema associated with urticaria.
- • Use of androgens, antifibrinolytics, or investigational products (other than garadacimab) for routine prophylaxis against HAE attacks.
- • Known or suspected hypersensitivity to monoclonal antibody therapy or hypersensitivity to the active substance (garadacimab) or to any of the excipients.

Locations (11 total)

Research Solutions of Arizona, Litchfield Park, Arizona, United States
Allergy and Asthma Clinic of Northwest Arkansas, Bentonville, Arkansas, United States
Donald Levy M.D., Orange, California, United States
... and 8 more locations