

Extension Study of Two Doses of Linsitinib in Subjects With Active, Moderate to Severe Thyroid Eye Disease (TED)

NCT06112340

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| Status | RECRUITING |
| Phase | Phase 2, Phase 3 |
| Sponsor | Sling Therapeutics, Inc. |
| Enrollment | 75 participants |

Key Eligibility Criteria

Inclusion (4)

- Subject who completed the 24-week double-mask period of VGN-TED-301 and are proptosis non-responders (< 2 mm reduction in proptosis in the study eye) at Week 24 of VGN-TED-301 study or proptosis responders at Week 24 who relapse during the Follow-Up period of VGN-TED-301
- Subject has not received any treatment for TED since Week 24 of VGN-TED-301
- Subjects must be euthyroid with the participant's baseline disease under control or have mild hypo- or hyperthyroidism (defined as free thyroxine $[FT4]$ and free triiodothyronine levels $[FT3]$ $< 50\%$ above or below the normal limits) at Baseline. Every effort should be made to correct mild hypo- or hyperthyroidism promptly and maintain the euthyroid state for the duration of the clinical trial
- Does not require immediate ophthalmic surgery, radiotherapy to orbits or other ophthalmological intervention at the time of Baseline and is not planning for any such treatment during the course of the study

Locations (2 total)

Bascom Palmer Eye Institute, Miami, Florida, United States
West Virginia University Eye Institute, Morgantown, West Virginia, United States