

# A Study to Investigate Efficacy and Safety of TOUR006 in Participants 18 to 80 Years of Age With Thyroid Eye Disease

NCT06088979

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Status	RECRUITING
Phase	Phase 2
Sponsor	Tourmaline Bio, Inc.
Enrollment	81 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Clinical diagnosis of Graves' disease associated with moderate to severe active TED
- Onset of active TED symptoms within approximately 15 months
- Proptosis (exophthalmos) e3 mm above the normal range per investigator judgment (based upon race and gender) for the study eye
- CAS e4 (on the 7-item scale) for the study eye
- Presence of TSI  $\geq 130\%$  of the normal reference standard or  $>0.55$  IU/L (depending on assay method) and laboratory reference ranges

### Exclusion (7)

- Anticipated need for intervention due to sight-threatening complications or other significant and acute deterioration in vision
  - Any previous treatment with teprotumumab or other agent that inhibits the IGF-1 receptor
  - History of systemic (eg, oral or IV) steroid use with a cumulative dose equivalent to  $>1$  g of methylprednisolone for the treatment of TED. Previous oral steroid use with a cumulative dose of  $\geq 1$  g methylprednisolone (or equivalent dosage for other systemic corticosteroid) for the treatment of TED, however, is allowed if the corticosteroid was discontinued at least 6 weeks before baseline (Day 1) and completely tapered by Baseline (if applicable).
  - Systemic (oral or IV) corticosteroid use for conditions other than TED within 6 weeks of baseline (Day 1) or not completely tapered by baseline (if applicable).
  - Any major illness/condition or evidence of an unstable clinical condition that, in the investigator's judgment, will substantially increase the risk to the participant, or confound the interpretation of safety assessments, if they were to participate in the study
- ... and 2 more (see full listing online)

## Locations (56 total)

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Catalina Eye Care - Site 840-121, Tucson, Arizona, United States  
Headlands Research - AMCR - Site 840-131, Escondido, California, United States  
Foothill Eye Institute - Site 840-116, Pasadena, California, United States  
... and 53 more locations