A Clinical Study to Evaluate the Efficacy and Safety of IBI311 in Subjects With Inactive Thyroid Eye Disease

NCT07113262

Status	RECRUITING
Phase	Phase 3
Sponsor	Innovent Biologics (Suzhou) Co. Ltd.
Enrollment	111 participants

Key Eligibility Criteria

Inclusion (5)

- At screening and baseline, the following diagnostic criteria for inactive TED were met:
- CAS of both eyes d 2 points during the screening period and baseline;
- According to the subject's medical history, CAS of both eyes d 2 points at least 6 months before screening, or according to the subject's chief complaint or medical history, with all of the following characteristics: no progression of proptosis and no new diplopia caused by TED at least 6 months before screening or no progression of diplopia caused by TED and no new inflammatory TED symptoms;
- According to the subject's chief complaint or medical history, the first TED diagnosis before screening was e 2 years and \< 10 years.
- At baseline, the proptosis of the study eye was e20 mm. 3.If the subject is a female, she should be infertile or have a negative blood pregnancy test during the screening period and agree to take contraceptive measures from the screening period to 120 days after the last medication. If the subject is a male, he should agree to take contraceptive measures from the screening period to 120 days after the last medication.

Exclusion (26)

- Subjects who meet any of the following conditions will not be eligible to participate in this study:
- At baseline, the eyeball protrusion of the study eye decreased by e2 mm compared with the screening period;
- Subjects who have been previously diagnosed with DON, or who are determined by the investigator to have DON during screening (defined as: orbital MRI/CT showing orbital apex crowding or optic nerve compression, and at least 2 of the following ophthalmological examination abnormalities that cannot be explained by other reasons: ` best corrected visual acuity \[BCVA\] \< 0.8 or BCVA decreased by e 2 lines compared with before the onset; a abnormal pupillary light reflex or relative pupillary afferent disorder; b color vision abnormalities; c optic disc edema and optic disc pallor on fundus examination; d visual field loss; e visual evoked potential with prolonged latency and/or decreased amplitude);
- Patients with corneal ulcers that are judged by the researchers to have no relief after treatment;
- Planned to receive orbital radiotherapy or surgical treatment for TED (including orbital decompression, strabismus correction, eyelid correction, etc.) at any time before baseline or during the study period;

... and 21 more (see full listing online)

Locations (1 total)

The First Affiliated Hospital of Medical University, Shenyang, Liaoning, China