

Open-Label Extension Study of MHB018A in Subjects With Thyroid Eye Disease

NCT07262476

Status	RECRUITING
Phase	Phase 3
Sponsor	Minghui Pharmaceutical (Hangzhou) Ltd
Enrollment	258 participants

Key Eligibility Criteria

Inclusion (10)

- Subjects voluntarily participating in the study and signing the informed consent form;
- Aged 18-75 years (inclusive), of any gender;
- Completed the 24-week double-blind treatment period in either the MHB018A-P-301 or MHB018A-P-302 study, and within 28 days after Week 24 visit of the previous study when enrolled in this OLE study (does not apply to subjects who meet the relapse criteria during the safety follow-up period).
- Proptosis non-responder at Week 24 visit in the double-blind treatment period of either the MHB018A-P-301 or MHB018A-P-302 study (defined as a ≤ 2 mm reduction from baseline in the study eye, or a ≥ 2 mm reduction in the study eye accompanied by a ≥ 2 mm worsening from baseline in proptosis of the fellow eye), and/or who meet the retreatment criteria for relapse during the safety follow-up period.
- Does not require immediate surgical ophthalmological intervention, and no corrective surgery/orbital radiotherapy is planned during the study.

... and 5 more (see full listing online)

Exclusion (11)

- Decreased best corrected visual acuity due to optic neuropathy as defined by a decrease in vision within the last 6 months of two lines of Snellen chart, new visual field defect or color defect secondary to optic nerve involvement.
- Corneal decompensation unresponsive to medical management.
- Free thyroxine (FT4) and free triiodothyronine (FT3) levels $\leq 50\%$ above or below the normal reference range at screening.
- Received any treatment for TED, intravenous corticosteroids, immunosuppressive agents, investigational drug from the last visit of the MHB018A-P-301 or MHB018A-P-302 trial until participation in this study.
- Identified pre-existing ophthalmic disease that would preclude study participation or complicate interpretation of the study results.

... and 6 more (see full listing online)

Locations (1 total)

Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai Municipality, China

<https://clinicaltrials.gov/study/NCT07262476>

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