

Sling Therapeutics Announces First Patients Dosed in Global Phase 3 ORBIT Pivotal Trial of Linsitinib for Thyroid Eye Disease

Linsitinib is the first and only oral IGF-1R inhibitor in Phase 3 development, poised to address multiple TED patient populations

Actively enrolling patients

ANN ARBOR, MI, September 16, 2026 – Sling Therapeutics, Inc., a clinical-stage biopharmaceutical company developing the first and only late-stage oral small-molecule therapy for thyroid eye disease (TED), today announced the first patients have been dosed in the global Phase 3 ORBIT pivotal trial, a global, randomized, double-masked, placebo-controlled study evaluating the efficacy and safety of linsitinib, an oral small molecule inhibitor of the insulin-like growth factor-1 receptor (IGF-1R), in adults with moderate to severe active thyroid eye disease (TED).

“ORBIT represents the next step toward what we believe could be a meaningful advancement in the treatment of TED. Linsitinib has already demonstrated the potential to deliver clinically meaningful improvements in proptosis with a differentiated safety profile, and it does so as an oral therapy – an important distinction in a treatment landscape currently defined by infused biologics,” said Ryan Zeidan, Ph.D., President and Chief Executive Officer of Sling Therapeutics. “The ORBIT trial is the second pivotal study with linsitinib in TED and will add to the totality of evidence supporting linsitinib as an effective disease-modifying therapy for TED without the treatment burden and safety tradeoffs associated with currently available biologic options.”

“TED is a serious ocular autoimmune disease that can progress rapidly, cause permanent damage and, in severe cases, threaten vision. Early treatment is critical, yet many patients remain untreated due to limitations of currently available therapies, including concerns about long-term hearing loss and the burden of traveling to infusion centers,” said Raymond Douglas, M.D., Ph.D., board-certified aesthetic and reconstructive oculoplastic surgeon. “An effective oral therapy such as linsitinib could help address these barriers and meaningfully expand access to treatment. With the proptosis responses and favorable safety profile observed with linsitinib to date, I look forward to seeing its potential further evaluated in the ORBIT trial.”

ORBIT is expected to enroll approximately 130 participants, randomized 1:1 to receive oral linsitinib 150 mg or placebo twice daily for 24 weeks. The primary endpoint is the proportion of proptosis responders at Week 24, defined as participants achieving a reduction of at least 2 mm in proptosis in the study eye without a corresponding worsening in the fellow eye. Secondary endpoints include mean change from baseline in proptosis, overall responder rate, Clinical Activity Score (CAS), and the Graves' Ophthalmopathy

Quality of Life (GO-QoL) questionnaire. Following the 24-week double-masked placebo-controlled treatment period, patients will be eligible to enroll in a 24-week open-label extension. To learn more about the ORBIT clinical trial, visit clinicaltrials.gov (identifier: NCT07753603).

About Thyroid Eye Disease (TED)

Thyroid Eye Disease (TED) is a serious, progressive, and vision-threatening rare autoimmune disease that is estimated to affect more than 200,000 people in the U.S. TED often occurs in people living with Graves' disease and hyperthyroidism and is caused by dysfunction in the IGF-1R (insulin-like growth factor 1 receptor) signaling pathway, which results in fibrous tissue growth behind the eyes. This leads to several negative symptoms that may have long-term, irreversible damage as the tissue growth pushes the eyes forward or causes the eyes and eyelids to become red and swollen. As the disease progresses, it can lead to pain, eye bulging (proptosis), and vision loss in severe cases, thus dramatically impacting a patient's quality of life. TED predominantly affects women, and most frequently affects people with hyperthyroidism due to Graves' disease. The current standard of care typically involves either invasive orbital surgery or a lengthy series of infusions with potential adverse events like loss of hearing, hyperglycemia, or menstrual cycle changes.

About Linsitinib

Linsitinib is a convenient oral small molecule in clinical development for thyroid eye disease (TED). Linsitinib works by inhibiting IGF-1R (insulin-like growth factor 1 receptor), a validated target in TED and the only target for currently approved therapies. Activation of the IGF-1R target leads to inflammation and proptosis seen in TED. Linsitinib has an established safety profile through treatment of more than 900 patients in 15 clinical trials in multiple diseases. Linsitinib has received Fast Track Designation from the U.S. FDA.

About Sling Therapeutics

Sling Therapeutics is a clinical-stage biopharmaceutical company focused on the late-stage advancement of an oral small molecule therapy for the treatment of thyroid eye disease (TED). Linsitinib, an IGF-1R (insulin-like growth factor 1 receptor) inhibitor, is designed to provide TED patients with an effective, convenient oral treatment option while reducing the treatment burden on patients, physicians and the healthcare system. For more information, visit www.slingtx.com.

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