



## Belite Bio Announces Completion of Enrollment in the Pivotal Global Phase 3 PHOENIX Trial Evaluating Oral Tlnlarebant in Geographic Atrophy

July 2, 2025

- 500 subjects enrolled across the United States, the United Kingdom, France, Czech Republic, Switzerland, China, Taiwan, and Australia

SAN DIEGO, July 02, 2025 (GLOBE NEWSWIRE) -- [Belite Bio, Inc.](#) (NASDAQ: BLTE), a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, today announced the completion of enrollment in the PHOENIX trial, a global, 24-month Phase 3 pivotal trial evaluating the safety and tolerability of Tlnlarebant and its potential to reduce atrophic lesion growth rate in patients diagnosed with geographic atrophy (GA) in dry age-related macular degeneration (AMD).

"Completing enrollment in the PHOENIX trial marks an important milestone for Belite Bio as we advance our lead candidate, Tlnlarebant, for the treatment of geographic atrophy," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "This achievement brings us one step closer to evaluating the potential of Tlnlarebant to slow atrophic lesion growth in this serious and progressive disease for which there are no approved oral treatments. There remains a significant unmet need for this patient population. We remain committed to advancing Tlnlarebant through late-stage development and look forward to sharing interim results at the midpoint of the PHOENIX trial."

"We are pleased to announce the completion of enrollment in our pivotal clinical trial in geographic atrophy, a milestone that reflects strong global interest in our investigational therapy," says Dr. Hendrik Scholl, Chief Medical Officer of Belite Bio. "The United States led enrollment by a significant margin, underscoring the appeal of a convenient, once-daily oral tablet compared to existing invasive treatment options."

"Geographic atrophy is a progressive and debilitating condition that can severely impact a person's vision and therefore quality of life, yet treatment options remain limited," said Dr. David Rhee, Principal Investigator at one of the top recruiting sites for the PHOENIX trial. "The PHOENIX study is designed to evaluate the efficacy of Tlnlarebant in slowing the growth of atrophic lesions, a key clinical marker of disease progression. Completing enrollment is a meaningful step in advancing research for this patient population, and I look forward to seeing the results from this important study."

Dry AMD is a leading cause of vision loss in older adults. GA is the advanced stage of dry AMD. People living with GA develop lesions within the retina that can impact their vision and diminish the ability to perform everyday activities like reading and driving. As the lesions expand, patients typically experience progressive loss of central vision. Currently, there are no approved, orally administered treatments for GA and no approved therapies for the earlier stages of dry AMD, such as intermediate AMD.

The PHOENIX study is a 24-month, randomized, double-masked, placebo-controlled, multicenter, pivotal Phase 3 trial. The study is ongoing across sites in the United States, the United Kingdom, France, Czech Republic, Switzerland, China, Taiwan, and Australia.

### About Tlnlarebant

Tlnlarebant is an orally administered, once-a-day tablet intended as an early intervention for maintaining the health and integrity of retinal tissues in Stargardt disease type 1 (STGD1) and Geographic Atrophy (GA) patients. Currently, there are no FDA approved treatments for STGD1 and no approved orally administered treatments for GA. Therefore, if approved, Tlnlarebant would be a novel oral therapeutic addressing an unmet medical need in both STGD1 and GA. Tlnlarebant has been granted Rare Pediatric Disease designation, Fast Track Designation, and Breakthrough Therapy Designation in the United States as well as Orphan Drug Designation in the United States, Europe, and Japan. It has also received Sakigake (Pioneer Drug) Designation in Japan for STGD1.

### About Belite Bio

Belite Bio is a clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, such as Stargardt disease type 1 (STGD1) and Geographic Atrophy (GA) in advanced dry age-related macular degeneration (AMD), in addition to specific metabolic diseases. Belite's lead candidate, Tlnlarebant, an oral therapy intended to reduce the accumulation of toxins in the eye, is currently being evaluated in a Phase 3 study (DRAGON) and a Phase 2/3 study (DRAGON II) in adolescent STGD1 subjects and a Phase 3 study (PHOENIX) in subjects with GA. For more information, follow us on [X](#), [Instagram](#), [LinkedIn](#), and [Facebook](#) or visit us at [www.belitebio.com](http://www.belitebio.com).

### Important Cautions Regarding Forward Looking Statements

This press release contains forward-looking statements about future expectations and plans, as well as other statements regarding matters that are not historical facts. These statements include but are not limited to statements regarding Belite Bio's advancement of, and anticipated future activities on preclinical studies, clinical development, regulatory milestones, and commercialization of its product candidates; and any other statements containing the words "expect", "hope", "indicate", "look forward to", and similar expressions. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Belite Bio's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the timing

to complete relevant clinical trials and/or to receive the interim/final data of such clinical trials; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; the potential efficacy of Tmlarebant, as well as those risks more fully discussed in the "Risk Factors" section in Belite Bio's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Belite Bio, and Belite Bio undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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