



Belite Bio Announces Oral Presentation at the ASRS Annual Meeting Featuring Additional Positive Secondary Endpoint Data from the Phase 3 Trial of Tinarebant in Stargardt Disease Type 1

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- *Tinarebant is the first therapeutic candidate to demonstrate clinical efficacy in Stargardt disease type 1, having met the primary efficacy endpoint, reduction in lesion growth*
- *Presentation to include positive update on secondary endpoints, with quantitative autofluorescence showing a marked divergence between treatment groups*
- *New Drug Application to the U.S. Food and Drug Administration for tinarebant completed*

SAN DIEGO, July 20, 2026 (GLOBE NEWSWIRE) -- [Belite Bio](#), Inc (NASDAQ: BLTE) ("Belite Bio" or the "Company"), a clinical-stage drug development company focused on advancing novel therapeutics targeting degenerative retinal diseases that have significant unmet medical needs, today announced additional, positive secondary endpoint data from its Phase 3 DRAGON trial of tinarebant in Stargardt disease type 1 (STGD1). The findings, along with previously reported topline data, were delivered in an oral presentation at the American Society of Retina Specialists (ASRS) 2026 Annual Meeting on July 18, 2026, in Montréal, Canada.

Notably, the presentation reported that quantitative autofluorescence (qAF), a marker of toxic bisretinoid accumulation, showed a marked divergence between treatment groups. At month 25, in subjects treated with tinarebant, qAF values remained stable to slightly decreased from baseline (approximately 2%), whereas placebo-treated subjects showed an approximate 20% increase in qAF from baseline. The presentation also provided encore data. As previously [announced](#), the Phase 3 DRAGON trial, which enrolled 104 subjects across 11 jurisdictions worldwide, with a 2:1 randomization (tinarebant:placebo), met its primary efficacy endpoint, demonstrating a statistically significant and clinically meaningful 35.7% reduction in the growth rate of retinal lesions, measured as definitely decreased autofluorescence (DDAF) by fundus autofluorescence imaging, compared with placebo. Tinarebant was well tolerated throughout the trial.

"These additional results from the Phase 3 DRAGON trial continue to reinforce our conviction that tinarebant has the potential to meaningfully slow retinal lesion growth in Stargardt disease. The data presented at ASRS builds on our foundational knowledge, adding to our understanding of tinarebant's effect across secondary and supportive measures," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "We were pleased that these findings were shared at this retina's flagship scientific meeting of the US and international community of retinal specialists as we advance through the regulatory review process and towards the potential approval of the first therapy for people living with STGD1."

"These new secondary endpoint analyses reinforce the consistency of the treatment effect of tinarebant. qAF values from baseline remained stable to slightly decreased, consistent with tinarebant's mechanism of reducing the bisretinoid accumulation that drives disease progression," said Dr. Hendrik Scholl, Chief Medical Officer of Belite Bio. "We believe these results deepen our understanding of tinarebant and further support its continued clinical development and potential in Stargardt disease."

About Tinarebant (a/k/a LBS-008)

Tinarebant is a novel oral therapy that is intended to reduce the accumulation of vitamin A-based toxins (known as bisretinoids) that cause retinal disease in Stargardt disease type 1 (STGD1) and also contribute to disease progression in geographic atrophy (GA), or advanced dry age-related macular degeneration (AMD). Bisretinoids are by-products of the visual cycle, which is dependent on the supply of vitamin A (retinol) to the eye. Tinarebant works by reducing and maintaining levels of serum retinol binding protein 4 (RBP4), the sole carrier protein for retinol transport from the liver to the eye. By modulating the amount of retinol entering the eye, tinarebant reduces the formation of bisretinoids. Tinarebant has been granted Breakthrough Therapy Designation, Fast Track Designation, and Rare Pediatric Disease Designation in the U.S., Orphan Drug Designation in the U.S., Europe, Japan, and Switzerland, and Sakigake Designation in Japan for the treatment of STGD1.

About Stargardt Disease Type 1 (STGD1)

STGD1 is the most common inherited macular dystrophy in both adults and children. The disease is caused by mutations in a retina-specific gene (ABCA4), which results in progressive accumulation of bisretinoids leading to retinal cell death and progressive loss of central vision. The fluorescent properties of bisretinoids and the development of high-resolution retinal imaging systems have helped ophthalmologists identify and monitor disease progression. Currently, there are no approved treatments for STGD1.

About Belite Bio

Belite Bio is a clinical-stage 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 Bio's lead candidate, tinarebant, is an oral therapy intended to reduce the accumulation of bisretinoid toxins in the eye. The Company has completed a Phase 3 trial (DRAGON) in adolescent and adult subjects with STGD1,

which met its primary endpoint, and the drug is currently being evaluated in a Phase 2/3 trial (DRAGON II) in adolescent and adult subjects with STGD1 and a Phase 3 trial (PHOENIX) in subjects with GA. For more information, follow us on [X](#), [Instagram](#), [LinkedIn](#), and [Facebook](#), or visit us at www.belitebio.com.

Important Cautions Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to future expectations, plans and prospects, 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 regulatory review process, the ability of tinlarebant to treat STGD1 and GA, the potential of tinlarebant to meaningfully slow retinal lesion growth, the potential approval of tinlarebant as the first therapy for people living with STGD1, as well as any other statements regarding matters that are not historical facts, and any other statements containing the words "may", "will", "expect", "believe", "target", "plan", "intend", "continue", "hope", "potential", "anticipate", "estimate", "look forward", and other similar expressions. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors related to Belite Bio's business, 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; expectations for the timing of initiation, enrollment and completion of, and data relating to, its clinical trials; the timing to complete any ancillary clinical trials and/or to receive the interim/final data of such clinical trials; the timing to communicate with and submit trial data to regulatory authorities for drug approval in various jurisdictions; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio's drug candidates; Belite Bio's ability to successfully commercialize tinlarebant, if approved, including its ability to build out commercial infrastructure, achieve market acceptance, and execute a timely product launch; timing for Belite Bio to share additional data at upcoming medical meetings; the potential efficacy of tinlarebant to set a new benchmark for future research in inherited retinal disorders, 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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