



## Belite Bio Completes Rolling Submission of New Drug Application to U.S. Food and Drug Administration for Tinarebant for the Treatment of Stargardt Disease Type 1

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SAN DIEGO, June 12, 2026 (GLOBE NEWSWIRE) -- [Belite Bio](#), Inc (NASDAQ: BLTE) ("Belite Bio<sup>®</sup>" 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 the completion of its rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tinarebant. Tinarebant is an investigational, once-daily oral therapy for the treatment of Stargardt disease type 1 (STGD1), a rare, inherited retinal disease caused by mutations in the ABCA4 gene that leads to progressive and irreversible vision loss. STGD1 affects an estimated 53,000 people in the U.S. alone, and there are currently no approved treatment options for the disease.

The rolling NDA was initiated in April 2026 and was submitted under Breakthrough Therapy Designation (BTD), which was granted by the FDA due to the high unmet need among patients living with STGD1. The completed application will undergo the 60-day review period with the FDA, and if accepted, a Prescription Drug User Fee Act (PDUFA) target action date will be assigned.

"The completion of our NDA submission marks a pivotal moment for Belite Bio and represents an important step forward for those affected by Stargardt disease who have long faced a future of progressive vision loss without an approved treatment option," said Dr. Tom Lin, Chairman and Chief Executive Officer of Belite Bio. "We are immensely grateful to everyone who made this milestone possible, including the patients, families, and investigators who participated in our clinical trials, and the entire Belite team. We look forward to honoring them by working with the FDA to advance tinarebant through the regulatory review process, while continuing to focus on our commercial preparedness activities in anticipation of a timely and efficient launch following potential approval."

"Stargardt disease places a profound burden on patients, often affecting them early in life and steadily diminishing central vision during critical years of education and independence," said Dr. Hendrik Scholl, Chief Medical Officer of Belite Bio. "We believe that the results from the Phase 3 DRAGON trial, which demonstrated tinarebant's ability to significantly reduce the growth rate of retinal lesions as compared to placebo, underscore its benefit and pave the way for it to potentially become the first approved therapy for this devastating 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 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 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 need, 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](http://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 the estimated STGD1 patient population in the U.S., Belite Bio's advancement of regulatory milestones and planned commercialization of its product candidates, Belite Bio's commercial preparedness and the timing and execution of a potential product launch following regulatory approval, the ability of tinarebant to treat STGD1 and GA, the timing for the FDA to review Belite Bio's NDA for tinarebant, the potential acceptance by the FDA and the potential assignment of the PDUFA target action date, 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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