Belite Bio Initiates Rolling Submission of New Drug Application to the U.S. Food and Drug Administration for Tinlarebant for the Treatment of Stargardt Disease

April 21, 2026

- *Belite expects to complete the new drug application submission in the second quarter of 2026*
- *Rolling submission initiated under Breakthrough Therapy Designation*

SAN DIEGO, April 21, 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 that it has initiated a rolling submission of an New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tinlarebant, an investigational novel oral therapy for the treatment of Stargardt disease type 1 (STGD1), a rare, inherited retinal disorder caused by mutations in the ABCA4 gene. Tinlarebant has previously been granted Breakthrough Therapy Designation (BTD) by the FDA for STGD1, and the FDA has previously granted Belite approval for the rolling submission of the NDA. The Company expects to complete the NDA rolling submission in the second quarter of 2026.

"Stargardt disease is a devastating, progressive disease that typically begins in adolescence and leads to legal blindness in virtually all cases, severely impacting quality of life for those affected. The initiation of the NDA submission marks an important milestone for patients, caregivers, physicians, and the entire Stargardt community, as tinlarebant has the potential to become the first-ever approved treatment for Stargardt disease," said Dr. Hendrik Scholl, Chief Medical Officer of Belite Bio. "I am proud of the data package that we are submitting to the FDA, including the transformative results from our Phase 3 DRAGON trial, and look forward to completing the NDA submission in the second quarter of this year."

"I would like to extend my deepest gratitude to the patients, caregivers, investigators and all who participated in and supported our clinical trials, along with the entire Belite team, for helping us reach this important step," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "Our team has been working toward this milestone since we released our pivotal trial data demonstrating tinlarebant's impact on slowing retinal degeneration. We are dedicated to bringing this potential treatment to patients in the U.S. and worldwide, and we are focused on continuing our commercialization preparation work, building out key teams including sales, market access, medical affairs, marketing, regulatory, and operations to ensure a seamless potential launch next year. We look forward to completing our NDA submission and working closely with the FDA during the review process."

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

Tinlarebant 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. Tinlarebant 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, tinlarebant reduces the formation of bisretinoids. Tinlarebant 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, and Japan, 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, tinlarebant, 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 STGD1 subjects, and the drug is currently being evaluated in a Phase 2/3 trial (DRAGON II) in adolescent STGD1 subjects 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 regarding future expectations, plans and prospectus, as well as other statements regarding matters that are not historical facts. These statements include but are not limited to statements regarding the potential implications of clinical data for patients, and Belite Bio's advancement of, and anticipated regulatory milestones, and commercialization of its product candidates, the ability of tinlarebant to treat STGD1 and GA, the timing to submit trial data to regulatory authorities for drug approval, as well as any other statements regarding matters that are not historical facts, and any other statements containing the words "expect", "believe", "target", "plan", "hope" "potential" 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; 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; 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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