Belite Bio Completes Enrollment in the DRAGON II Clinical Trial of Tinlarebant for Stargardt Disease (STGD1)

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- Tinlarebant is the first therapeutic candidate to demonstrate clinical efficacy in Stargardt disease, having met the primary endpoint in the pivotal, global Phase 3 DRAGON trial with 36% reduction in lesion growth (p-value=0.0033)
- 60 adolescent STGD1 subjects enrolled in DRAGON II clinical trial across Japan, the United States, and the United Kingdom
- Belite Bio plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in 1H 2026

SAN DIEGO, Jan. 27, 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 the completion of enrollment of 60 subjects, including 15 Japanese subjects, in the Phase 2/3 DRAGON II clinical trial evaluating tinlarebant for the treatment of Stargardt disease type 1 (STGD1).

DRAGON II clinical trial is a global, 24-month, randomized, double-masked, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of tinlarebant in adolescent patients with STGD1. The trial had a targeted enrollment of 60 adolescent subjects aged 12 to 20 years old across Japan, the United States, and the United Kingdom, with participants randomized 1:1 to receive either tinlarebant or placebo.

"We are pleased to complete enrollment in the DRAGON II clinical trial and sincerely thank the investigators, the adolescent participants, and their families who made this study possible," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "Their commitment reflects the strong engagement of the Stargardt disease community and supports our broader clinical development and commercialization efforts. Importantly, we remain on track to submit an NDA to the FDA for tinlarebant in the first half of 2026."

"Completing enrollment in DRAGON II clinical trial represents continued execution of our tinlarebant clinical development program," said Dr. Hendrik Scholl, Chief Medical Officer of Belite Bio. "We are pleased to have implemented a registration-enabling study that aligns with the requirements of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), supporting Belite Bio's ability to pursue potential approval in Japan while advancing research for adolescents living with Stargardt disease globally."

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 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 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 prospects, 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 preclinical activities, clinical development, regulatory milestones, and commercialization of

its product candidates, the ability of Tinlarebant to treat STGD1 and GA, the timing to complete relevant clinical trials and/or to receive the interim/final data of such clinical trials; 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”, “will”, “believe”, “target”, “plan,” 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 in various jurisdictions for drug approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Belite Bio’s drug candidates; 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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