Belite Bio Announces Extension of FDA Review Timeline for Tinlarebant NDA

November 20, 2026

SAN DIEGO, Nov. 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 that the U.S. Food and Drug Administration (FDA) has informed the Company that (i) it has extended the review period for the New Drug Application (NDA) for tinlarebant for the treatment of Stargardt disease type 1 (STGD1) by three months, with the extended Prescription Drug User Fee Act (PDUFA) action date being May 12, 2027, and (ii) if no major deficiencies are identified during FDA's ongoing review, the FDA plans to communicate proposed labeling requests and any anticipated postmarketing requirement requests, if necessary, with the Company by April 12, 2027.

The extension provides the FDA with additional time to review information provided in support of the NDA. Belite Bio remains committed to working closely with FDA throughout the review process, and is confident in the clinical evidence supporting tinlarebant and its potential to address the significant unmet medical need in the STGD1 patient population.

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 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. 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, 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 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, 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 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 belief in the totality of evidence supporting tinlarebant and its ability to potentially bring tinlarebant as the first-ever approved treatment for STGD1, Belite Bio's advancement of regulatory milestones and planned commercialization of its product candidates, FDA's ongoing review of the NDA, the likelihood that the NDA will be approved and the timing of any approval decision, the tentative PDUFA date and anticipated date for the FDA to communicate proposed labeling requests and postmarketing requirement requests with the Company, 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", "remain", "committed", "confident", "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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