



Belite Bio Announces Multi-Market Submission of Marketing Authorization Applications Via the Access Consortium Pathway for Tinarebant for the Treatment of Stargardt Disease Type 1

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- *If approved, tinarebant would be the first-ever approved treatment for Stargardt Disease Type 1 in Singapore, United Kingdom, and Switzerland*
- *Access pathway submission combined with accepted new drug applications in the U.S. (Prescription Drug User Fee Act target action date of February 12, 2027) and in Japan, further advance the Company's goal to bring tinarebant to Stargardt disease type 1 patients around the world*

SAN DIEGO, Oct. 14, 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 Marketing Authorization Application (MAA) submissions to the regulatory authorities in Singapore, the United Kingdom, and Switzerland for tinarebant in the treatment of Stargardt disease type 1 (STGD1). Tinarebant is an investigational, once-daily oral therapy for the treatment of STGD1, a rare, inherited retinal disease caused by mutations in the ABCA4 gene that leads to progressive and irreversible vision loss. There are currently no approved treatment options for the disease in Singapore, the United Kingdom, or Switzerland.

The three MAAs have been submitted via the Access Consortium framework in an agreement by the Health Sciences Authority (HSA), Medicines and Healthcare products Regulatory Agency (MHRA), and Swissmedic. The Access Consortium is a collaborative initiative comprised of multiple regulatory authorities designed to maximize regulatory collaboration across countries and support a timely review process.

"These submissions are an important step toward making tinarebant available globally to people living with STGD1. Filing through the Access Consortium allows us to pursue authorization across three additional countries in parallel. We are confident in our robust data showing tinarebant's ability to slow the growth rate of retinal lesions compared to placebo, and we look forward to working with each agency through their reviews," said Dr. Tom Lin, Chairman and Chief Executive Officer of Belite Bio. "If approved, tinarebant would become the first therapy approved for STGD1 in Singapore, the United Kingdom, and Switzerland. I want to thank my colleagues across the organization for their contributions, as well as the patients, their families, and the healthcare professionals who made these submissions possible."

These MAA submissions in addition to NDA submissions in the U.S. with Priority Review and Japan under the SAKIGAKE Designation System for accelerated review, support Belite's mission of building a global footprint for tinarebant for STGD1 worldwide.

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 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 and efficacy of tinlarebant to treat STGD1 and GA, the potential approval of tinlarebant as the first therapy in the U.S., Japan, Singapore, United Kingdom and Switzerland for people living with STGD1, Belite's ability to successfully launch and market tinlarebant after its potential approval, 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; 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, 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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