Belite Bio Announces China NMPA Agrees to New Drug Application with Priority Review based on Interim Analysis Results for the Treatment of Stargardt Disease with Tinlarebant

October 15, 2025

- *NMPA's response is based on the Phase 3 DRAGON interim analysis results*
- *Topline final data expected in Q4 2025*

SAN DIEGO, Oct. 15, 2025 (GLOBE NEWSWIRE) -- Belite Bio, Inc. (NASDAQ: BLTE), 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 Center for Drug Evaluation of China's National Medical Products Administration ("NMPA") has agreed to accept the New Drug Application (NDA) with priority review for Tinlarebant for the treatment of Stargardt disease based on the interim analysis results from the Phase 3 DRAGON trial.

"Having China NMPA agreed to review the NDA based on interim Phase 3 data is a remarkable milestone for Belite Bio and the Stargardt community," said Dr. Tom Lin, Chairman and CEO of Belite Bio. "This milestone underscores the strength of the program and the urgent need for therapies in this devastating disease, where no approved treatment options exist. This achievement positions Belite Bio to advance Tinlarebant through the final stages of development and, if successful, bring the first treatment to people living with Stargardt disease."

NMPA's response is based on the interim analysis results showing statistical significance in the primary endpoint of the Phase 3 DRAGON trial. The Company remains on track to report final topline data from the Phase 3 DRAGON trial in the fourth quarter of 2025. These results are expected to be submitted to the NMPA as part of the NDA that is currently under preparation in accordance with China CDE's guidance.

The pivotal Phase 3 DRAGON trial is a randomized, double-masked, placebo-controlled, global study designed to evaluate the safety and efficacy of Tinlarebant in adolescent patients with Stargardt disease. The trial enrolled 104 subjects across 11 jurisdictions, including the U.S., United Kingdom, Germany, France, Belgium, Switzerland, Netherlands, China, Hong Kong, Taiwan, and Australia, with a 2:1 randomization (Tinlarebant:placebo). The primary efficacy endpoint is the growth rate of atrophic lesions, alongside the assessment of safety and tolerability.

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 (Pioneer Drug) 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 STGD1 and GA in advanced dry AMD, in addition to specific metabolic diseases. Belite's lead candidate, Tinlarebant, an oral therapy intended to reduce the accumulation of bisretinoid toxins in the eye, is currently being evaluated in a Phase 3 study (DRAGON) and a Phase 2/3 study (DRAGON II) in adolescent STGD1 subjects and a Phase 3 study (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 about future expectations and plans, 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 Stargardt disease and geographic atrophy, and any other statements containing the words "expect", "hope" and similar expressions. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, 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 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; 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, 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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