Belite Bio announces submission of Clinical Trial Application for Phase 3 Stargardt Disease study of Tinlarebant (LBS-008) in South Korea

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- Tinlarebant (a/k/a LBS-008) is Belite Bio's **orally administered tablet** intended to halt or slow disease progression in patients affected with Stargardt Disease (STGD1) and advanced Dry Age-related Macular Degeneration (Dry AMD)
- A 2-year Phase 2 study in adolescent STGD1 patients is ongoing and a global Phase 3 study in adolescent STGD1 patients (the "DRAGON" study) is now recruiting subjects
- 12-month interim data from the ongoing Phase 2 STGD1 study continues to show halting or slowing of lesion growth
- Tinlarebant has been granted Fast Track Designation and Rare Pediatric Disease Designation in the U.S., and Orphan Drug Designation in both the U.S. and Europe for STGD1

Belite Bio, Inc (NASDAQ: BLTE), a San Diego based clinical stage biopharmaceutical drug development company targeting currently untreatable eye diseases, today announces the submission of a Clinical Trial Application to the Ministry of Food and Drug Safety (MFDS) to initiate a Phase 3 clinical trial of Tinlarebant (a/k/a LBS-008) for STGD1, or the DRAGO study, in the Republic of Korea.

The DRAGON study is a phase 3, randomized, double-masked, placebo-controlled, global and multi-center study, designed to evaluate the safety and efficacy of Tinlarebant in adolescent STGD1 patients. To date, the Company has commenced the DRAGON trial in the U.S., the United Kingdom, Germany, France, Belgium, Switzerland, Netherlands, China, Hong Kong, Taiwan, and Australia. At least 60 patients are targeted for enrollment in this study with a 2:1 randomization (active:placebo). (For more information, visit clinicaltrials.gov at https://www.clinicaltrials.gov/ct2/show/NCT05244304?term=belite+bio&draw=2&rank=1)

About Tinlarebant (a/k/a LBS-008)
Tinlarebant is a novel oral therapy intended to prevent the accumulation of vitamin A-based toxins (bisretinoids) that cause STGD1 and contribute to pathogenesis in Dry AMD. Bisretinoids are formed as by-products of vitamin A in the visual cycle. Tinlarebant works by reducing the level of serum RBP4, the carrier protein which transports the retinol to the eye. By modulating the amount of retinol entering the eye, Tinlarebant reduces the formation of bisretinoids to preserve the health of retinal tissues.

About Stargardt Disease

STGD1 is the most common inherited retinal dystrophy (causing blurring or loss of central vision) in both adults and children. The disease is caused by a dysfunctional retina-specific protein (ABCA4) which causes an early, aberrant accumulation of cytotoxic byproducts of vitamin A in the retina leading to retinal cell death and progressive loss of vision. There are currently no approved treatments available for STGD1.

About Dry Age-related Macular Degeneration
There are an estimated 20 million patients with AMD in the U.S. and 196 million patients worldwide with an estimated global direct healthcare cost of US$255 billion. Dry AMD accounts for approximately 90% of AMD cases and is a leading cause of vision loss in the U.S. Dry AMD has a heterogenous etiology but shows a pathophysiology that is similar to that of STGD1 in which the excessive accumulation of cytotoxic bisretinoids leads to retinal cell death and loss of vision. An advanced vision-threatening form of dry AMD is Geographic Atrophy (GA), which is characterized by progressive atrophy of the retinal pigment epithelium and underlying choriocapillaris, followed by loss of photoreceptors within the retina, and ongoing visual impairment. The incidence of GA is expected to rise as the age-burden of developed countries is increasing. There are currently no approved orally administered treatments for GA.

About Belite Bio

Belite Bio is a San Diego based clinical stage biopharmaceutical drug development company targeting currently untreatable eye diseases, such as atrophic age-related macular degeneration (commonly known as Geographic Atrophy or advanced Dry AMD) and STGD1, and metabolic diseases. For more information, follow us on Twitter, Instagram, LinkedIn, Facebook or visit us at www.belitebio.com.

Important Cautions Regarding Forward Looking Statements

This press release contains forward-looking statements, including 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, and any other statements containing the words "expect", "will", "believe" 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 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.

Media and Investor Relations Contact:
Jennifer Wu /ir@belitebio.com
Tim McCarthy /tim@lifesciadvisors.com