Belite Bio Receives Approval to Initiate LBS-008 Phase 1b Clinical Trial for Elderly Subjects in Australia

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- LBS-008 (a/k/a Tinlarebant) is Belite Bio's **orally administered tablet** intended as an **early intervention** to slow disease progression in patients affected with Stargardt Disease (STGD1) and Dry Age-related Macular Degeneration (Dry AMD)
- The Phase 1b dose-finding study in healthy adult volunteers aged between 50 to 85 is intended to determine the optimal dose for elderly subjects
- Currently, a 2-year Phase 2 study in adolescent STGD1 patients is ongoing and a global Phase 3 study in adolescent STGD1 patients is recruiting subjects
- 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

SAN DIEGO, Nov 14, 2022- Belite Bio, Inc (NASDAQ: BLTE), a San Diego based clinical stage biopharmaceutical drug development company targeting currently untreatable eye diseases, today announced the approval from Bellberry Human Research Ethics Committee to initiate the Phase 1b clinical trial of Tinlarebant in Australia. Tinlarebant is a specific and potent antagonist of serum retinol binding protein 4 (RBP4), the carrier protein which transports vitamin A (retinol) to the eye.

The Phase 1b dose-finding study is an open-label, parallel, single-dose study designed to evaluate the pharmacokinetics and pharmacodynamics of Tinlarebant in healthy volunteers aged between 50 to 85. This study targets to enroll sixteen participants. The study objective is to determine the optimal dose for elderly subjects.

About Tinlarebant (a/k/a LBS-008)

Tinlarebant is a novel oral therapy intended as an early intervention 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.

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.

Dry Age-related Macular Degeneration

Dry AMD is a leading cause of vision loss in the U.S. There are no approved treatments available for Dry AMD. 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. There are an estimated 11 million Dry AMD patients in the U.S. and over 196 million patients worldwide with an estimated global direct healthcare cost of US$255 billion.

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 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 "intend", "target", "will", 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 on the treatment of Dry AMD, 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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