Belite Bio Announces Presentation at the American Academy of Ophthalmology 2023 Annual Meeting

October 27, 2023

- Two-year data from the two-year Phase 1b/2 trial of Tinlarebant (LBS-008) in adolescent Stargardt Disease (STGD1) to be presented
- A two-year global Phase 3 trial in adolescent STGD1 (the “DRAGON” study) and a two-year global Phase 3 trial in Geographic Atrophy (GA) patients (the “PHOENIX” study) are on-going
- Tinlarebant has been granted Fast Track and Rare Pediatric Disease Designations in the U.S. and Orphan Drug Designation in both the U.S. and Europe for STGD1, for which there are no FDA approved treatments

SAN DIEGO, Oct. 27, 2023 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE), a clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases that have significant unmet medical needs, today announced that the two-year data from the Phase 1b/2 trial of Tinlarebant (LBS-008) in adolescent STGD1 will be presented at the American Academy of Ophthalmology Annual Meeting (AAO 2023) being held November 3 – November 6, 2023, in San Francisco, CA.

Details of the presentation are as follows:

Title: A Phase 1b/2 Study of the Safety and Tolerability of Tinlarebant in Adolescent Stargardt Subjects
Session: PA050
Date and Time: Sunday, November 5, 2023; 3:57 PM to 4:04 PM PST
Location: Moscone Center, San Francisco
Presenting Author: Dr. John Grigg, MBBS

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

Tinlarebant is a novel oral therapy that is intended to reduce the accumulation of toxins in the eye that cause STGD1 and contribute to GA, or advanced Dry Age-Related Macular Degeneration (AMD). These toxins are byproducts 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 the toxins that cause STGD1 and contribute to GA.

Stargardt Disease (STGD1)

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 mutations in a retina-specific gene (ABCA4) that results in massive accumulation of toxic vitamin A byproducts (known as “bisretinoids”) in the retina leading to retinal cell death and progressive loss of central vision. The fluorescent properties of bisretinoids and the development of retinal imaging systems have helped ophthalmologists identify and monitor disease progression. Currently, there are no FDA approved treatments for STGD1.

Importantly, STGD1 and GA, or advanced Dry AMD, share a similar pathophysiology that is characterized by the excessive accumulation of cytotoxic bisretinoids, retinal cell death, and loss of vision. Vision loss occurs slowly, despite peripheral expansion of “dead retina,” until the disease reaches the center of the eye (the macula). Therefore, Belite Bio intends to evaluate safety and efficacy of Tinlarebant in GA patients in its Phase 3 PHOENIX study.

GA in advanced Dry Age-related Macular Degeneration (Dry AMD)

Dry AMD is a leading cause of vision loss in older adults. GA is the advanced stage of AMD. Currently, there are no FDA approved, orally administered treatments for GA and no FDA approved therapies for stages of Dry AMD other than GA. There are an estimated 20 million 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 clinical-stage biopharmaceutical drug development company focused on advancing novel therapeutics targeting retinal degenerative eye diseases that have significant unmet medical needs, such as STGD1 and GA in advanced Dry AMD, in addition to specific 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 Belite Bio's advancement of, and anticipated preclinical activities, and clinical development . 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.

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