Belite Bio Receives Approval to Initiate LBS-008 Phase 3 Study at CERA Clinical Trial Site in Australia

June 20, 2022

SAN DIEGO, June 20, 2022- Belite Bio, Inc (NASDAQ: BLTE) (“Belite” or the “Company”), a San Diego based clinical stage biopharmaceutical drug development company targeting untreatable eye diseases, today announced the approval to initiate the Phase 3 clinical trial of LBS-008 at Centre for Eye Research Australia (CERA), a clinical trial site in Melbourne, Australia.

Belite’s Phase 3 clinical trial is a randomized, double-masked, placebo-controlled, global, multi-center, study, and is designed to evaluate the safety and efficacy of LBS-008 in adolescent Stargardt Disease patients. Approximately 60 patients are targeted for enrollment in this study with a 2:1 randomization (active:placebo). For more details, please click on link.

About LBS-008

LBS-008 is a novel oral therapy that prevents the buildup of toxins in the eye that cause STGD1 and contribute to dry AMD. These toxins are by-products of the visual cycle, which is dependent on the supply of vitamin A (retinol) to the eye. LBS-008 works by reducing and maintaining levels of serum retinol binding protein 4 (RBP4), a carrier protein that transports retinol to the eye. By modulating the amount of retinol entering the eye, LBS-008 reduces the formation of toxins which have been implicated in STGD1 and dry AMD in order to maintain the health of retinal tissues. LBS-008 has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of STGD1.

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 gene (ABCA4) which 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 have helped ophthalmologists identify and monitor disease progression. Additionally, STGD1 and dry AMD share a similar pathophysiology characterized by 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).

Dry Age-related Macular Degeneration
Dry AMD is a leading cause of vision loss in the U.S., and has zero approved treatments available. 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 untreatable eye diseases, such as atrophic age-related macular degeneration (commonly known as dry AMD) and Stargardt disease, 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 certain "forward-looking statements" within the meaning of federal securities laws. All statements, other than statements of historical facts, included herein are "forward-looking statements" including, among other things, statements about Belite’s beliefs and expectations. The expectations reflected in these forward-looking statements involve significant assumptions, risks and uncertainties, and these expectations may prove to be incorrect. Investors should not place undue reliance on these forward-looking statements, which speak only as of the date of this press release.Potential risks and uncertainties include, but are not limited to, risks discussed in Belite’s filings with the U.S. Securities and Exchange Commission at www.sec.gov. Other than as required under the securities laws, the Company does not assume a duty to update these forward-looking statements.

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