

Belite Bio to Host Key Opinion Leader Webinar on October 27, 2022 to discuss LBS-008 Interim Data

October 20, 2022

"Potential Early Intervention with an Oral Treatment for Stargardt Disease and Dry Age-Related Macular Degeneration"

Thursday, October 27th at 11 AM ET

SAN DIEGO, Oct. 20, 2022 (GLOBE NEWSWIRE) -- Belite Bio, Inc (NASDAQ: BLTE), a San Diego based clinical stage biopharmaceutical drug development company targeting currently untreatable eye diseases, will host a key opinion leader (KOL) event with a focus on LBS-008 (aka Tinlarebant), the Company's lead asset for the treatment of Stargardt Disease (STGD1) and Dry Age-Related Macular Degeneration (Dry AMD) on Thursday, October 27, 2022 at 11 a.m. Eastern Time.

The webinar will feature a presentation from Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, from Stanford University School of Medicine, who will discuss Belite Bio's one-year interim data from the two-year Phase 1b/2 trial of LBS-008, an oral treatment intended as a potential early intervention for the treatment of STGD1 and Dry AMD.

A live Q&A session will follow. To register for the event, please click here.

Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS

Dr. Quan Dong Nguyen is currently Professor of Ophthalmology at the Byers Eye Institute and Professor of Pediatrics (Rheumatology) and Professor of Medicine (Immunology and Rheumatology) at the Stanford University School of Medicine.

Dr. Nguyen earned his medical degree at the University of Pennsylvania School of Medicine. He completed an internship in Internal Medicine at the Massachusetts General Hospital and a residency in Ophthalmology at the Massachusetts Eye and Ear Infirmary, Harvard Medical School. Dr. Nguyen also completed fellowships in Immunology and Uveitis at the Massachusetts Eye and Ear Infirmary, Ocular Immunology at the Wilmer Eye Institute of the Johns Hopkins Medical Institutions, and medical and surgical retina at the Schepens Eye Research Institute and the Massachusetts Eye and Ear Infirmary.

Dr. Nguyen serves as principal investigator on multiple clinical trials sponsored by the National Eye Institute and other organizations for macular edema (from diabetes and uveitis), neovascular (wet) and non-neovascular (dry) age-related macular degeneration (AMD), and ocular inflammatory and uveitic diseases. Dr. Nguyen and his team were among the first clinician scientists in the world to evaluate aflibercept for neovascular AMD and aflibercept and ranibizumab for diabetic macular edema (DME). Dr. Nguyen has led the SAVE, and the multi-centered SAVE-2, STOP-UVEITIS, and ACTHAR studies to evaluate the role of new pharmacologic agents in uveitis and ocular inflammatory diseases.

Throughout his career thus far, Dr. Nguyen has shared his scientific work in more than 350 manuscripts published in the literature and was chosen as the Founding and Inaugural Editor-in-Chief of American Journal of Ophthalmology Case Reports. In 2004, Dr. Nguyen became the first US medical school graduate to lead the Vietnamese American Medical Association (VAMA) as President and was re-elected in 2007, serving until 2010. Most recently, Dr. Nguyen was elected as Chairman of the Board of Directors of the VAMA (2016-2019). Moreover, Dr. Nguyen has also been very involved in helping to enhance and promote activities of the International Ocular Inflammation Society (IOIS) and has been elected to serve as Secretary General for the Executive Committee of the IOIS for the term 2015-2023.

At the Byers Eye Institute at Stanford, Dr. Nguyen has an active uveitis and ocular inflammatory diseases as well as clinical and surgical retina practice while he continues his research in pharmacotherapy and ocular imaging.

About LBS-008 (aka Tinlarebant)

Tinlarebant is a novel oral therapy that prevents the buildup of toxins in the eye that cause STGD1 and contribute to advanced Dry AMD. These toxins 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), a carrier protein that transports retinol to the eye. By modulating the amount of retinol entering the eye, Tinlarebant reduces the formation of toxins that have been implicated in STGD1 and Dry AMD. Tinlarebant has been granted Fast Track Designation and Rare Pediatric Disease designation in the U.S., and Orphan Drug Designation in the U.S. and Europe 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. Importantly, STGD1 and Dry AMD share a similar pathophysiology which 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).

Dry Age-related Macular Degeneration

Dry AMD is a leading cause of vision loss in the U.S. and has no 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's STGD1 Study

Belite Bio is currently conducting an open label, two-year, Phase 2 study and a placebo controlled, two-year, Phase 3 study of Tinlarebant in adolescent STGD1 subjects. Belite Bio expects the next data readout in its Phase 2 study to occur during the second quarter of 2023 when all subjects will have completed 18 months of treatment. The two-year Phase 3 study (DRAGON) is a multi-center, randomized, **D**ouble-masked, placebo-controlled study to evaluate the safety and efficacy of Tinla**R**ebant in the treatment of St**ArG**ardt Disease in ad**O**lesce**N**t subjects. To date, Belite Bio has commenced the Phase 3 study in the U.S., the United Kingdom, Germany, Belgium, Switzerland, Hong Kong, Taiwan, mainland China and Australia. Approximately 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 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, 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 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. 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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