



Belite Bio Announces Start of LBS-008 Phase 3 Stargardt Disease Trial

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San Diego

SAN DIEGO, June 30, 2021- Belite Bio, a clinical stage biopharmaceutical drug development company announced the initiation of Phase 3 clinical trial in Stargardt disease for tinlarebant (LBS-008), a First-in-Class oral small molecule RBP4 antagonist aimed to treat atrophic Age-related Macular Degeneration (commonly known as dry AMD) and Stargardt disease, an inherited juvenile form of macular degeneration. Since Stargardt patients suffer from progressive vision loss since childhood, they urgently need treatments as early as possible. LBS-008 entering Stargardt Phase 3 is an important development milestone for Belite Bio and at the same time, brings hope to Stargardt patients and their families.

Stargardt disease is an inherited juvenile form of macular degeneration, which affects 1 in 8,000-10,000 children. Some Stargardt patients suffer severe visual impairment by the age of 20, and currently there is no treatment available. The disease is caused by a mutation in the ABCA4 gene, which leads to the accelerated formation and accumulation of excess vitamin A toxic by-products known as A2E. A2E accumulates in the retina that cause progressive retinal cell death and permanent loss of vision.

LBS-008 has received US and EU orphan drug designation (ODD), and rare pediatric disease designation (RPD) from the FDA. LBS-008 has completed its Stargardt Phase 2 patient enrollment and initiated a global Phase 3 in Stargardt disease.

About LBS-008

LBS-008 is a first-in-class oral therapy that prevents the buildup of toxins in the eye that cause Stargardt Disease and contribute to atrophic Age-related Macular Degeneration (dry AMD). The toxins are a by-product of the eye's visual cycle, which is dependent on the excess supply of vitamin A (retinol) to the eye. LBS-008 works by reducing and controlling circulating levels of retinol binding protein (RBP4), a carrier protein that transports vitamin A to the eye. By modulating the amount of retinol entering the visual cycle, LBS-008 reduces the formation of toxins associated with macular degeneration and maintains the health of retinal tissues.

Dry Age-related Macular Degeneration

Atrophic age-related macular degeneration (dry AMD) is the main cause of vision loss in the United States, and has zero approved treatments available. There are an estimated 11 million dry AMD patients in the US and over 170 million patients worldwide¹ with a global direct healthcare cost of 255 billion US dollars ².

About Belite Bio

Belite Bio, a subsidiary of Lin BioScience, is a San Diego based clinical stage biopharmaceutical drug development company targeting untreatable diseases, including age-related macular degeneration, Stargardt disease, and liver diseases. For more information, please visit www.belitebio.com.

Reference:

1. [Katie L. Pennington](#) and [Margaret M. DeAngelis](#) (2016). Epidemiology of age-related macular degeneration (AMD): associations with cardiovascular disease phenotypes and lipid factors. URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5178091/> (accessed 17 April 2019)
2. BrightFocus Foundation. Sources for Macular Degeneration: Facts & Figures. URL: <https://www.brightfocus.org/sources-macular-degeneration-facts-figures> (accessed 17 April 2019)