



FDA Grants Lin BioScience (Now Belite Bio™) Rare Pediatric Disease Status for LBS-008 to Treat Stargardt Disease

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San Diego

Lin BioScience (now Belite Bio™), a drug development company targeting untreatable conditions in oncology, ophthalmology and metabolic diseases, announced today that the US Food and Drug Administration (FDA) has granted Rare Pediatric Disease (RPD) designation to [LBS-008](#), a first-in-class oral therapy for the treatment of Stargardt Disease.

The Priority Review Voucher Program is intended to encourage development of therapies to prevent and treat rare pediatric diseases. If LBS-008 is approved by the FDA for Stargardt Disease, the RPD designation qualifies Lin BioScience for the Priority Review Voucher. The voucher, which can be sold or transferred to another entity, can be used by the sponsor to receive Priority Review for a future NDA or BLA submission and reduce the candidate's FDA review time to six months.

"We continue to be encouraged by the regulatory support for LBS-008 and the opportunities provided by the Rare Pediatric Disease designation and the Priority Review Voucher Program", stated Dr. Tom Lin, CEO of Lin BioScience (now Belite Bio).

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 atrophic Age-related Macular Degeneration (dry AMD). The NIH's Blueprint Neurotherapeutics Network, which funded the therapy's discovery and development, provides support and funding through to the completion of Phase I clinical trials. LBS-008 received both US and EU orphan drug designation in 2017 and 2018, respectively.

About Stargardt Disease

Stargardt Disease is an untreatable inherited condition that causes permanent vision loss in children during childhood and adolescence. This rare disease is caused by a mutation in the ABCA4 gene, which leads to the accelerated formation and accumulation of toxic vitamin A dimers in the retina that cause progressive retinal cell death and permanent loss of vision.

About Lin BioScience, Inc (Now Belite Bio, Inc)

Lin BioScience, Inc. (now Belite Bio, Inc.) is a drug development company targeting untreatable diseases. Our therapeutic pipeline, which includes two candidates with Orphan Drug Status, is focused on meeting the unmet needs of patients suffering from cancer, macular degeneration, liver disease and diabetes.