Press Release

Abliva AB (publ), 556595-6538
24 November 2021 20:40:00 CET - Lund, Sweden

Abliva's IND for clinical development of KL1333 approved by FDA

Abliva AB (Nasdaq Stockholm: ABLI), a clinical-stage biopharmaceutical company developing medicines for the treatment of rare and severe primary mitochondrial diseases, today announced that the US Food and Drug Administration has approved Abliva's Investigational New Drug (IND) application for KL1333, enabling the start of a registrational Phase 2/3 study with first patients due to be recruited in 2022.

"The approval of the IND is an important milestone for Abliva as it means that the FDA has reviewed the full package of data supporting KL1333 and the proposed design of our Phase 2 /3 study and has given us permission to proceed to dosing of PMD patients with KL1333", said Abliva's CEO Ellen Donnelly. "We can now commence our global, registrational Phase 2/3 study with KL1333, continued Donnelly."

"With this approval, we now intend to move forward with a financing round. The Board has growing confidence that the quality of the asset and the IND approval are attractive to specialist life science investors and companies", said
David Laskow-Pooley, Chair of Abliva AB.

This information is information that Abliva AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out below, at 2021-11-24 20:40 CET.

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About primary mitochondrial diseases

Primary mitochondrial diseases are metabolic diseases that affect the cells' ability to convert energy. The disorders can manifest differently depending on the organs in which the genetic defects are present. They have historically been viewed as clinical syndromes and more recently as disease spectra, caused by genetic defects affecting mitochondrial function. An estimated 125 in every 1,000,000 people suffer from a primary mitochondrial disease. The diseases often present in early childhood and lead to severe symptoms such as mental retardation, fatigue, myopathy, heart failure and rhythm disturbances, diabetes, movement disorders, stroke-like episodes, and epileptic seizures.

About KL1333

KL1333 is being developed towards a treatment for a subset of adult primary mitochondrial disease patients suffering from multiple debilitating symptoms, including chronic fatigue and myopathy. Diagnoses can include MELAS-MIDD and KSS-CPEO spectrum disorders as well as MERRF syndrome. The KL1333 compound is a potent modulator of the cellular levels of NAD+ and NADH, central co-enzymes in the cell's energy metabolism. In a cohort of PMD patients in a Phase 1a/b study, the patients who received KL1333 showed both improvements in symptoms of fatigue as well as functional improvements. KL1333 has received orphan drug designation in both the USA and Europe.

Attachments

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