

Press Release

Positive clinical effect in Phase 2 trial in patients with the rare disease alpha-Mannosidosis

The biotechnologically derived human enzyme rhLAMAN (Lamazym™), which is produced by the Danish biotech company Zymenex and developed for the treatment of patients suffering from the rare lysosomal storage disease alpha-Mannosidosis, has successfully completed a Phase 2a clinical trial.

“9 patients aged 7 to 18 years were recruited to the Phase 2a clinical trial from European hospitals and each week flown to Copenhagen, Denmark to be treated here at the Department of Clinical Genetics, Copenhagen University Hospital”, says Chief Physician Dr. Allan Meldgaard Lund MD, who is the Principal Investigator and treating physician. “There is an unmet need for the patients suffering from this disease and we are very encouraged by the results we see.”

The patients were divided into two cohorts receiving doses of 1 mg/kg or 2mg/kg respectively each week. Apart from finding the minimum effective dose, the goal of the Phase 2a trial was to demonstrate that the enzyme was effective and improved the patient's condition. There was a clinically relevant improvement in the parameters measured and thus the goal has been achieved.

This now allows the 9 patients to be moved forward into a 6 -month Phase 2b clinical trial, where the aim is to verify the minimum effective chosen dose of 1mg/kg, by monitoring the effect on chosen composite efficacy endpoints in order to confirm the clinical effect of repeated weekly i.v dosing.

“The positive results of the clinical trials are due to the collaborations over the years between the Zymenex team and many leading scientific and clinical colleagues from different European countries in the joint EURAMAN, HUE-MAN and presently ALPHA-MAN EU Framework projects,” says Dr. Jens Fogh, President and CEO of Zymenex A/S. “We have spent 10 years developing this product and are now near to our goal, which is to provide an enzyme replacement therapy available for ALL alpha-Mannosidosis patients.”

Further information:

Alpha-Mannosidosis is an inherited, rare disease, with a prevalence of 1 in 500,000 people. The disease is due to a lack of the lysosomal enzyme α -Mannosidase (LAMAN) that is responsible for lysosomal degradation of oligosaccharides. The lack of enzyme leads to accumulation of oligosaccharides in the cells, which negatively affects cell function and leads to mental retardation, severe skeletal and muscular changes, hearing loss and recurrent infections. The disease belongs to the category of lysosomal storage disorders, into which Zymenex has previously documented research competence. Lamazym has received Orphan Drug Designation in both Europe and the US.

Positive change from baseline to after 26 weeks of dosing has been demonstrated in the primary measured clinical endpoints.

- Statistically significant reduction was demonstrated in oligosaccharide levels in urine and serum as well as in the CNS biomarker TAU protein.
- The change in the 6 minute walk test (6MWT) was a marked increase of 39 meters.
- Statistically significant improvement in the 3 minute stair climb test (3MSC) with an increase of 30 steps.
- The forced vital capacity (FVC), lung function showed a marked increase of 4,7%.
- There was a statistically significant improvement of 6,3% in the Leiter Cognitive test, which measures intellectual ability.

The clinical data is expected to be presented at a meeting in the Danish Neuropaediatric Society, November 25-26, 2011 in Hindsgavl and at the Lysosomal Disease Network World Symposium, February 6-10, 2012 in San Diego, California USA.

Zymenex A/S www.zymenex.com, was founded in 1998 as a Danish biopharmaceutical company with headquarters in Hillerød north of Copenhagen, Denmark and with research laboratories in Stockholm, Sweden.

The company is focused on research and development of pharmaceutical products for the treatment of rare, genetic diseases, for which there is no treatment today. Zymenex has two other lysosomal projects in the pipeline: Galaczym for the treatment of Krabbe Disease, which is in pre-clinical and an early discovery project which is very new.

Danish venture capital investor Sunstone Capital supports Zymenex financially.

Denmark, Hilleroed, October 17, 2011

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