

P R E S S R E L E A S E

Hillerød, Denmark, April 15, 2008

Zymenex gets US Orphan Approval

The FDA has granted Zymenex Orphan Designation for its enzyme Metazym, for the treatment of the rare, lysosomal disease Metachromatic Leukodystrophy (MLD). Orphan designation qualifies the sponsor of the product for tax credits and marketing exclusivity incentives of the Orphan Drug Act. Zymenex has previously received Orphan Designation in the EU.

Zymenex has just recently also received US FDA approval of its Investigational New Drug (IND) application, for its enzyme Metazym. Based on the successfully completed EU Phase 1 trial results, the company can go directly into Phase 2 clinical trials in the US.

The US Phase 2 clinical trial is being conducted by Dr. Maria Escolar at the Program for Neurodevelopmental Function in Rare Disorders, Center for the Study of Development and Learning, University of North Carolina (UNC), Chapel Hill, North Carolina, USA.

Metazym is in Phase 2 clinical trials in European MLD patients. The trials have now been running for over a year and expect to be completed in the second half of 2008. Drs Allan M. Lund and Christine i Dali from the University Hospital of Copenhagen, Denmark are responsible for the European trial, which takes place in Denmark.

Supplemental information:

Metachromatic Leukodystrophy (MLD), is one of 45 diseases within the family of Lysosomal Storage Diseases.

MLD is caused by an increased concentration of sulphatide in cells and an ensuing breakdown of "myelin", a substance that protects the nerves in the brain and the rest of the body. The disease occurs due to a lack of the enzyme Arylsulfatase A (ASA), which causes irreparable neurological damage and death. There are no clear benefits from any other present therapy for children with Late-infantile MLD who are often diagnosed at the age of two years. Once symptoms become evident they have rapid neurological deterioration, become bedridden until they die within three to four years. The disease is rare and therefore unknown to the general public. The disease can in some ways be compared to Multiple Sclerosis, which also exists in several forms and can have a very quick and lethal progression.

Zymenex is a Scandinavian biopharmaceutical company, founded in 1998, with headquarters in Hillerød north of Copenhagen, Denmark and 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 and which, due to the small patient populations, fall within “Orphan Diseases” and the Orphan Drug Acts.

Zymenex has two other projects for Orphan Diseases in the development pipeline; Lamazym for Alpha-mannosidosis and Galaczym for Globoid Cell Leukodystrophy (Krabbe Disease).

Zymenex is supported financially by the Danish venture capital investors BankInvest and Sunstone Capital and has received gifts from The British Trust for The Myelin Foundation, the MLD Foundation (USA) and the Athena’s Hope Foundation.

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