

## Press release

Hillerød, Denmark , March 10 , 2008

# Zymenex gets FDA approval of IND

Zymenex has received FDA approval of its Investigational New Drug (IND) application for its enzyme Metazym, which is intended for use in the treatment of the rare, lysosomal disease Metachromatic Leukodystrophy (MLD). The company is now preparing for Phase 2 clinical trials in the USA.

“This milestone is very important and paves the way towards a treatment for the patients in the USA suffering from this lethal disease,” says CEO Jens Fogh, Zymenex A/S.

The Phase 2 trial will include 10 patients with late-infantile MLD and will be performed by Dr. Maria L. 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. The FDA IND approval is the first step towards being able to initiate the trial. The trial protocol must now be approved by the Ethical Committee at UNC, along with formalizing various administrative and logistical issues. These processes will take at least 6 months before the trial can begin.

“We are very excited about the prospect of evaluating a potential new therapy for this neurologically devastating disease”, says Dr. Escolar.

In Europe, Metazym has been in Phase 2 clinical trials in MLD patients for a year. Drs Allan M. Lund and Christine i Dali from Rigshospitalet, Copenhagen are responsible for the trial and the treatment of the patients.

## 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 A/S has developed Metazym. The company 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.

#### **Further information**

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