

OxThera updates on Phase 3 study with Oxabact® in Primary Hyperoxaluria

OxThera AB, a Stockholm-based privately-held biopharmaceutical company, today announced that the Phase 3 study with Oxabact® in Primary Hyperoxaluria (PH) is now fully open for recruitment. All clinics participating in the study are approved by Competent authorities in Europe and US and are initiating patient screening.

"We are pleased to announce that we are now fully open for enrolment in our Phase 3 study with Oxabact® in Primary Hyperoxaluria", says Matthew Gantz, CEO of OxThera. "In fact, we have already enrolled several patients. We are confident that our new Oxabact® product has potential in helping patients with this devastating disease".

The placebo-controlled clinical trial, OC5-DB-02, is conducted at 10 clinical sites in Europe and US and will enroll a total of 22 patients. The last patient is expected to complete study procedures in 2019. Oxabact® is an oral treatment composed of highly concentrated freeze-dried live bacteria (*Oxalobacter formigenes*), administered as capsules twice a day. The drug is designed for delivery to the small intestine, and the study is aiming to improve secretion of oxalate from plasma to the gut, where oxalate is broken down by the microbiome.

"The development of new treatments for PH represents an opportunity for patients to have more treatment options in the future" added Kim Hollander, Executive Director at the Oxalosis and Hyperoxaluria Foundation.

Primary hyperoxaluria is a rare autosomal recessive disorder leading to markedly elevated levels of endogenous oxalate in plasma and urine. High levels of oxalate cause kidney damage, including crystallization of oxalate in tissues and in the kidney. If left untreated, the disease can cause kidney failure and premature death.

Participating sites are Universitätsklinikum Bonn, Germany, Hôpital Femme Mère Enfant, Lyon, France, Hôpital Robert Debré, Paris, France, Academic Medical Center, Amsterdam, Netherlands, Hospital Vall d'Hebron, Barcelona, Spain, Royal Free Hospital, London, UK, Centre Hospitalier Universitaire de Liège, Liège, Belgium, Mayo Clinic, Rochester, US, Boston Children's Hospital, Boston, US and Vanderbilt Hospital, Nashville, US.

For information about the study and active study sites, please visit www.clinicaltrials.gov or contact Bastian Dehmel, MD, Chief Medical Officer at OxThera, email: bastian.dehmel@oxthera.com. For information on Primary Hyperoxaluria, please visit www.ohf.org or www.oxaleurope.org.

OxThera holds proprietary rights to pharmaceutical preparations of enzymes and bacteria and their use for treatment of hyperoxaluria. Oxabact® holds orphan drug designations in the EU and the US for the treatment of PH.

For further information, please contact

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About OxThera

OxThera currently has two products in its pipeline: Oxabact[®] for the treatment of Primary hyperoxaluria, and Oxazyme[®], an oxalate decarboxylase, for the treatment of oxalate superabsorption and kidney failure in enteric hyperoxaluria.