

Press release
Stockholm, Sweden, 15 March 2018

OxThera

OxThera announces the randomization of the first patient into its phase III EPHEX study with Oxabact

Stockholm – 15 March 2018 - OxThera AB, a Stockholm-based privately-held biopharmaceutical company with a product in late stage clinical development focusing on Primary hyperoxaluria (PH), announces the randomization of the first patient into its phase III study, EPHEX, with Oxabact.

Study OC5-DB-02 (EPHEX) is a randomized, placebo-controlled, 52-week study with the goal to investigate the efficacy and safety of Oxabact in patients with PH. The purpose of the study is to show that Oxabact can halt or delay the disease progression and preserve kidney function.

“This is an important step for OxThera in developing a promising treatment approach for patients suffering from Primary hyperoxaluria, a devastating disease with high unmet medical need. With Oxabact, we are attempting to reduce the systemic oxalate crystal burden and hope to demonstrate that chronic treatment with Oxabact can preserve kidney function for these patients.” said Matthew Gantz, CEO of OxThera.

Oxabact is an oral product, composed of highly concentrated freeze-dried live bacteria (*Oxalobacter formigenes*). This commensal bacteria promotes the enteric elimination of oxalate, thereby reducing the oxalate burden in the kidneys. A complete clinical development plan for Oxabact has been presented in Protocol Assistance and End-of-Phase II meetings with EMA and FDA respectively.

PH is a rare autosomal recessive disorder leading to markedly elevated levels of endogenous oxalate causing kidney deterioration and a gradual calcification of soft tissues. If left untreated, the disease can cause kidney failure and premature death. Currently, the sole available cure is a combined transplantation of liver and kidneys.

Oxabact holds orphan drug designations in the EU and the US for the treatment of PH, and in EU for treatment of Short Bowel Syndrome (SBS).

For further information, please contact

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About OxThera

OxThera holds worldwide rights for compositions and methods of use for treatment of hyperoxaluria for two products; Oxabact and Oxazyme.