OxThera announces completion of recruitment in Phase 3 ePHex study with Oxabact® in patients with primary hyperoxaluria

Stockholm - 6 April 2020. OxThera AB, a privately-held biopharmaceutical company dedicated to improving the lives of people with Primary Hyperoxaluria (PH), announced today that it has completed enrollment in its Oxabact ePHex phase III study.

Oxabact is an investigational bi-modal enteric biotherapy containing a lyophilized formulation of Oxalobacter formigenes for the treatment of adults and children with primary hyperoxaluria (PH) of all types. The objective of the study is to treat PH and prevent or delay kidney deterioration.
OxThera is on track to report top-line results from ePHex in mid 2021 . The Company also announced completion of its 36-months Phase 2 clinical study in patients with PH and ESRD treated with intensive maintenance dialysis, and reiterated continued positive results previously presented at the 2020 American Society of Nephrology held in Washington, DC.
“We are pleased to have reached two important milestones for our Oxabact program in PH, timely completion of enrollment in ePHex – our 12-month Phase 3 pivotal study – and successful completion of our 36-month Phase 2 study with Oxabact in dialysis patients,” said Matthew Gantz, CEO of OxThera. “We look forward to reporting topline results from the ePHex study in mid 2021. We believe that Oxabact has the potential to provide a clinically meaningful treatment option for patients living with PH.”

Study OC5-DB-02 (ePHex) is a 12-month randomized, double-blind, placebo-controlled, global, multicenter Phase 3 study to evaluate the efficacy and safety of Oxabact OC5 in approximately 22 patients with a documented diagnosis of PH, an eGFR < 90 ml/min/1.73m2 and a total plasma oxalate > 10 µmol/L. The study is followed by a 24-month extension period where all patients will receive Oxabact. Patients are randomized 1:1 to receive twice daily Oxabact OC5 or placebo. The primary endpoint is the change from baseline in total plasma oxalate concentration after 52 weeks of treatment in the patients treated with Oxabact OC5 as compared to placebo. Key secondary and exploratory endpoints will evaluate estimated glomerular filtration rate (eGFR), frequency of kidney stone events, myocardial function, urinary oxalate as well as additional measures of tubular function, number of O. formigenes in stool, safety and tolerability, and quality of life. For more information on ePHex (NCT03116685) please visit clinicaltrials.gov.

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About Oxabact
Oxabact is a bi-modal enteric biotherapy containing a lyophilized formulation of *Oxalobacter formigenes*, a non-pathogenic, oxalate-degrading bacterium. Oxabact is administered orally as a coated capsule. By promoting active and passive secretion of oxalate from the plasma into the gut, Oxabact potentials elimination of oxalate via the gut, lowering the oxalate burden in the kidneys.

About OxThera
OxThera AB is a Swedish biotech company developing a new treatment for primary hyperoxaluria (PH) - a rare genetic and devastating disease with fatal outcomes. Currently pharmaceutical treatment is not available and median age of death is 30, if patients are not transplanted. A phase 3 study and a follow-up, extension study of Oxthera's investigational drug candidate Oxabact are ongoing in patients with PH Type I-, II- and III- patients with maintained renal function. Oxabact has received orphan drug designation in the US and the EU for the treatment of PH.