OxThera presents continuous strong data from an interim analysis of its Phase 2 study with Oxabact in Primary Hyperoxaluria

STOCKHOLM, SWEDEN – June 27, 2019. OxThera AB, a privately-held biopharmaceutical company dedicated to improve the lives of people living with Primary Hyperoxaluria (PH), today announced continuous strong data from a two-year interim analysis of its Phase 2 study with Oxabact® in PH.

OC5-OL-01 is the longest efficacy and safety study of any intervention to lower the oxalate burden in patients with PH. The two-year interim analysis shows continuous reductions in Pox (level of oxalate in the blood plasma) of -40% (-67 µmol/L) compared with baseline. In addition, a normalization in cardiac function was observed in the patients.

”We are pleased to present results that show continuous clinically relevant reductions in Pox. We are excited about the potential of Oxabact in helping patients with this devastating disease”, says Matthew Gantz, CEO of OxThera.

OC5-OL-01, is an ongoing Phase 2 study that enrolled PH-patients on stable dialysis regimen into a long-term treatment phase of up to 3 years, or until liver/kidney transplantation. In PH patients, the dialysis regimen is often intensified in an attempt to remove excessive oxalate produced in the liver of these patients.

”Since we did not change the dialysis regimen substantially, the observed reductions in Pox are a result of gastrointestinal removal of oxalate facilitated by Oxabact treatment. This validates the mechanism of action of Oxabact and provides evidence that systemic oxalate deposition not only can be slowed down, but potentially reversed. Addressing the crystallization aspect of PH, Oxabact should, together with siRNA approaches, open the possibility of halting disease progression”, says Prof. Bernd Hoppe, M.D., Head of the Division of Pediatric Nephrology in the Department of Pediatrics at the University Hospital Bonn, Germany, and Principal Investigator in this study.

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.

Oxabact® is an oral drug candidate composed of highly concentrated freeze-dried live bacteria (*Oxalobacter formigenes*), administered in capsules. The product is designed for delivery to the small intestine. In parallel with the Phase 2 study, an ongoing Phase 3 study is aiming to confirm its ability to improve secretion of oxalate from plasma to the gut, where oxalate is broken down by the microbiome.

OxThera holds proprietary rights to pharmaceutical preparations of enzymes and bacteria and their use for treatment of Hyperoxaluria.

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About OxThera
OxThera AB is a Swedish biotech company developing a new treatment for primary hyperoxaluria - a rare genetic and devastating disease with fatal outcomes. Currently pharmaceutical treatment is not available. A phase 3 study of Oxthera's drug candidate Oxabact® is ongoing, and an application for registration is expected to be submitted in the second half of 2021. Oxabact® has received orphan drug status in the US and the EU.