

OxThera Raises SEK 150 Million in New Round of Financing

A consortium of investors has agreed to invest SEK 150 million in OxThera AB in a new round of financing. Existing investors HealthCap, Scandinavian Life Science Venture and Q-Med AB are joined by Industrifonden and a private investor. The capital will primarily be used to finance the company's pivotal clinical trials with Oxabact™, as well as clinical trials with Oxazyme™.

Oxabact™ will shortly enter pivotal clinical trials for the treatment of primary hyperoxaluria and OxThera plans for a launch of Oxabact™ in 2009. Primary hyperoxaluria is a rare genetic disease which causes the liver to produce excess amounts of oxalate. The disease normally results in kidney stones and/or calcification of the kidneys, eventually leading to renal injury, failure and death. Oxabact™ has been granted an orphan drug designation by the EMEA and by the FDA. OxThera estimates that there are at least 2,000 patients with primary hyperoxaluria in the US and EU combined.

Oxazyme™ is an orally delivered formulation of a recombinant enzyme which is being developed for the prevention of recurrent kidney stones. It is designed as a dietary intercept therapeutic for secondary hyperoxaluria (excessive absorption of dietary oxalate) causing recurrent kidney stone disease. This is common in patients with excessive absorption of dietary oxalate and in patients with, fat malabsorption due to underlying enteric diseases such as IBD¹, cystic fibrosis, or as a result of jejunoileal bypass surgery or bariatric surgery. OxThera plans to initiate phase I studies with Oxazyme™ in late 2007. OxThera estimates that the target patient population for Oxazyme™ corresponds to about six million people in the US and EU combined.

Bengt Ågerup, chairman of OxThera: "We have been very pleased with the high level of interest in this round of financing and welcome the new investors to take part in the exciting development of two innovative therapies, addressing important but often forgotten diseases."

HealthCap and Scandinavian Life Science Venture have been engaged in OxThera since 2005, while Industrifonden is a new investor: "OxThera's two promising projects for the treatment of hyperoxaluria/kidney stone disease have potential to turn the company into a leading player within the Swedish biotech community", says Jonas Brambeck, Investment Manager with Industrifonden.

Jon Heimer, CEO of OxThera comments: "We are very much looking forward to initiating pivotal trials with Oxabact™. There is a great unmet medical need for the treatment of primary hyperoxaluria, a terrible disease affecting children with a life expectancy of only 20 years after diagnosis. Oxazyme™ will soon enter the clinic in order to be tested in humans, and we hope to be able to develop a preventive treatment for secondary hyperoxaluria, a growing problem not least due to the increased number of bariatric surgeries."

Hjalmarsson & Gunterberg Corporate Finance AB has acted as financial advisers to OxThera in relation to this financing.

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¹ Inflammatory Bowel Disease

Short facts about OxThera

OxThera is a biotechnology company active in the development of products for the treatment of metabolic disorders resulting from excess levels of oxalate from endogenous and exogenous sources. Currently, OxThera has two products in its pipeline, Oxabact™ for the treatment of primary hyperoxaluria, and Oxazyme™, for the prevention of recurring calcium-oxalate kidney stones due to secondary hyperoxaluria. Oxabact™ is expected to enter pivotal phase II/III clinical studies in September 2007 and Oxazyme™ is in a pre-clinical development stage and expected to enter phase I clinical studies in December 2007. Although both therapies (Oxabact™ and Oxazyme™) degrade oxalate, they significantly differ in their site of action in the GI-tract.

The Company is a spin-out from Q-Med AB and is based in Sweden (Uppsala) and Florida (Gainesville). Originally, OxThera has its origin in Ixion Biotechnology, Inc., a US based biotechnology company. Q-Med AB, a world leading biotechnology company in the field of hyaluronic acid, was formerly the majority owner of Ixion.

Oxalate is a metabolic end product in humans. It is endogenously produced by the liver and also derived by absorption from the diet. The majority of oxalate is eliminated from the body through the kidneys and a small percentage is eliminated through the GI-tract. Oxalate forms a calcium-oxalate salt which is insoluble at physiological pH and its accumulation can result in serious renal conditions. Consistent high levels of urinary oxalate are known as “hyperoxaluria”, which can result in recurrent kidney stones and renal complications. Hyperoxaluria is classified as:

- ❑ Primary hyperoxaluria types I, II and III are rare genetic diseases resulting from overproduction of oxalate in the liver; urinary oxalate excretion is usually greater than 100 mg/day (normal level <40 mg/day).
- ❑ Secondary hyperoxaluria due to excessive absorption of dietary oxalate. This is common in patients with excessive absorption of dietary oxalate and in patients with, fat malabsorption due to underlying enteric diseases such as IBD, or cystic fibrosis. Further, it is often seen in patients following jejunioileal bypass surgery or bariatric surgery, and in patients with absorptive hyperoxaluria.

Primary hyperoxaluria is a rare, serious disease with very limited treatment options available. The urine oxalate excretion rate in affected patients is typically three to six times normal with severe clinical consequences. Kidney stones and/or calcification of the kidney occur in childhood or adolescence. Renal injury due to oxalate and consequences of the stones often leads to renal failure. Loss of renal function, if not addressed promptly by transplantation, leads to markedly increased plasma concentrations of oxalate with deposition of calcium-oxalate in body tissues. Resulting organ system dysfunction is the cause of severe morbidity and mortality. Renal failure occurs in 50% of the patients by the age of 15 years and has reached 80% by the age of 30 years.