Oxidien Announces Publication of Clinical Results Demonstrating Significant Reduction in Urinary Oxalate

A Prospective, Double-Blind, Randomized, Placebo-Controlled, Cross-Over Study Using a Proprietary Orally Administered Oxalate Decarboxylase (OxDC)

GAINESVILLE, FLA, USA, September 10, 2020 /EINPresswire.com/ -- Oxidien Pharmaceuticals, a clinical-stage biopharmaceutical company mitigating kidney stone disease by treating secondary hyperoxaluria, announced today the publication of data from a clinical study on the effectiveness of its highly potent and acid stable Oxalate Decarboxylase (OxDC) to reduce urinary oxalate in subjects on a high oxalate diet. The study was published in Kidney360, a new addition to the American Society of Nephrology portfolio of journals.

This was an inpatient study where treatment with OxDC at relatively low doses of 1,000 units (umol/min/mg) with meals 3 times per day resulted in removal of over half of the oral bio-load of oxalate (56%) resulting in a significant reduction in urinary oxalate levels. The baseline corrected within-subject mean reduction in 24-hour urinary excretion was 12.5 mg or 29% with 94% of participants responding to the treatment. The net effect as compared to placebo was 24% reduction in urinary oxalate. All pre-determined endpoints were met. The study provides additional support for Synechococcus elongatus OxDC effectiveness in hyperoxaluria. The next planned trial will evaluate increased doses in a dose-finding study.

OxDC was well tolerated with no serious adverse events reported. In addition, there were no product related adverse events and any adverse events experienced were classified as mild or moderate in severity. All adverse events were resolved by the end of study and all subjects completed study.

“We are excited to see these data peer-reviewed and published as we continue to advance our secondary hyperoxaluria program in the clinic", said Helena Cowley, President and Chief Executive Officer of Oxidien. "We would like to thank the investigators, staff, and volunteers for their participation and for contributing to our understanding of this Synechococcus elongatus OxDC as we work to address a significant unmet need in hyperoxaluria.”

The paper titled “A Prospective, Double-Blind, Randomized, Placebo-Controlled, Cross-Over Study Using an Orally Administered Oxalate decarboxylase (OxDC)” is available online today by clicking here .

About Oxidien Pharmaceuticals, LLC
Oxidien Pharmaceuticals is a clinical stage biopharmaceutical company addressing a large unmet need in kidney disease. The company is focused on treating secondary hyperoxaluria using novel oral enzymatic approaches. The company is currently inviting new investors to participate in the financing of its Phase 2 clinical trial. Oxidien has a strong intellectual property position with issued and pending patents in all major markets. The leadership team has a proven track record of successful product development and regulatory approval, and is experienced in operating, growing and providing returns to its investors. Oxidien Pharmaceuticals is affiliated with UF Innovate | The Hub – a world-recognized leader in business incubation affiliated with one of the national leading research institutions, the University of Florida. Oxidien Pharmaceuticals is also a proud industry partner of the Oxalosis and Hyperoxaluria Foundation (OHF), a member of the Kidney Health Initiative (KHI), and a member of the Mayo Clinic Innovation Exchange (the Exchange). For more information on OHF, KHI, or the Exchange please visit www.ohf.org and www.khi.asn-online.org and https://innovationexchange.mayoclinic.org/, respectively. For additional information on Oxidien please visit www.oxidien.com.
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