# Oxidien Pharmaceuticals Announces Favorable Response from FDA on Proposed Development Plan

*Proceeds with Development of Lead Candidate to Address Unmet Need in Kidney Disease*

GAINESVILLE, FL, US, December 19, 2019 /EINPresswire.com/ -- Oxidien Pharmaceuticals, a clinical-stage biopharmaceutical company developing a best-in-class enzyme therapeutic for secondary hyperoxaluria, announced today that it has received encouraging responses from U.S. Food and Drug Administration (FDA) regarding their proposed Phase 1/2 trial in secondary hyperoxaluria patients and other development plans for its lead drug candidate.

The FDA reviewed Oxidien's IND enabling pre-clinical data, and results from a prospective, randomized, double-blind, placebo-controlled healthy volunteer study evaluating both safety and efficacy. The official record of the meeting detailed the FDA's requirements around the development plan (nonclinical and Phase 1/2) and confirmed that the proposed clinical end-points as well as the general trial design were reasonable.

"We are very pleased with the outcome of this interaction and appreciate the guidance from the agency," said Helena Cowley, Chief Executive Officer of Oxidien Pharmaceuticals.

Earlier this year, Oxidien Pharmaceuticals, LLC, spun out the hyperoxaluria research division from Captozyme Inc., a microbiome contract development and manufacturing organization. Having raised a total of $5.7 million to support the development of novel oxalate-reducing enzymes, Captozyme established a solid foundation of data enabling a well-informed clinical program.  Helena Cowley, former CEO of Captozyme, brings intimate understanding for the unmet need in hyperoxaluria from close to a decade of active participation in this area of disease.

"During the coming months we will work to secure the additional funds required to initiate and complete our Phase 1/2 trial. There is significant value and opportunity in the assets spun out. We are committed to realizing this value for our shareholders while making a big difference in patients' lives," Helena Cowley concluded.

About Hyperoxaluria
Approximately 2 million people in the U.S. are affected by hyperoxaluria, a condition for which there is currently no effective treatment option. Hyperoxaluria is a metabolic disorder presenting as elevated levels of oxalate in urine caused by either a defect in the handling of dietary oxalate (secondary hyperoxaluria) or a genetic condition causing increased liver production of oxalate (primary hyperoxaluria). Secondary hyperoxaluria increases the risk of recurrent stone disease, which can lead to progressive chronic kidney disease and end-stage renal failure.

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. Oxidien has a strong intellectual property position with patents pending world-wide. The leadership team has a proven track record of successful product development, regulatory approval, and with operating, growing and exiting healthcare

businesses. Oxidien Pharmaceuticals is located in Gainesville, FL, in UF Innovate the Hub - a world-recognized leader in biotechnology business incubation affiliated with one of the national leading research institutions, the University of Florida. For additional information on UF Innovate the Hub please visit http://innovate.research.ufl.edu/. For additional information on Oxidien please visit www.oxidien.com.

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