Allena Pharmaceuticals, Inc., is Actively Enrolling in Two Phase 2 Clinical Trials of ALLN-177, an Investigational Therapy for the Treatment of Hyperoxaluria.

NEWTON, Mass—Allena Pharmaceuticals, Inc., is a specialty biopharmaceutical company focused on developing and commercializing innovative, non-systemic, oral protein therapeutics to treat metabolic and orphan diseases. Allena’s lead compound is ALLN-177, an orally-administered, recombinant oxalate-degrading enzyme in development for the chronic management of hyperoxaluria.

Hyperoxaluria is a condition resulting from high oxalate levels in the urine due to either hyper-absorption of oxalate from the diet (secondary) or from overproduction of oxalate by the liver due to a genetic defect (primary). Oxalate is a terminal metabolite that cannot be further degraded by humans and is primarily excreted by the kidneys. Hyperoxaluria can initially cause the development of kidney stones, and may also lead to kidney damage (nephrocalcinosis), chronic kidney disease, end-stage renal disease and dialysis. Calcium oxalate is the most common constituent of kidney stones. There are currently no approved pharmacologic treatments for hyperoxaluria.

Allena is currently enrolling in two Phase 2 clinical trials of ALLN-177. These studies are designed to evaluate the efficacy and safety of ALLN-177 in adult patients with secondary hyperoxaluria.

For more information about these clinical trials and for participating research centers, visit www.clinicaltrials.gov and search for “ALLN-177” or contact Premier Research by phone 1-800-961-4641 or email: Allena.Studies@premier-research.com

ACTIVE STUDIES

Phase 2 Dose-Ranging Study in Adult Patients with Hyperoxaluria

Allena is currently enrolling in this dose-ranging study being conducted at a number of centers nationwide (Clinicaltrials.gov identifier NCT02503345). This Phase 2 randomized, double-blind, placebo-controlled, cross-over study is evaluating the safety, tolerability and efficacy of three different doses of ALLN-177 for reducing urinary oxalate excretion in patients with secondary hyperoxaluria and a history of kidney stones.

Phase 2 28-Day Study in Adult Patients with Hyperoxaluria

Allena is currently enrolling in this 28-day Phase 2 placebo-controlled study of ALLN-177 (Clinicaltrials.gov identifier NCT 02547805). This is a multicenter, randomized, double-blind, placebo-controlled study that will evaluate the safety, tolerability and efficacy of 28 days of treatment with ALLN-177 for reducing urinary oxalate excretion in patients with secondary hyperoxaluria.

“This is an important next study for our ALLN-177 clinical development program,” said Louis Brenner, M.D., chief operating officer of Allena Pharmaceuticals. “Both our Phase 1 and Phase 2a study results highlight the potential of ALLN-177 to help patients with oxalate disorders. We believe that the ongoing Phase 2 dose-ranging study and this 28-day Phase 2 study will together provide the necessary data to support design and initiation of the Phase 3 development program in 2017.”
COMPLETED STUDIES

Phase 2a Study in Patients with Secondary Hyperoxaluria

Allena presented results from the first Phase 2 trial of ALLN-177 in patients (NCT02289755) at the American Society of Nephrology (ASN) Kidney Week 2015. The Phase 2, single-arm, open-label study evaluated the safety and efficacy of orally administered ALLN-177 in sixteen kidney stone patients with elevated urinary oxalate excretion despite standard medical therapy.

ALLN-177 was shown to significantly reduce mean urinary oxalate levels (mg/24 hours) in patients (p = 0.0084). Urine oxalate decreased from a mean at baseline of 77.6 to 63.7 mg/24 hours, a decrease of 13.9 mg/24 hours (or 13.3%), and 50% of subjects had a decrease in urinary oxalate by at least 10 mg/24 hours. Greater decreases in urinary oxalate were observed in subjects with higher levels of urinary oxalate at baseline. A post-hoc analysis showed that ALLN-177 also significantly reduced the relative supersaturation index of calcium-oxalate, which correlates with the tendency to form crystals, from 11.6 to 8.8 (p <0.05). ALLN-177 was well tolerated, with no serious or significant adverse events reported, and all subjects completed the full course of treatment.

“Presently there are no effective treatments for hyperoxaluria. This study provides direct evidence that ALLN-177 can produce a statistically significant reduction in urinary oxalate excretion in patients with hyperoxaluria,” said study presenter Craig B. Langman, M.D., the Isaac A. Abt M.D. Professor of Kidney Diseases at Feinberg School of Medicine, Northwestern University and Head, Kidney Diseases at Lurie Children's Hospital of Chicago. “Hyperoxaluria is a major risk factor for kidney stones, and lowering urinary oxalate excretion is a therapeutic goal in patients with calcium oxalate kidney stones. ALLN-177 meaningfully reduced urinary oxalate excretion, and the magnitude of reduction directly correlated with the severity of hyperoxaluria.”

Phase 1 Study in Healthy Volunteers

Allena presented results from the Phase 1 trial of ALLN-177 in healthy volunteers at ASN Kidney Week 2014. The Phase 1, double-blind, randomized, placebo-controlled crossover study evaluated the safety and efficacy of ALLN-177 compared to placebo in 30 healthy volunteers who were placed on a high oxalate diet and showed a sustained increase in urinary oxalate levels, consistent with clinically meaningful hyperoxaluria.

ALLN-177 was shown to significantly reduce mean urinary oxalate levels (mg/day) compared with placebo (P= 0.0002). A pre-specified responder analysis was also performed comparing the number of responders for ALLN-177 and placebo and showed that all responders were on ALLN-177 and none on placebo. Responders demonstrated a mean reduction of oxalate excretion of 20 mg/day (range 8.3 to 43.7 mg/day). The onset of the effect of ALLN-177 was rapid and the effect was maintained during the duration of the treatment as measured by a reduction in 24-hour urinary oxalate levels.

“ALLN-177 is the first pharmacologic treatment to produce a statistically significant reduction in urinary oxalate excretion in a controlled trial, a positive finding for patients with hyperoxaluria,” said study presenter Craig B. Langman, M.D., the Isaac A. Abt
M.D. Professor of Kidney Diseases at Feinberg School of Medicine, Northwestern University and Head, Kidney Diseases at Lurie Children's Hospital of Chicago. “Many patients with hyperoxaluria also experience kidney-related complications like kidney stones, nephrocalcinosis and oxalate nephropathy, which can lead to chronic kidney disease. Allena’s progress is extremely encouraging and holds enormous potential for patients who currently have no effective treatments for this serious condition.”

About ALLN-177

ALLN-177 is an orally-administered, recombinant oxalate-degrading enzyme in development for the chronic management of hyperoxaluria and kidney stones (nephrolithiasis). ALLN-177 targets oxalate in the gastrointestinal tract in an effort to reduce the burden of both dietary and endogenously produced oxalate. ALLN-177 has the potential to decrease the oxalate available systemically for deposition as calcium oxalate crystals or stones in the kidneys, as well as reduce the incidence of calcium oxalate related complications. Effective management of hyperoxaluria could reduce long-term kidney complications, as well as the number of interventions required for the management of kidney stones.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing and commercializing non-systemic protein therapeutics to treat metabolic and orphan diseases. Allena is currently conducting two Phase 2 clinical trials of its lead product candidate, ALLN-177, in patients with hyperoxaluria. The company’s technological approach enables the design and development of oral protein therapies that remain in the gastrointestinal (GI) tract, where the protein exerts its therapeutic effect by degrading metabolites, without being absorbed into the bloodstream. Led by a proven management team with deep expertise in protein therapeutic design and development, Allena is committed to bringing breakthrough new treatments to patients with unmet medical needs. Based in Newton, MA, the company is supported by a top-tier investor syndicate including Frazier Healthcare, Third Rock Ventures, Bessemer Venture Partners, HBM Partners, Pharmstandard International, S.A, Partner Fund Management, Fidelity Management & Research Company, and other investors. For more information, please visit www.allenapharma.com.