Allena Pharmaceuticals Announces Presentation of Successful Phase 2 Data from ALLN-177 Program at American Society of Nephrology Kidney Week

NEWTON, Mass. – Nov. 12, 2015 – Allena Pharmaceuticals, Inc., a specialty biopharmaceutical company focused on developing and commercializing innovative non-systemic oral protein therapeutics to treat metabolic and orphan diseases, presented successful results from the first Phase 2 trial of ALLN-177 (NCT02289755) at the American Society of Nephrology (ASN) Kidney Week 2015 on Saturday, November 7th. ALLN-177 is currently being developed for the treatment of secondary hyperoxaluria in patients with a history of calcium oxalate kidney stones. Treatment with ALLN-177 resulted in a statistically significant reduction of urinary oxalate excretion in patients with secondary hyperoxaluria ($p = 0.0084$). The study also showed that ALLN-177 was well tolerated in the target patient population. Based on this positive Phase 2 data, the company has initiated two additional Phase 2 clinical trials of ALLN-177 in patients with secondary hyperoxaluria (NCT02503345, NCT02547805).

“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.”

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 and substantially reduce mean urinary oxalate levels (mg/24 hours) from baseline ($p = 0.0084$). 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 excretion 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.

“We are encouraged by the positive Phase 2 results in patients with secondary hyperoxaluria and a history of calcium oxalate kidney stones, which builds on the previously presented proof-of-concept data on reduction of urinary oxalate excretion in healthy volunteers,” said Louis Brenner, M.D., chief operating officer at Allena Pharmaceuticals. “There are no specific

pharmacologic treatments available for the treatment of hyperoxaluria, so we are excited to advance the development of ALLN-177 with our two additional ongoing Phase 2 trials."

About Hyperoxaluria and ALLN-177

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 (primary) due to a genetic defect. 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.

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.

Allena is presently conducting two additional Phase 2 trials in the United States for calcium oxalate kidney stone patients with hyperoxaluria. The first trial (NCT02503345) is a double-blind, placebo-controlled crossover dose-ranging study. The second trial (NCT02547805) is a double-blind, placebo-controlled parallel design study of 28 days duration.

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's lead program, ALLN-177, is currently conducting two additional Phase 2 clinical trials 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, Mass., the company is backed by top-tier venture investors including Frazier Healthcare, Third Rock Ventures, HBM Partners, Bessemer Venture Partners and other investors. For more information, please visit www.allenapharma.com.