Allena Pharmaceuticals Initiates Patient Treatment in Third Phase 2 Trial of ALLN-177 for Secondary Hyperoxaluria

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28-Day Treatment Advances Program toward Anticipated Pivotal Studies in 2017

NEWTON, Mass., February 10, 2016 – Allena Pharmaceuticals, Inc., a specialty biopharmaceutical company focused on developing and commercializing innovative, non-systemic, oral protein therapeutics to treat metabolic and orphan diseases, today announced that patient treatment has commenced in its 28-day Phase 2 study of ALLN- 177, an orally administered recombinant oxalate-degrading enzyme being developed for the management of hyperoxaluria and kidney stones.

“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 2b 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.”

This Phase 2 Multicenter, Randomized, Double-Blind, Placebo-controlled Study (Clinicaltrials.gov identifier NCT 02547805) 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. ALLN-177 degrades 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. Previously completed studies, including a Phase 1 trial in healthy volunteers and an open-label Phase 2a trial in patients with secondary hyperoxaluria (Clinicaltrials.gov identifier NCT02289755), have demonstrated proof-of-concept for the reduction of urinary oxalate excretion using ALLN-177. A Phase 2b, Multicenter, Randomized, Double-Blind, Placebo-controlled, Crossover Study to evaluate multiple doses of ALLN-177 in recurrent calcium oxalate kidney stone formers with hyperoxaluria is also ongoing (Clinicaltrials.gov identifier NCT 02503345).

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 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.

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 additional 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.

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