Allena Pharmaceuticals Presents Phase 1 Data on ALLN-177 at American Society of Nephrology Kidney Week 2014

NEWTON, Mass. – Nov. 17, 2014 – 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 Phase 1 results from ALLN-177, the company's oral, highly active recombinant oxalate degrading enzyme for the chronic management of hyperoxaluria, at the American Society of Nephrology (ASN) Kidney Week 2014. The results, presented in an oral presentation on Saturday, November 15, showed that the company's double-blind, placebo-controlled crossover study was safe, well-tolerated and demonstrated a statistically significant difference in the reduction of urinary oxalate levels in healthy subjects of 12 mg/day in those treated with ALLN-177 compared with placebo (P= 0.0002). All responders were on ALLN-177 and none on placebo. Responders demonstrated a significant mean reduction of oxalate excretion of 20 mg/day (range 8 to 44 mg/day).

Hyperoxaluria is a serious metabolic condition resulting from high oxalate levels in the urine due to either hyper-absorption of oxalate from the diet or from overproduction of oxalate by the liver. Based on this positive Phase 1 data, the company has initated a Phase 2 program of ALLN-177 in patients with secondary hyperoxaluria.

"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 MD 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."

Clinical Study Summary

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.

For both the primary and secondary endpoints, ALLN-177 was shown to significantly and substantially reduce mean urinary oxalate levels (mg/24 hours) 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.

About Hyperoxaluria
Hyperoxaluria is a serious metabolic disorder and is one of the major risk factors for nephrolithiasis, nephrocalcinosis, and oxalate nephropathy that leads to chronic kidney disease. Hyperoxaluria is a direct result of either hyper-absorption of oxalate from the diet (secondary hyperoxaluria) or from overproduction of oxalate due to a hereditary enzyme deficiency in the liver (primary hyperoxaluria). No effective pharmacologic treatment exists for hyperoxaluria.

About ALLN-177
Allena's lead product, ALLN-177 is an orally administered highly active recombinant oxalate-degrading enzyme for the chronic management of hyperoxaluria and kidney stones. ALLN-177 has the potential to degrade both dietary and endogenously produced oxalate in the gastrointestinal tract and decrease its absorption. This degradation of oxalate may reduce or prevent oxalate deposition as calcium oxalate crystals or stones in the kidneys and urinary tract, as well as other related complications. ALLN-177 is in an ongoing Phase 2 clinical trial in patients with secondary hyperoxaluria.

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. The company's proven approach enables the design and development of oral protein therapies that remain in the gastrointestinal tract, where the protein exerts its therapeutic effect by reducing toxic 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. For more information, please visit www.allenapharma.com.

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