Allena Pharmaceuticals Initiates Phase 2b Trial of ALLN-177 for Secondary Hyperoxaluria

Appoints Annamaria Kausz, M.D., Nephrology and Clinical Development Expert, as Vice President of Clinical Development

NEWTON, Mass., August 4, 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, today announced that the first patient has been treated in its Phase 2b dose-ranging study of ALLN-177, an orally administered recombinant oxalate-degrading enzyme being developed for the chronic management of hyperoxaluria and kidney stones. In conjunction with advancing its lead program into Phase 2b studies, Allena has also expanded its leadership team with the appointment of Annamaria Kausz, M.D., as vice president of clinical development.

"Allena has made significant recent progress with the advancement of our ALLN-177 clinical program and with the addition of Dr. Annamaria Kausz to our management team," said Louis Brenner, M.D., chief operating officer of Allena Pharmaceuticals. "Our Phase 1 and Phase 2a study results highlight the potential of ALLN-177 to help patients with oxalate disorders, and we are fortunate to secure Annamaria's leadership for our clinical development organization."

The Phase 2b randomized, crossover study (Clinicaltrials.gov identifier NCT02503345) will evaluate the safety, tolerability and efficacy of three different doses of 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 a 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.

Management Team Appointment

As Allena's vice president of clinical development, Dr. Kausz, an adult and pediatric nephrologist, brings to Allena nearly a decade of industry experience in pharmaceutical clinical development and regulatory strategy. Dr. Kausz joins Allena from EMD-Serono, where she led the development of early-stage immunology compounds. She has played key roles in the clinical programs and the regulatory applications for chronic kidney disease therapies Auryxia™ at Keryx Biopharmaceuticals and Feraheme® at AMAG Pharmaceuticals. Dr. Kausz earned an M.D. from the University of Virginia and an M.S. in epidemiology from the University of Washington. She completed her residency in

internal medicine and pediatrics at the University of North Carolina, and her fellowships in nephrology and pediatric nephrology at the University of Washington Hospital and Seattle Children's Hospital.

"I am excited to join Allena during this transformative period. Hyperoxaluria is a serious metabolic disease that leads to kidney disorders. As a targeted enzymatic approach to oxalate degradation, ALLN-177 has the potential to address the unmet need of patients with hyperoxaluria," said Dr. Kausz.

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. 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's lead program, ALLN-177, is currently conducting a Phase 2b clinical trial 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 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. 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.

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