



## **Allena Pharmaceuticals Licenses Worldwide Rights to Hyperoxaluria Portfolio from Althea Technologies**

March 28, 2012

*Accelerates Development of Allena's Oral Enzyme Therapy ALLN-177; Allena Expects to Initiate Clinical Trial in Hyperoxaluria Patients Early Next Year*

NEWTON, Mass. and San Diego, CA – March 28, 2012 - Allena Pharmaceuticals, Inc., a company developing and commercializing innovative non-systemic oral protein therapeutics to treat metabolic and orphan diseases, and Althea Technologies, a leading contract manufacturing organization providing development and manufacturing services, today announced a licensing agreement under which Allena has obtained the exclusive worldwide rights to Althea's broad hyperoxaluria portfolio including product patents, regulatory information and development data related to oxalate degrading enzymes. This license agreement strengthens Allena's ongoing research and development activities for ALLN-177, its orally delivered enzyme therapy, and helps advance the company's clinical development program for patients with hyperoxaluria. Hyperoxaluria is characterized by excessively high levels of oxalate in the urine, due to over- absorption of oxalate from the intestinal tract and abnormalities of oxalate production in the body. Hyperoxaluria can lead to kidney stones or chronic kidney disease and, if left untreated, end-stage renal disease and dialysis.

"Currently there are no effective pharmacological treatments for hyperoxaluria or the nearly 2.6 million Americans who suffer from kidney stones annually," said Alexey Margolin, Ph.D., co-founder, president and CEO of Allena Pharmaceuticals. "Given this unmet need, there is significant demand for a novel, convenient therapy like ALLN-177, which we believe will reduce oxalate levels and prevent further progression to chronic kidney disease. The license of this portfolio enables us to accelerate our current hyperoxaluria program, including starting clinical trials in hyperoxaluria patients early next year."

Allena's founders and other members of the Allena team have considerable experience in the development of oral enzyme replacement and non-systemic protein therapeutics, including oxalate-degrading enzymes. The licensed hyperoxaluria portfolio from Althea also includes supportive Phase 1 clinical data in 58 healthy volunteers (originally generated by Altus Pharmaceuticals' ALTU-237 program, which was acquired by Althea).

"There is significant value and opportunity in this hyperoxaluria portfolio and a real patient need for an effective treatment. We know the Allena team and feel they are best equipped to translate

the potential of this portfolio and the previous clinical findings into a new and novel protein therapy," said Magda Marquet, Ph.D., founder and co-chairman of Althea Technologies. "We are looking forward to working closely with the Allena team to support the development of ALLN- 177."

"We have moved quickly and efficiently to prepare ALLN-177 for clinical trials in patients with hyperoxaluria," said Robert Gallotto, co-founder and chief operating officer of Allena Pharmaceuticals. "There have been considerable advances in optimizing protein expression, production and formulation to position Allena for commercial scale production. We have also developed novel preclinical large animal models for different forms of hyperoxaluria, which we believe will expedite our development activities."

### **About Hyperoxaluria**

Hyperoxaluria is a condition resulting from high oxalate levels in the urine due to over- absorption of oxalate from the intestinal tract and abnormalities of oxalate production in the body. It can initially cause the development of kidney stones or can lead to chronic kidney disease, end-stage renal disease and dialysis. Hyperoxaluria can be caused by either excessive absorption of dietary oxalate (enteric hyperoxaluria) or increased endogenous production of oxalate (this is known as primary hyperoxaluria, a rare disease that affects approximately 5,000 - 7,000 patients worldwide). Enteric hyperoxaluria is a global problem, with nearly 2.6 million episodes of kidney stones annually in the U.S. Enteric hyperoxaluria can also occur in people who have intestinal diseases, such as Crohn's Disease and inflammatory bowel disease, pancreatic insufficiency or may occur in patients following gastric surgery.

### **About Althea Technologies**

Althea Technologies is a fully integrated, contract development and manufacturing organization located in San Diego, CA providing clinical and commercial product development services. Althea offers cGMP drug product filling in both vials and syringes, and production of microbial- derived recombinant proteins and plasmid DNA. In conjunction with these manufacturing operations, Althea offers comprehensive development services including: upstream and downstream process development, analytical development, product release and ICH-compliant stability testing. Althea's formulation technology platform includes Crystalomics®, a technology that offers a formulation solution for large molecule products that must be delivered at high concentrations or as sustained release formulations. For more information, visit [www.altheatech.com](http://www.altheatech.com).

### **About Allena Pharmaceuticals**

Allena Pharmaceuticals, Inc. is developing and commercializing non-systemic protein therapeutics to treat metabolic and orphan diseases, with a particular focus on nephrologic and urologic conditions. Allena's lead program, ALLN-177, is expected to enter clinical trials in patients with hyperoxaluria in early 2013. The company's proven 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 Bessemer Venture Partners, Frazier Healthcare and Third Rock Ventures. For more information, please visit [www.allenapharma.com](http://www.allenapharma.com).