# Allena Pharmaceuticals Completes Enrollment in Pivotal Phase 3 URIROX-1 Trial Evaluating Reloxaliase in Patients with Enteric Hyperoxaluria

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**Topline data from URIROX-1 expected in 4Q 2019**

NEWTON, Mass., Sept. 16, 2019 (GLOBE NEWSWIRE) -- Allena Pharmaceuticals, Inc. (NASDAQ: ALNA), a late-stage, biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders, today announced that it has completed enrollment in its pivotal Phase 3 URIROX-1 clinical trial. URIROX-1 is a multi-center, global, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of reloxaliase for the treatment of patients with enteric hyperoxaluria. The company expects to report topline data from the trial in the fourth quarter of 2019.

"We would like to thank the dedicated patients and physicians who helped us achieve this development milestone for our reloxaliase program. We are excited to complete enrollment in this Phase 3 trial, as it brings us one step closer to achieving our foundational goal of providing reloxaliase as a first-in-class therapy for patients with enteric hyperoxaluria. These patients suffer from the burden of excess oxalate, including kidney stones and kidney damage," said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. "We look forward to reporting topline data from URIROX-1 in the fourth quarter, as we also continue to partner with the community to increase awareness of enteric hyperoxaluria and advance the ongoing URIROX-2 pivotal trial."

**About the URIROXProgram**
The URIROX program consists of two pivotal Phase 3 clinical trials, URIROX-1 and URIROX-2, which are designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria. The primary efficacy endpoint for both trials is the percent change from baseline in 24-hour urinary oxalate (UOx) excretion measured during weeks 1-4, comparing reloxaliase to placebo. The primary long-term efficacy endpoint to confirm clinical benefit in URIROX-2 is the proportion of patients with kidney stone disease progression, defined as a composite of either symptomatic kidney stones or finding of new or enlarged kidney stones using imaging, over a minimum treatment period of two years. Allena expects to report topline data from URIROX-1 in the fourth quarter of 2019, and from URIROX-2 in the second half of 2021. The Company plans to pursue a Biologics License Application (BLA) submission for reloxaliase using the accelerated approval regulatory pathway.

**About Reloxaliase**
Reloxaliase is an orally-administered, recombinant oxalate-degrading enzyme that is being developed for the treatment of hyperoxaluria. Reloxaliase targets oxalate in the GI tract in an effort to reduce the burden of both dietary and endogenously-produced oxalate. Reloxaliase has the potential to decrease the oxalate available systemically for deposition as calcium oxalate crystals or stones in the kidneys, as well as reduce long-term kidney complications. In addition, reloxaliase has been granted separate orphan drug designations by the U.S. Food and Drug Administration for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria. The European Commission has granted orphan drug designation for reloxaliase for the treatment of primary hyperoxaluria.

**About Hyperoxaluria**
Hyperoxaluria is a metabolic disorder characterized by significantly elevated oxalate levels in the urine, due to either overproduction of oxalate by the liver from a genetic defect, called primary hyperoxaluria, or from the excess absorption of oxalate from the diet, called secondary hyperoxaluria. Secondary hyperoxaluria is further characterized either as enteric, resulting from a chronic and unremediable underlying gastrointestinal disorder associated with malabsorption, such as bariatric surgery complications or Crohn's disease, which predisposes patients to excess oxalate absorption, or idiopathic, meaning the underlying cause is unknown. Kidney stones, typically the first sign of hyperoxaluria, are often painful and may require interventional procedures. Severe hyperoxaluria in settings of enteric and primary hyperoxaluria may also lead to kidney damage (nephrocalcinosis), chronic kidney disease and end-stage renal disease, which may lead to death.

Enteric hyperoxaluria is the more severe subset of secondary hyperoxaluria. Allena estimates that there are approximately 200,000 to 250,000 patients with enteric hyperoxaluria and kidney stones in the United States.

**About Allena Pharmaceuticals**
Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. Allena's lead product candidate, reloxaliase, is a first in class, oral enzyme therapeutic for the treatment of hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, chronic kidney disease and other serious kidney disorders.

**Forward-Looking Statements**
This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding Allena's URIROX clinical program, statements regarding the timing of announcement of release of data from its ongoing clinical trials, statements regarding Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements regarding the ability of reloxaliase to provide clinical benefit to patients with hyperoxaluria, and statements regarding the clinical and commercial potential of reloxaliase for patients with hyperoxaluria. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the risk that results of earlier studies, or interim results, may not be predictive of future clinical trial results, and planned and ongoing studies may not establish an adequate safety

or efficacy profile for reloxaliase to support regulatory approval or the use of the accelerated approval regulatory pathway; risks related to Allena's ability to utilize the accelerated approval pathway for reloxaliase, including the risk that available data at the time of any sample size re-estimation or interim analysis conducted during the URIROX-2 trial may not be sufficient to demonstrate an increased probability of kidney stone events in patients with enteric hyperoxaluria and increasing UOx levels; the risk that the FDA may require that Allena increase the sample size or duration of treatment following the sample size reassessments to be conducted in accordance with the adaptive design element of the trial or otherwise collect additional clinical data from the URIROX-2 or other clinical trials prior to submitting a BLA for reloxaliase; risks associated with Allena's ability to enroll a sufficient number of patients to adequately power URIROX-2 in order to achieve ultimate statistical success for kidney stone disease progression in the long-term follow-up phase of the trial; risks related to Allena's use of UOx and/or plasma oxalate (POx) as surrogate endpoints in its ongoing clinical trials, neither of which it believes have been previously utilized as biomarkers to support regulatory approval of other drug candidates, and the risks related to validating that reductions in UOx and/or POx correlate with meaningful clinical benefit; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Allena's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risk associated with Allena's ability to manage operating expenses and/or obtain additional funding to support its business activities; and risks associated with Allena's dependence on third parties. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Allena's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Item 1A of Part II of Allena's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, as well as discussions of potential risks, uncertainties and other important factors in Allena's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Allena undertakes no duty to update this information unless required by law.

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