Allena Pharmaceuticals to Present Data Characterizing Significant Unmet Need in Enteric Hyperoxaluria at ASN Kidney Week 2018

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– Highlights Additional Poster Presentation on the Design of URIROX-1, Ongoing Phase 3 Trial Evaluating Reloxaliase in Patients with Enteric Hyperoxaluria –

NEWTON, Mass., Oct. 25, 2018 (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 will present clinical data characterizing the significant unmet need in patients with enteric hyperoxaluria in a poster presentation at ASN Kidney Week 2018, held October 23-27, 2018 in San Diego, CA.

The poster presentation includes composite data, details on kidney stone burden, and case studies from 33 patients with enteric hyperoxaluria who enrolled across Allena's three Phase 2 clinical trials of reloxaliase (formerly ALLN-177). Data from these 33 patients confirmed that a majority experienced persistently high 24-hour urinary oxalate (UOx) excretion, despite following standard-of-care guidance for diet and hydration. Among 20 patients for whom kidney stone burden was assessed by CT scan, 16 had at least one kidney stone (KS) detected at enrollment (80%), with an average of three stones present. Additionally, 20% of patients presenting with KS had very large stones, which could require urological intervention.

"These data provide a detailed look at the effects of enteric hyperoxaluria on patients, and highlight the urgent need for new therapies that directly address the burden of oxalate and reduce its impact on the kidney," said Louis Brenner, M.D., President and Chief Operating Officer of Allena Pharmaceuticals. "As we continue progressing reloxaliase through clinical development, we are committed to better understanding the range of clinical manifestations that excess oxalate can inflict on patients. We look forward to partnering with the medical, advocacy, and regulatory communities to develop and, we hope, deliver reloxaliase as a first-in-class therapeutic for patients with enteric hyperoxaluria."

Also at ASN Kidney Week, Allena will present a poster describing the design of URIROX-1, its ongoing Phase 3 clinical trial evaluating reloxaliase in patients with enteric hyperoxaluria. Allena expects to report initial data from this trial in the second half of 2019. Pending ongoing interactions with the U.S. Food and Drug Administration (FDA), Allena expects to initiate URIROX-2, the second, larger Phase 3 clinical trial of reloxaliase in patients with enteric hyperoxaluria, in the fourth quarter of 2018.

"Allena's progress in developing reloxaliase, including the ongoing URIROX-1 Phase 3 clinical trial, is truly encouraging. As demonstrated by the nearly 30 abstracts focused on hyperoxaluria and other oxalate-related disorders at ASN, there is increasing awareness around oxalate as a disease target and the significant unmet need in severe hyperoxaluria," said Craig Langman, M.D., Head of the Division of Kidney Diseases, Ann & Robert H. Lurie Children's Hospital of Chicago and Isaac A. Abt, M.D. Professor of Kidney Diseases and Pediatrics at Northwestern University Feinberg School of Medicine. "As we continue to learn more about oxalate as a modifiable risk factor for kidney stones, nephropathy and chronic kidney disease, it is becoming increasingly clear that hyperoxaluria patients are at high-risk for severe renal complications, and that existing options do little to directly reduce the oxalate burden. Allena's pioneering work with the scientific and medical community is also advancing our understanding of the enteric hyperoxaluria patient journey, and I look forward to their further contributions as we try to address this significant unmet need."

About Hyperoxaluria

Hyperoxaluria is a metabolic disorder characterized by significantly elevated oxalate levels in the urine, or urinary oxalate excretion, 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 irremediable 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 Reloxaliase

Reloxaliase (formerly ALLN-177) is an orally-administered, recombinant oxalate-degrading enzyme therapeutic that is being developed for the treatment of severe hyperoxaluria. Reloxaliase is being developed to target 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. 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. In addition, the European Commission has granted orphan drug designation for reloxaliase for the treatment of primary hyperoxaluria.

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 statements regarding Allena's URIROX-1 clinical trial, including the timing of announcement of topline data from this trial and statements regarding Allena's planned Phase 3 pivotal program for reloxaliase (ALLN-177), including Allena's planned URIROX-2 trial, the resolution of the trial design for this trial with the FDA and the time of initiation of this trial. Allena remains in an active dialogue with the FDA regarding the design of the URIROX-2 study, including the endpoints and statistical analysis plan for this study, and whether reduction in UOx excretion may be used as a surrogate endpoint to support an accelerated approval for reloxaliase. If Allena is unable to reach consensus with the FDA on the magnitude of UOx reduction significant enough to predict clinical benefit, it may be required to demonstrate effectiveness by showing an effect on stone formation directly, or conduct one or more additional clinical trials to demonstrate this effect, prior to the submission of a BLA for reloxaliase. 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 may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for reloxaliase that support regulatory approval; risks associated with the fact that Allena has not yet finalized the design of its pivotal Phase 3 clinical program for reloxaliase, including the primary and secondary endpoints and the statistical analyses for URIROX-2, and that the FDA and comparable foreign regulators may not agree with the proposed Phase 3 clinical program, in which case Allena may be required to modify its planned clinical trials, or run additional clinical trials, before it can submit a BLA or comparable foreign applications for this product candidate; risks associated with a potential accelerated approval pathway, which would require that Allena conduct one or more confirmatory clinical trials to verify the clinical benefit of reloxaliase after approval; 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 year ended June 30, 2018, 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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