Allena Pharmaceuticals to Present New Data on Reloxaliase and ALLN-346 Development Programs at Upcoming ASN Kidney Week and ACR/ARP Annual Meeting

October 17, 2019

NEWTON, Mass., Oct. 17, 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 will present new data for reloxaliase, its first-in-class, oral enzyme for the treatment of hyperoxaluria, and for ALLN-346, its first-in-class, oral enzyme for the treatment of hyperuricemia in the setting of advanced chronic kidney disease (CKD) at upcoming medical meetings in November 2019.

“Our upcoming presentations highlight our ongoing efforts to develop oral enzyme therapeutics to degrade toxic metabolites and ultimately reduce kidney damage in patients living with excess oxalate or urate,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “Due to limitations of existing therapies, there is a significant unmet need for these patient populations and we are committed to rapidly progressing reloxaliase and ALLN-346 through clinical development, as we seek to make a difference for people living with metabolic and kidney disorders.”

The accepted abstracts are listed below and are now available on the American Society of Nephrology (ASN) and American College of Rheumatology (ACR) conference websites, respectively: https://www.asn-online.org/education/kidneyweek/ and https://acrabstracts.org/.

American Society of Nephrology (ASN) Kidney Week 2019
November 5-10, 2019 in Washington, D.C.

Poster Presentations:

Title: Pilot study of reloxaliase in subjects with severe enteric hyperoxaluria and hyperoxalemia: A pro tem analysis of study ALLN-177-206
Session Title: CKD: Clinical, Outcomes, Trials - II
Session Date and Time: November 8, 2019, 10:00am – 12:00pm ET
Location: Exhibit Hall, Walter E. Washington Convention Center
Authors: Felix Knauf, John C. Lieske, Anja C. Pfau, Danica Grujic, Kristine E. Bernard, Annamaria T. Kausz
Abstract ID: FR-PO316

Title: Prevalence of kidney stones in patients with enteric disorders
Session Title: Bone and Mineral Metabolism: Calcium, Magnesium, Kidney Stones
Session Date and Time: November 9, 2019, 10:00am – 12:00pm ET
Location: Exhibit Hall, Walter E. Washington Convention Center
Authors: Gregory E. Tasian, Brandon B. Wade, Julia A. Gaebler, Annamaria T. Kausz, Joseph J. Medicis, Christina M. Wyatt
Abstract ID: SA-PO276

Title: A phase 3, randomized, placebo controlled trial of reloxaliase in enteric hyperoxaluria (URIROX-1): Clinical characteristics and burden of illness
Session Title: Bone and Mineral Metabolism: Calcium, Magnesium, Kidney Stones
Session Date and Time: November 9, 2019, 10:00am – 12:00pm ET
Location: Exhibit Hall, Walter E. Washington Convention Center
Authors: John C. Lieske, James E. Lingeman, Pietro Manuel Ferraro, Zhiqun Zhang, Annamaria T. Kausz
Abstract ID: SA-PO278

Title: Dietary oxalate ingestion, urinary oxalate levels, and response to reloxaliase in three Phase 2 studies
Session Title: Health Maintenance, Nutrition, Metabolism - II
Session Date and Time: November 9, 2019, 10:00am – 12:00pm ET
Location: Exhibit Hall, Walter E. Washington Convention Center
Authors: Craig B. Langman, Linda H. Easter, Zhiqun Zhang, Annamaria T. Kausz, Sagar U. Nigwekar
Abstract ID: SA-PO815

Title: Establishing safety and efficacy of reloxaliase in patients with enteric hyperoxaluria (URIROX-2)
Session Title: Informational Posters - III
Session Date and Time: November 9, 2019, 10:00am – 12:00pm ET
Location: Exhibit Hall, Walter E. Washington Convention Center
Authors: Annamaria T. Kausz, Gary C. Curhan, Gregory E. Tasian, Charles D. Scales
Abstract ID: INFO16-SA

American College of Rheumatology 2019 ACR/ARP Annual Meeting
November 8-13, 2019 in Atlanta, Georgia

Poster Presentation:

Title: Enteral administration of ALLN-346, a recombinant urate-degrading enzyme, decreases serum urate in a pig model of hyperuricemia
Session Title: Metabolic & Crystal Arthropathies Poster II: Clinical Trials & Basic Science
Session Date and Time: November 11, 2019, 9:00am – 11:00am ET
Location: Hall B5, Georgia World Congress Center
Authors: Danica Grujic, Kateryna Pierzynowska, Paulina Szczurek, Stefan Pierzynowski, Aditi Deshpande, Olha Drahanchuck, Nadia Mosiichuk, Jarek Wolinski
Abstract ID: 1223

About Reloxaliase
Reloxaliase is an orally-administered, recombinant oxalate-degrading enzyme that is being developed for the treatment of severe 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 Pivotal Phase 3 URIROX Program
Allena's URIROX program consists of two pivotal Phase 3 trials, URIROX-1 and URIROX-2, which are designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria.

URIROX-1 is a multicenter, global, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of reloxaliase in an expected 124 patients for a four-week treatment period. Patients will be randomized 1:1 to reloxaliase vs. placebo and will take 284 mg (equivalent to 7,500 units) of reloxaliase or placebo with each meal or snack up to five times per day, consistent with the eating patterns of patients with enteric hyperoxaluria. Allena expects to report topline data from URIROX-1 in the fourth quarter of 2019.

URIROX-2 is a multicenter, global, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria, over a minimum treatment period of two years. The trial is designed to enroll 400 patients with 24-hour urine oxalate (UOx) excretion greater than or equal to 50 mg and a history of kidney stones, and will include patients with normal kidney function as well as chronic kidney disease.

The primary efficacy endpoint of URIROX-2 is the percent change from baseline in 24-hour UOx excretion during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo, the same primary endpoint as URIROX-1. Secondary endpoints in URIROX-2 include the proportion of subjects with a ≥ 20% reduction from baseline in 24-hour UOx excretion during Weeks 1-4 and percent change from baseline in 24-hour UOx excretion during Weeks 16 to 24. The primary long-term efficacy endpoint to confirm clinical benefit is the proportion of subjects 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. Secondary long-term efficacy endpoints to confirm clinical benefit include change in eGFR from baseline and emergency room visits, hospitalizations or procedures for the management of kidney stones.

In January 2019, Allena announced that it reached alignment with the U.S. Food and Drug Administration (FDA) on both the design of URIROX-2 and its strategy to pursue a Biologics License Application (BLA) submission for reloxaliase in patients with enteric hyperoxaluria using the accelerated approval regulatory pathway.

In March 2019, Allena announced an agreement with the Duke Clinical Research Institute (DCRI), a leading academic research institute within Duke University School of Medicine, to establish and lead an Academic Coordinating Center (ACC) in support of the URIROX-2 Phase 3 clinical trial and preparation for the potential launch of reloxaliase.

About ALLN-346
ALLN-346 is an orally administered, novel, engineered urate oxidase that has been optimized for stability in the gastrointestinal (GI) tract and high production yield. Allena has designed ALLN-346 to degrade urate in the GI tract and in turn, reduce the urate burden on the kidney and lower the risk of urate-related complications. ALLN-346 is targeted to lower serum uric acid in patients with CKD, whose renal function is decreased and who have diminished capacity for urinary excretion of uric acid.

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 upcoming presentation of new data for reloxaliase as well as the clinical and commercial potential of reloxaliase for patients with primary hyperoxaluria or enteric 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 interim results or results of earlier studies 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 in URIROX-2 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 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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