Allena Pharmaceuticals Doses First Subject in Phase 1 Clinical Trial of ALLN-346, in Development for the Treatment of Hyperuricemia in Patients with Gout and Advanced Chronic Kidney Disease

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Initial Data Expected in the Fourth Quarter of 2020

NEWTON, Mass., Sept. 08, 2020 (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 the first subject has been dosed in a Phase 1 clinical trial of ALLN-346. ALLN-346 is an investigational, orally administered, novel urate-degrading enzyme that has been designed for activity and stability in the gastrointestinal (GI) tract, and is intended for the treatment of hyperuricemia in patients with gout and advanced chronic kidney disease (CKD).

Hyperuricemia, or elevated levels of uric acid in the blood, is due to overproduction and/or insufficient excretion of uric acid and is a significant predisposing condition for gout. Increased uric acid excretion in the urine and hyperuricemia are also associated with kidney stone formation and kidney damage. CKD patients with hyperuricemia and gout are often not optimally managed due to limitations of available therapies, including decreased tolerability, dose restrictions, drug-drug interactions, and contraindications. According to a published study, there are approximately 375,000 patients in the United States with hyperuricemia and CKD on urate lowering therapy who have uncontrolled gout.[1]

“We are thrilled to advance ALLN-346, our second product candidate, into the clinic. Like reloxaliase, ALLN-346 was designed using our proprietary oral enzyme technology platform. Our goal is to create the first orally-delivered, non-absorbed, stable enzyme that degrades urate in the GI tract, in order to reduce the metabolic burden of urate on the kidney,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “This is another compelling application of our oral enzyme platform, as our scientific team continues to innovate and provide potential new treatments for patients with difficult metabolic diseases.”

This Phase 1 clinical trial is a randomized, double blind, placebo-controlled, single ascending dose study of orally administered ALLN-346 in approximately 24 healthy volunteers. The primary objective of the study is to assess safety and tolerability over 28 days. Allena expects to report initial clinical data in the fourth quarter of 2020, subject to the impact of COVID-19. For more information about the clinical trial design, please visit: www.clinicaltrials.gov (NCT04236219).

At the 2018 American College of Rheumatology (ACR/ARHP) Annual Meeting, Allena presented preclinical proof-of-concept data for ALLN-346, demonstrating urate reduction in a urate oxidase knock-out mouse model, an animal model of severe hyperuricemia with kidney damage due to urate crystal deposition. After one week of treatment, mice treated with ALLN-346 achieved a substantial reduction in urate burden on the kidney, as evidenced by normalization in urine uric acid and a significant reduction in plasma urate. These data were subsequently supported in a porcine model with acutely induced hyperuricemia that was presented at the ACR/ARHP Annual Meeting in 2019.

“Patients with gout and moderate-to-severe CKD are in need of new therapeutic options, which can help lower the levels of uric acid in their blood and urine and help limit painful flares of gouty arthritis and potentially limit kidney stones. The oral therapies available to treat hyperuricemia in gout patients all are limited by CKD in their dosing and efficacy, and boosting convenient oral uric acid lowering therapies with this approach is compelling,” said Robert Terkeltaub, M.D., Professor of Medicine at University of California San Diego. “By leveraging the gut-kidney-axis, ALLN-346 relies on a novel mechanism of action, which corresponds to the underlying physiology of hyperuricemia and the extrarenal pathway for uric acid elimination. There is potential for improved reduction in uric acid burden in gout patients with moderate-to-severe CKD.”

About Hyperuricemia

Hyperuricemia, or elevated levels of uric acid in the blood, results from overproduction or insufficient excretion of urate, or often a combination of the two. Hyperuricemia is associated with gout, a kind of arthritis caused by excess uric acid in the blood that leads to the formation of hard crystals in the joints. Hyperuricemia can also lead to increased uric acid excretion in the urine and subsequently to kidney stone formation and kidney damage also known as urate nephropathy. In addition, hyperuricemia has been linked to hypertension, CKD, glucose intolerance, dyslipidemia, insulin resistance and obesity.

About ALLN-346

ALLN-346 is an investigational, orally administered, novel, engineered urate oxidase that has been optimized for stability in the 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. In September 2020, Allena announced first enrollment in a Phase 1 clinical trial of ALLN-346 and expects to report initial clinical data in the fourth quarter of 2020.

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 currently being evaluated in a pivotal Phase 3 clinical program for the treatment of enteric 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. Allena is also

developing ALLN-346, currently being evaluated in a Phase 1 clinical trial, for the treatment of hyperuricemia in the setting of gout and advanced chronic kidney disease.

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 the Allena's development of ALLN-346 and the Phase 1 clinical trial, statements regarding implementation of the amended trial design for URIROX-2 , the timing of sample size reassessments and interim analyses during the URIROX-2 trial, Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, the impact of the COVID-19 coronavirus on Allena's business, the biotech sector generally and the broader macroeconomic environment, statements concerning the future clinical, regulatory and commercial potential of reloxaliase statements regarding Allena's financial position and need for capital. 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: market and other conditions, the timing for completion of Allena's clinical trials of its product candidates, 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 financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of reloxaliase and its ability to continue as a going concern; risks associated with Allena's dependence on third parties; and risks related to the COVID-19 coronavirus. 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 I of Allena's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, 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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[1] Lim, J., Fu, A., Reasner, D. & Taylor, D. (2017, April). *Prevalence of CKD and Uncontrolled Gout Among US Adults: Results From NHANES 2007–2012*. Poster presented at the National Kidney Foundation Spring Clinical Meetings, Orlando, FL.

Source: Allena Pharmaceuticals, Inc.