Allena Pharmaceuticals Receives Fast Track Designation from FDA for the Development of ALLN-346 for Chronic Treatment of Hyperuricemia in Patients With Gout and Advanced Chronic Kidney Disease

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- Novel oral therapeutic candidate ALLN-346 targets uric acid in the intestinal tract -

- Patients with gout and CKD have a serious condition with an unmet need for urate-lowering–therapies –

-Two Phase 2a studies currently enrolling patients with hyperuricemia and CKD -

- Initial bioactivity data expected in late 2021 or early 2022 -

NEWTON, Mass., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Allena Pharmaceuticals, Inc. (NASDAQ: ALNA) (“Allena” or the “Company”), a late-stage biopharmaceutical company deploying its novel oral biologic platform to discover, develop and commercialize first-in-class, oral enzyme therapeutics for difficult-to-treat metabolic diseases, today announced that its orally-administered, urate-degrading enzyme, ALLN-346, has received Fast Track designation from the U.S. Food and Drug Administration (FDA). ALLN-346 is in Phase 2 development for the treatment of hyperuricemia in gout patients with advanced chronic kidney disease (CKD).

“We are delighted to have received Fast Track designation for ALLN-346," commented, David J. Clark, M.D., Chief Medical Officer of Allena. " ALLN-346 has a novel mechanism of action for this indication as it is designed to exert its effect in the intestinal tract, leading us to believe that this oral biologic may represent a meaningful new approach to treat gout patients with advanced chronic kidney disease, if approved. With approximately 500,000 patients in the U.S. affected by both disorders, this is an area of high unmet medical need. The timing of this news is also fortuitous with many of our advisors in the nephrology and rheumatology communities gathering virtually for the American Society of Nephrology and American College of Rheumatology meetings this week."

In gout patients with advanced CKD, the intestinal tract becomes the primary route of elimination for urate, and ALLN-346 is specifically designed to capitalize on this physiologic adaptation by enhancing the breakdown and secretion of urate in the intestinal tract. Currently available therapies are either dose-limited or contraindicated in this challenging patient population due to safety and tolerability concerns.

Robert Terkeltaub, M.D., Professor of Medicine, University of California, San Diego School of Medicine and scientific advisor to Allena Pharmaceuticals, noted, “Hyperuricemia and gout in the setting of advanced CKD are not only more difficult to treat, but also are associated with higher risk of progression to end-stage renal disease (ESRD). Currently available urate-lowering therapies are limited in their use for CKD patients based on dosing restrictions, tolerability and safety concerns, and reduced effectiveness, compared to options for the broader gout population. By directly breaking down uric acid in the intestinal tract, ALLN-346 has the potential to provide a well-tolerated new therapeutic tool, if approved, for this difficult-to-treat patient population.”

About the Phase 2a Program for ALLN-346

The Phase 2a program, comprised of a one-week inpatient trial (Study 201) and a two-week outpatient trial (Study 202), is designed to assess initial bioactivity data and additional safety data for ALLN-346, the second orally delivered, non-absorbed enzyme developed using Allena's proprietary oral enzyme technology platform.

Study 201 is a one-week study being conducted at a clinical pharmacology unit enrolling patients with hyperuricemia. Patients are to be randomized (2:1) to receive either five capsules of ALLN-346 or matching placebo three times daily.

Study 202 is a two-week, outpatient study expected to enroll 24 hyperuricemic patients with gout and mild-to-moderate CKD. Patients are to be randomized (2:1) to receive either five capsules of ALLN-346 or a matching placebo three times daily. Of the two currently planned cohorts of 12 patients each, one cohort will consist of patients with an estimated glomerular filtration rate (eGFR) of 60-89 mL/minute (CKD Stage 2), and the other will consist of patients with an eGFR of 30-59 mL/minute (CKD Stage 3).

For both studies, key bioactivity endpoints will include measurements of serum urate and urine uric acid. Both studies will also assess safety and tolerability in the hyperuricemia, gout and CKD patient populations.

Allena plans to report initial data from these studies beginning in late 2021 or early 2022. Initial data from the Phase 2a program will potentially assist the Company in determining the optimal dosing paradigm and target population for later stage clinical trials.

About ALLN-346

ALLN-346 is an investigational first-in-class, non-absorbed, orally administered enzyme for the treatment of hyperuricemia and gout, a metabolic disorder characterized by high systemic levels of urate that can lead to several complications, including arthritis, kidney stones, and CKD.

Allena recently completed a Phase 1b multiple ascending dose study of ALLN-346. The study included 18 healthy volunteers, who received either ALLN-346 or placebo (2:1 randomization) for seven days. There were two cohorts consisting of nine subjects each, with the first receiving three

capsules of ALLN-346 three times daily, and the second receiving five capsules of ALLN-346 three times daily. ALLN-346 was well tolerated with no evidence of systemic absorption, as confirmed by an enzyme-linked immunosorbent assay (ELISA). Evaluation of clinical and laboratory parameters revealed no significant safety signals.

About Fast Track Designation

Fast Track is an FDA process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose of the program is to make important new drugs available to the patient earlier. Filling an unmet medical need is defined as providing a therapy where none exists or providing a potential improvement upon the current standard of care. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the sponsor is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company leveraging its novel oral biologic platform to discover, develop and commercialize first-in-class, oral enzyme therapeutics for difficult-to-treat metabolic diseases. 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, CKD and other serious kidney disorders. Allena is also developing ALLN-346 for the treatment of hyperuricemia and gout in the setting of advanced CKD, with a Phase 1 multiple ascending dose study recently completed and a Phase 2a program underway.

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 concerning the future clinical, regulatory and commercial potential of reloxaliase, and, statements regarding Allena's development of ALLN-346, including the timing of planned clinical trials and the announcement of topline data for these trials. 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; risks 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 ALLN-346 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 Allena's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, 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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