Allena Pharmaceuticals Announces Completion of Enrollment of Cohorts A and B of ALLN-346 Phase 2a Study 202 in Patients with Gout and Stages 2 and 3 Chronic Kidney Disease

July 19, 2022

NEWTON, Mass., July 19, 2022 (GLOBE NEWSWIRE) -- Allena Pharmaceuticals, Inc. (NASDAQ: ALNA) ("Allena" or the "Company"), a 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 reported completion of enrollment of the first two cohorts of its ALLN-346 Phase 2a Study 202 in gout patients with stage 2 (cohort A) and stage 3 (cohort B) chronic kidney disease (CKD). ALLN-346, which has received Fast Track Designation from the U.S. Food and Drug Administration (FDA), is a first-in-class, non-absorbed, orally administered enzyme in development for the treatment of hyperuricemia and gout in the setting of advanced CKD, an indication with high unmet need. ALLN-346 is a bio-engineered enzyme specifically designed to degrade urate in the gastrointestinal tract without systemic absorption and thereby reduce systemic urate levels in patients with hyperuricemia, gout and CKD.

Study 202 is a two-week, outpatient study assessing safety and tolerability in hyperuricemic patients with gout and CKD. Patients are randomized (2:1) to receive either five capsules of ALLN-346 or a matching placebo three times daily, with enrollment of up to four planned cohorts, each consisting of up to 12 patients. Cohort A has enrolled seven patients with an estimated glomerular filtration rate (eGFR) of 60-89 mL/minute (considered to have Stage 2, or mild CKD), and Cohort B has enrolled twelve patients with an eGFR of 30-59 mL/minute (considered to have Stage 3, or moderate CKD). Of note, because Study 201, a one-week inpatient study conducted at a clinical pharmacology unit, has enrolled primarily hyperuricemic patients with Stage 2 CKD, targeted enrollment of Stage 2 CKD patients in Cohort A of Study 202 was reduced from twelve to seven. Topline safety and efficacy data from cohort A and cohort B of Study 202 are expected to be available later this quarter. Pending review of the Phase 2a data and the availability of sufficient financial resources, the Company expects to open two additional cohorts later this year, consisting of gout patients with Stage 4, or advanced CKD (Cohort C) and an allopurinol combination therapy cohort in gout patients with Stage 3 CKD (Cohort D).

As previously reported, ALLN-346 demonstrated a significant reduction in serum uric acid and a well-tolerated safety profile in the first 11 patients enrolled in Study 201, a one-week inpatient study in hyperuricemic patients with either normal renal function or CKD up to stage 2 randomized (2:1) to receive either five capsules of ALLN-346 or a matching placebo three times daily. Since reporting this data, an additional five patients have been enrolled in this study. The Company plans to provide an update on topline safety and efficacy data that includes all 16 patients enrolled in Study 201 during Q3 2022.

David J. Clark, M.D., M.R.C.P., Chief Medical Officer of Allena Pharmaceuticals, Inc., stated, "We are pleased with the progress of our ALLN-346 Phase 2a program, and thank our patients, investigators and business partners for helping us achieve this operational milestone. This is an important step in our efforts to develop a new treatment option for patients with hyperuricemia, gout and advanced CKD. There is an established pathophysiologic adaptation of increased intestinal elimination of uric acid in patients with impaired kidney function, so we believe the ALLN-346 therapeutic strategy of degrading uric acid in the GI tract is based on a strong scientific rationale. We have been encouraged by initial data from Study 201, which have provided evidence supporting the GI mechanism of action for ALLN-346, including the positive correlation between serum uric acid reduction and the degree of renal impairment. We look forward to reporting additional topline safety and efficacy data from the cohorts thus far enrolled in the ALLN-346 Phase 2a development program later this quarter."

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a 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 is currently conducting a Phase 2a program for ALLN-346, which has received Fast Track Designation from the FDA for the treatment of hyperuricemia and gout in the setting of 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 concerning the future clinical, regulatory and commercial potential of reloxaliase and ALLN-346; statements regarding Allena's development of ALLN-346 including the timing of planned clinical trials and the announcement of topline data for these trials; and 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. ***Of note, the failure to obtain sufficient additional funds on commercially acceptable terms to fund our operations will have a material adverse effect on our business, results of operations and financial condition and jeopardize our ability to continue operations. We may need to implement additional cost reduction strategies, which may include amending, delaying, limiting, reducing, or terminating one or more of our ongoing or planned clinical trials or development programs of our product candidates, and we may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such future liquidation or bankruptcy proceeding, holders of our common stock and other securities will likely suffer a total loss of their investment.*** *Additional 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 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; risks associated with Allena's ability to identify and consummate financing and strategic alternatives that yield additional value for shareholders; the timing, benefits and outcome of the Company's strategic alternatives review process, including the determination of whether or not to pursue or consummate any strategic alternative, the structure, terms and specific risks and uncertainties associated with any potential strategic transaction, potential disruptions in Allena's business and stock price as a result of its exploration, review and pursuit of strategic alternatives or the public announcement thereof and any decision or transaction resulting from such review. 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 March 31, 2022, 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.

Investor Relations Contact:
Ashley R. Robinson
LifeSci Advisors, LLC
Tel: 617-430-7577
arr@lifesciadvisors.com

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