Allena Pharmaceuticals Announces $28 Million Registered Direct Offering Priced At-the-Market under Nasdaq Rules

July 14, 2021

NEWTON, Mass., July 13, 2021 (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 has entered into definitive agreements with several healthcare-focused institutional and accredited investors for the purchase and sale of 21,357,744 shares of the Company's common stock (or common stock equivalents) and warrants to purchase up to an aggregate of 10,678,872 shares of the Company's common stock, at a purchase price of $1.311 per share of common stock (or common stock equivalent) and associated warrant, in a registered direct offering priced at-the-market under Nasdaq rules. The closing of the offering is expected to occur on or about July 16, 2021, subject to the satisfaction of customary closing conditions.

H.C. Wainwright & Co. is acting as the exclusive placement agent for the offering.

The warrants have an exercise price of $1.25 per share, are exercisable immediately and have a term of five years.

The gross proceeds to the Company from this offering are expected to be approximately $28 million, before deducting the placement agent's fees and other offering expenses payable by the Company. The Company intends to use the net proceeds from this offering for working capital and general corporate purposes.

The foregoing securities are being offered by the Company pursuant to a "shelf" registration statement on Form S-3 (File No. 333-228656) previously filed with the Securities and Exchange Commission (the "SEC") on December 3, 2018, and declared effective by the SEC on December 26, 2018. The offering of the securities is made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement. A final prospectus supplement and accompanying prospectus relating to the securities being offered will be filed with the SEC. Electronic copies of the final prospectus supplement and accompanying prospectus may be obtained, when available, on the SEC's website at http://www.sec.gov or by contacting H.C. Wainwright & Co., LLC at 430 Park Avenue, 3rd Floor, New York, NY 10022, by phone at (212) 865-5711 or e-mail at placements@hcwco.com.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to discovering, developing and commercializing first-in-class, oral biologic 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 for the treatment of hyperuricemia in the setting of gout and advanced chronic kidney disease, with a Phase 1 multiple-ascending dose study recently completed and a Phase 2a program planned for the second half of 2021.

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 completion of the registered direct offering, the satisfaction of customary closing conditions related to the registered direct offering and the intended use of net proceeds from the registered direct offering. In addition, it should be noted that additional capital will be required to complete the company's planned URIROX-2 clinical trial, which capital may not be available to Allena on terms that are acceptable to it, if at all. If adequate funds are not available on a timely basis, Allena may be required to delay, limit, reduce or terminate its clinical development of reloxaliase. The impact of the COVID-19 coronavirus on Allena's business, the biotech sector generally and the broader macroeconomic environment is uncertain and could harm Allena's business by delaying regulatory review timelines, clinical development plans and our ability to raise necessary capital. Furthermore, Allena does not have sufficient cash to operate its business for the next 12 months, which raises substantial doubt about its ability to continue as a going concern. Allena will require additional capital to fund its planned operations, which may not be available to it on attractive terms or at all. If the company is unable to secure additional capital, it will be forced to delay, limit, reduce or terminate its development of reloxaliase and may not be able to continue as a going concern. 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 the results of the URIROX-1 clinical trial may not be replicated in the URIROX-2 or other clinical trials of reloxaliase; the risk that the reduction in 24-hour UOx excretion observed in the placebo arm of the URIROX-1 trial may be observed in the URIROX-2 or other clinical trials of reloxaliase, which may have a negative impact on Allena's ability to secure regulatory approval for this product candidate; the risk that results of earlier studies, or interim results, 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 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 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 March 31, 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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