Allena Pharmaceuticals Reports Third Quarter 2021 Financial Results and Recent Corporate Progress

November 10, 2021

- *ALLN-346, a first-in-class, non-absorbed, orally administered enzyme in development for the treatment of hyperuricemia and gout in the setting of advanced chronic kidney disease, receives Fast Track Designation from FDA*
- *Two Phase 2a trials for ALLN-346 enrolling patients with gout and chronic kidney disease; initial data expected in Q1 2022*
- *First interim analysis for URIROX-2 Phase 3 trial of reloxaliase for the treatment of enteric hyperoxaluria planned for Q1 2022*
- *Registered direct offering completed in Q3 raising gross proceeds of $28.0 million*

NEWTON, Mass., Nov. 10, 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 reported financial results for the third quarter and nine months ended September 30, 2021, and highlighted recent corporate progress.

"We continue to make good progress advancing the clinical development of our two novel oral enzymes focusing on patients with urate and oxalate disorders," noted Louis Brenner, M.D., President and Chief Executive Officer of Allena. "We are pleased to have recently received Fast Track Designation for ALLN-346, our novel oral biologic for the treatment of hyperuricemia and gout in patients with chronic kidney disease. We believe that ALLN-346 has the potential to address a significant unmet medical need, as currently available agents are either dose-limited or contraindicated in this patient population due to safety and tolerability concerns. For reloxaliase, the most-advanced drug candidate in development for patients with enteric hyperoxaluria, we remain on track to conduct the first interim analysis of the pivotal Phase 3 URIROX-2 trial during Q1 2022."

Recent and Third Quarter Corporate Developments

- **Fast Track Designation Received for ALLN-346**

  In November, Allena 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 and gout in patients with advanced chronic kidney disease (CKD). 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.

- **Initiation of Phase 2a Program for ALLN-346**

  During Q3 Allena initiated two Phase 2a studies of ALLN-346, study 201 and study 202. Study 201 is a one-week study being conducted at a clinical pharmacology unit (CPU) 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 Q1 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.

- **Updated Plan and Timing for First Interim Analysis of the URIROX-2 Phase 3 Trial**

  In July, the Company announced an updated plan and timing related to the first interim analysis of the URIROX-2 Phase 3 trial investigating reloxaliase, a first-in-class, orally administered, non-absorbed enzyme in development for enteric hyperoxaluria. Reloxaliase is being studied in the adaptive-design URIROX-2 trial, the second of two pivotal Phase 3 clinical trials in the URIROX program. The revised interim analysis, which will be conducted by an independent data monitoring committee, will assess whether the study continues to be adequately powered to evaluate efficacy against the primary endpoint, the change in urinary oxalate levels during weeks 1-4 versus baseline, with the planned enrollment of 200 subjects, or whether the study size should be increased. Any adjustment in study size would be designed to ensure that the statistical power of the study remains sufficiently robust. As previously planned, the interim analysis will also include an assessment of futility with respect to the primary endpoint.

- **$28.0 Million Registered Direct Offering Priced At-the-Market under Nasdaq Rules**

  In July, Allena completed a registered direct offering priced at-the-market under Nasdaq rules. Net proceeds to the Company were $25.4 million after deducting placement agent fees and other offering expenses.

Third Quarter (Three-Month) 2021 Financial Results and Cash Position:

- **Research and Development Expenses:** Research and development expense was $9.0 million for the third quarter of 2021 compared to $5.0 million for the third quarter of 2020. The increase was primarily due to increased costs incurred for the ALLN-346 program, including costs for the Phase 2a studies (Study 201 and Study 202), along with increased costs associated with the reloxaliase program, primarily related to the URIROX-2 trial.
- **General and Administrative Expenses:** General and administrative expense was $3.4 million for the third quarter of 2021 compared to $3.0 million for the third quarter of 2020. The increase was primarily due to an increase in consulting and professional services costs and insurance costs.
- **Net Loss:** Primarily reflecting the factors noted above, net loss was $12.7 million for the third quarter of 2021, compared to $8.0 million for the third quarter of 2020.
- **Cash Position:** Total cash and cash equivalents as of September 30, 2021 was $40.4 million. This amount includes $25.4 million of net proceeds that the Company raised during the third quarter from a registered direct offering.

Year to Date (Nine-Month) 2021 Financial Results:

- **Research and Development Expenses:** Research and development expense was $27.0 million for the nine months ended September 30, 2021 compared to $13.4 million for the nine months ended September 30, 2020. The increase was primarily due to increased costs incurred for the reloxaliase program, primarily related to the URIROX-2 trial, along with an increase in costs associated with the ALLN-346 program, including costs associated with the Phase 2a studies.
- **General and Administrative Expenses:** General and administrative expense was $10.6 million for the nine months ended September 30, 2021 compared to $8.6 million for the nine months ended September 30, 2020. The increase was primarily due to an increase in consulting and professional services costs and insurance costs.
- **Net Loss:** Primarily reflecting the factors noted above, net loss was $38.3 million for the nine months ended September 30 2021, compared to $22.6 million for the nine months ended September 30, 2020.

Allena Pharmaceuticals, Inc
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	As of September 30, 2021	As of December 31, 2020
Cash and cash equivalents	$ 40,421	$ 35,042
Working capital (1)	34,281	31,127
Total assets	43,870	38,931
Loan payable, net of current portion and discount	9,893	9,853
Total stockholders' equity	26,030	22,569

(1) The Company defines working capital as current assets less current liabilities. See the Company's condensed consolidated financial statements for further detail regarding its current assets and current liabilities.

Allena Pharmaceuticals, Inc
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 9,024	$ 4,952	$ 26,966	$ 13,406
General and administrative	3,407	2,966	10,562	8,595
Total operating expenses	12,431	7,918	37,528	22,001
Other expense, net	(261)	(108)	(772)	(586)
Net loss	$ (12,692)	$ (8,026)	$ (38,300)	$ (22,587)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.17)	$ (0.22)	$ (0.61)	$ (0.77)
Weighted-average common shares outstanding—basic and diluted	76,658,487	36,260,973	63,283,268	29,317,787

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, chronic kidney disease and other serious kidney disorders. Allena is also developing ALLN-346 for the treatment of hyperuricemia and gout in the setting of advanced chronic kidney disease, with a Phase 2a program recently initiated.

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 enrollment and the timing of the planned interim analysis in the URIROX-2 trial, the impact of an earlier initial interim analysis on the size and duration of the URIROX-2 trial, statements regarding Allena's strategy of pursuing a BLA submission for reloxaliase based upon data from its URIROX program using the accelerated approval regulatory pathway, which strategy is predicated on the FDA's agreement with our predictive model supporting a relationship between UOx levels and kidney stone formation rates, 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. 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 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 September 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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Source: Allena Pharmaceuticals, Inc.