Allena Pharmaceuticals Reports Second Quarter 2018 Financial Results and Provides Business Update

August 7, 2018

- Enrolling Global Phase 3 URIROX-1™ Trial; Plan to Initiate URIROX-2™ in 2H18 -

- Treated First Patients in Phase 2 Basket Study of Reloxaliase (ALLN-177) for Primary Hyperoxaluria or Enteric Hyperoxaluria with Advanced Chronic Kidney Disease (CKD) -

- Completed Animal Proof-of-Concept Study Supporting Selection of ALLN-346 as Lead Product Candidate for Hyperuricemia in Patients with Gout and CKD -

- Reiterates Guidance Based on Progress Toward Key Objectives Across Portfolio -

NEWTON, Mass., Aug. 07, 2018 (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 reported financial results for the second quarter ended June 30, 2018 and also provided a business update.

“Our second quarter and recent accomplishments demonstrate significant progress across our pipeline of proprietary oral enzyme product candidates. We continue to execute against our key objectives for 2018,” said Alexey Margolin, Ph.D., Chief Executive Officer of Allena Pharmaceuticals. “We have continued activating sites globally for our URIROX-1 study of reloxaliase in enteric hyperoxaluria and are encouraged by the initial enrollment. Based on constructive engagement with the U.S. Food and Drug Administration (FDA), we have also begun start-up activities for URIROX-2, including entering into an agreement with our contract research organization, and continue to expect to initiate this trial in the second half of the year. Additionally, we treated the first patients in our Phase 2 basket trial of reloxaliase in the most severe forms of hyperoxaluria. We have also expanded our pipeline with the selection of ALLN-346 as our lead product candidate for the treatment of hyperuricemia in patients with gout and CKD. We are committed to building out our product pipeline to address a broad range of severe metabolic and kidney-related disorders and believe we have made important strides towards this goal year-to-date.”

Recent Business Highlights and Upcoming Milestones:

Reloxaliase (ALLN-177): Reloxaliase, also known as ALLN-177, is a first-in-class, non-absorbed, orally-administered enzyme for the treatment of severe hyperoxaluria. Allena is currently evaluating reloxaliase in URIROX-1, the first of two anticipated Phase 3 clinical trials intended to support a potential accelerated approval filing of a Biologic License Application (BLA) for reloxaliase in patients with enteric hyperoxaluria. Allena continues to engage with the FDA to finalize the design of URIROX-2, the second, larger, planned Phase 3 clinical trial of reloxaliase in patients with enteric hyperoxaluria, and to discuss the potential eligibility of ALLN-177 for an accelerated approval pathway. In addition, the Company is evaluating reloxaliase in Study 206, a Phase 2 basket trial in adults and adolescents with primary hyperoxaluria or enteric hyperoxaluria with advanced CKD and elevated plasma oxalate.

- In July 2018, Allena announced the treatment of the first patients in Study 206. The multi-center, open-label, single arm study is enrolling between 15 and 20 patients ages 12 and older in the U.S. and Europe for treatment with reloxaliase for 12 consecutive weeks. Clinical trial sites in the U.S. are enrolling patients, and investigators are preparing to enroll patients at European sites in the third quarter of 2018.

Consistent with prior guidance, Allena expects to achieve the following key milestones:

- Pending ongoing interactions with the FDA, initiate the URIROX-2 Phase 3 clinical trial in the second half of 2018;
- Report interim data from Study 206 in the second half of 2018; and
- Report topline data from the URIROX-1 Phase 3 clinical trial in the second half of 2019.

ALLN-346: ALLN-346 is a first-in-class, orally administered, novel urate degrading enzyme that has been optimized for stability in the gastrointestinal (GI) tract and is in preclinical development for the treatment of hyperuricemia in patients with gout and CKD. These patients have high unmet need due to limitations of existing therapies, such as poor tolerability, reduced efficacy, dose restriction or contraindications.

- In June 2018, Allena announced the completion of an animal proof-of-concept study supporting the selection of ALLN-346 as its lead product candidate for the treatment of hyperuricemia in patients with gout and CKD. ALLN-346 demonstrated a robust reduction in both plasma and urine uric acid levels in an established urate oxidase knock-out mouse model, a severe animal model of hyperuricemia with advanced CKD and kidney damage due to urate crystal deposition.

Consistent with prior guidance, Allena expects to achieve the following key milestones:

- Present detailed preclinical data for ALLN-346 at a scientific conference in the second half of 2018; and
- File an IND application with the FDA in the first half of 2019.

Corporate:

- In June 2018, Allena announced the appointment of Andrew A. F. Hack, M.D., Ph.D., to its Board of Directors, where he serves as Chair of the Audit Committee.

Second Quarter 2018 Financial Results:

- **Cash Position**: As of June 30, 2018, cash and cash equivalents were $78.9 million, as compared to $94.5 million as of December 31, 2017. This decrease was primarily due to cash used in operating activities.
- **R&D Expenses**: R&D expenses were $5.9 million for the second quarter of 2018, as compared to $3.5 million for the second quarter of 2017. This increase was primarily due to costs incurred for URIROX-1 and Study 206, which were both initiated in the first quarter of 2018, in addition to an increase in employee-related costs due to the hiring of additional clinical and technical operations personnel to support the URIROX Phase 3 program.
- **G&A Expenses**: G&A expenses were $2.3 million for the second quarter of 2018, as compared to $1.0 million for the second quarter of 2017. This increase was primarily due to increases in compensation and benefit costs, including stock-based compensation, and costs attributable to operating as a public company during the second quarter of 2018, as compared to the second quarter of 2017.
- **Net Loss**: Net loss was $8.6 million for the second quarter of 2018, or a net loss per basic and diluted share of $0.42, as compared to a net loss of $4.6 million for the second quarter of 2017, or a net loss per basic and diluted share of $3.46. The decrease in net loss per share for the second quarter of 2018 as compared to the second quarter of 2017 is primarily due to an increase in weighted average shares outstanding for the second quarter of 2018, following completion of the Company's IPO and concurrent conversion of its preferred stock into common stock in November 2017.

Financial Guidance:

Based on its current plans, Allena continues to expect that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital requirements into 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 (ALLN-177), is a first in class, oral enzyme therapeutic for the treatment of 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.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Allena's URIROX-1 clinical trial, including the timing of announcement of topline data from this trial, statements regarding Allena's planned Phase 3 pivotal program for ALLN-177, including Allena's planned URIROX-2 trial, the resolution of the trial design for this trial with the FDA and the time of initiation of this trial, statements regarding Allena's ability to utilize the accelerated approval and conditional approval pathways for ALLN-177, statements regarding Allena's Study 206 trial and the announcement of data from such clinical trial, statements regarding ALLN-346, including the timing of presentation of data and filing the IND, and statements concerning the sufficiency of its cash, cash equivalents and short-term investments to fund operating expenses and capital requirements into 2020. Allena remains in an active dialogue with the FDA regarding the design of the URIROX-2 study, including the endpoints and statistical analysis plan for this study, and whether reduction in UOx excretion may be used as a surrogate endpoint to support an accelerated approval for ALLN-177. If Allena is unable to reach consensus with the FDA on the magnitude of UOx reduction significant enough to predict clinical benefit, it may be required to demonstrate effectiveness by showing an effect on stone formation directly, or conduct one or more additional clinical trials to demonstrate this effect, prior to the submission of a BLA for ALLN-177. 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 results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for ALLN-177 that support regulatory approval; risks associated with the fact that Allena has not yet finalized the design of its pivotal Phase 3 clinical program for ALLN-177, including the primary and secondary endpoints and the statistical analyses for URIROX-2, and that the FDA and comparable foreign regulators may not agree with the proposed Phase 3 clinical program, in which case Allena may be required to modify its planned clinical trials, or run additional clinical trials, before it can submit a BLA or comparable foreign applications for this product candidate; risks associated with a potential accelerated approval pathway, which would require that Allena conduct one or more confirmatory clinical trials to verify the clinical benefit of ALLN-177 after approval; 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 ability to manage operating expenses and/or obtain additional funding to support its business activities; and risks associated with Allena's dependence on third parties. 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 II of Allena's Quarterly Report on Form 10-Q for the year ended June 30, 2018, 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.

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

	As of June 30, 2018	As of December 31, 2017
Cash and cash equivalents	$ 78,853	$ 94,494
Working capital (1)	77,039	88,490
Total assets	80,064	96,249
Loan payable, net of current portion and discount	9,979	5,516
Total stockholders' equity	67,354	82,870

(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 June 30,		For the Six Months Ended June 30	
	2018	2017	2018	2017
	(unaudited)			
Operating expenses:				
Research and development	$ 5,860	$ 3,458	$ 11,791	$ 7,809
General and administrative	2,275	1,017	4,317	2,208
Total operating expenses	8,135	4,475	16,108	10,017
Other income (expense), net	(512)	(157)	(419)	(286)
Net loss	$ (8,647)	$ (4,632)	$ (16,527)	$ (10,303)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.42)	$ (3.46)	$ (0.80)	$ (7.70)
Weighted-average common shares outstanding—basic and diluted	20,733,043	1,342,957	20,714,319	1,342,628

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