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

November 7, 2018

-- Global Phase 3 URIROX-1™ Trial Ongoing; Expect to Initiate Second Phase 3 Study, URIROX-2™, in 2018 --

-- Presented Preclinical Proof-of-Concept Data on ALLN-346 at American College of Rheumatology (ACR/ARHP) Annual Meeting and New Data Characterizing Unmet Need in Enteric Hyperoxaluria at ASN Kidney Week 2018 --

NEWTON, Mass., Nov. 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 third quarter ended September 30, 2018 and also provided a business update.

"As new research emerges on oxalate's damaging effects on the kidneys, we are encouraged by the growing awareness of enteric hyperoxaluria and widespread focus on addressing the significant burden of kidney stone disease and kidney damage that it causes. We are similarly pleased to see an increased recognition of the unmet need for new therapies to treat hyperuricemia in patients living with gout and CKD, who are not optimally managed by existing therapies," said Alexey Margolin, Ph.D., Chief Executive Officer of Allena Pharmaceuticals. "By designing first-in-class enzyme therapeutics that target the underlying causes of these diseases, we believe we are positioned to meaningfully impact the treatment landscape for patients. We have been encouraged by our productive dialogue with the U.S. Food and Drug Administration (FDA) on the protocol and statistical plan for URIROX-2 and with the steady rate of enrollment in our ongoing URIROX-1 trial and Study 206. Looking ahead to 2019, we are excited to read out data from both our ongoing trials and to advance our clinical pipeline with ALLN-346, while continuing to drive understanding and awareness around the daily experience of people living with rare and severe metabolic and kidney disorders."

Recent Business Highlights and Upcoming Milestones:

Reloxaliase: Reloxaliase 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 protocol and statistical plan for URIROX-2, the second, larger, planned Phase 3 clinical trial of reloxaliase in patients with enteric hyperoxaluria, and to discuss the potential eligibility of reloxaliase for an accelerated approval pathway. Allena's most recent interaction with the FDA focused on two elements for the post-approval outcome phase of the trial. Allena is also evaluating reloxaliase in Study 206, a Phase 2 basket trial in adults and adolescents with primary hyperoxaluria or enteric hyperoxaluria with advanced chronic kidney disease (CKD) and elevated plasma oxalate.

- In October 2018, Allena presented new data characterizing the significant unmet need in enteric hyperoxaluria in a poster session at ASN Kidney Week 2018 in San Diego, CA. The presentation included composite data, details on kidney stone burden, and case studies from 33 patients who enrolled across Allena's three Phase 2 studies of reloxaliase. Data confirmed that a majority of these patients experienced persistently high 24-hour urinary oxalate excretion, despite following standard-of-care guidance for diet and hydration. Additionally, among 20 patients for whom kidney stone burden was assessed by CT scan, 16 had at least one kidney stone detected at enrollment, with an average of three stones present.

Allena expects to achieve the following key milestones:

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

ALLN-346: ALLN-346 is a first-in-class, orally administered, novel urate degrading enzyme that has been designed for activity and stability in the GI tract. Allena is working to complete its preclinical development of ALLN-346 for the treatment of hyperuricemia in patients with gout in the setting of advanced CKD, and to scale its manufacturing processes to support clinical studies.

- In October 2018, Allena presented preclinical proof-of-concept data at the 2018 American College of Rheumatology (ACR/ARHP) Annual Meeting from a study evaluating ALLN-346 in a urate oxidase knock-out mouse model, an animal model of severe hyperuricemia with kidney damage due to urate crystal deposition. After one week of treatment, mice treated with ALLN-346 achieved a substantial reduction in urate burden on the kidney, as evidenced by the normalization of urine uric acid and a significant reduction in plasma urate.

Allena expects to achieve the following key milestones:

- File an investigational new drug (IND) application with the FDA in 2019.
- Initiate first clinical trial in the first half of 2020.

Third Quarter 2018 Financial Results:

- **Cash Position**: As of September 30, 2018, cash and cash equivalents were $70.6 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 $7.3 million for the third quarter of 2018, as compared to $2.9 million for the third 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; start-up costs incurred for URIROX-2; and 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 $2.4 million for the third quarter of 2018, as compared to $1.4 million for the third 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 third quarter of 2018, as compared to the third quarter of 2017.
- **Net Loss**: Net loss was $9.5 million for the third quarter of 2018, or a net loss per basic and diluted share of $0.46, as compared to a net loss of $4.7 million for the third quarter of 2017, or a net loss per basic and diluted share of $3.49. The decrease in net loss per share for the third quarter of 2018 as compared to the third quarter of 2017 is primarily due to an increase in weighted average shares outstanding for the third quarter of 2018, following completion of the Company's initial public offering 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, 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 reloxaliase, 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 reloxaliase, statements regarding Allena's Study 206 trial and the announcement of data from such clinical trial, statements regarding ALLN-346,including the timing of 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 trial, 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 reloxaliase. 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 reloxaliase. 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 reloxaliase 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 reloxaliase, 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 reloxaliase 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 September 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 Pharmacecuticals, Inc
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	As of September 30, 2018	As of December 31, 2017
Cash and cash equivalents	$ 70,559	$ 94,494
Working capital (1)	67,799	88,490
Total assets	73,397	96,249
Loan payable, net of current portion and discount	9,977	5,516
Total stockholders' equity	58,445	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 September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 7,316	$ 2,949	$ 19,107	$ 10,758
General and administrative	2,389	1,413	6,706	3,621
Total operating expenses	9,705	4,362	25,813	14,379
Other income (expense), net	195	(308)	(224)	(594)
Net loss	$ (9,510)	$ (4,670)	$ (26,037)	$ (14,973)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.46)	$ (3.49)	$ (1.26)	$ (11.19)
Weighted-average common shares outstanding—basic and diluted	20,753,215	1,343,429	20,727,426	1,342,898

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