Allena Pharmaceuticals Reports Second Quarter 2019 Financial Results and Provides Business Update

August 7, 2019

-- Interim Data from Study 206 Demonstrated Substantial Treatment Effect in Patients with Enteric Hyperoxaluria and Advanced Chronic Kidney Disease, Including Robust Reductions in Both Urine and Plasma Oxalate --

-- Closed $10.0 Million Registered Direct Offering, Extending Cash Runway into the Fourth Quarter of 2020 --

-- Topline Data from Phase 3 URIROX-1 Trial and Study 206 On Track for the Second Half of 2019 --

NEWTON, Mass., Aug. 07, 2019 (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, 2019 and also provided a business update.

“At Allena, we are committed to providing a first-in-class treatment for the full spectrum of patients with enteric hyperoxaluria (EH),” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “The initial data from Study 206 represent meaningful progress toward achieving this vision, as we showed for the first time reloxaliase’s ability to reduce both urine and plasma oxalate in patients with EH and impaired kidney function, including patients with advanced chronic kidney disease, dialysis-dependence, and transplantation. Importantly, these data are consistent with our prior clinical experience in enteric hyperoxaluria, increasing our confidence in our ongoing URIROX-1 trial and supporting our belief that reloxaliase’s mechanism of action can impact all stages of the disease. With a strengthened balance sheet following our registered direct offering, we look forward to advancing our two ongoing URIROX Phase 3 trials and to reporting topline data from URIROX-1 and Study 206 before year-end.”

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 two ongoing pivotal Phase 3 trials, URIROX-1 and URIROX-2, which are designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria. Allena plans to pursue a Biologics License Application (BLA) submission for reloxaliase using the accelerated approval regulatory pathway.

The URIROX program consists of two pivotal Phase 3 clinical trials, URIROX-1 and URIROX-2, which are designed to evaluate the safety and efficacy of reloxaliase in patients with EH. The primary efficacy endpoint for both trials is the percent change from baseline in 24-hour urinary oxalate (UOx) excretion measured during Weeks 1-4, comparing reloxaliase to placebo. The primary long-term efficacy endpoint to confirm clinical benefit in URIROX-2 is the proportion of patients with kidney stone disease progression, defined as a composite of either symptomatic kidney stones or finding of new or enlarged kidney stones using imaging, over a minimum treatment period of two years. Allena expects to report topline data from URIROX-1 in the second half of 2019, and from URIROX-2 in the second half of 2021.

Allena is also evaluating reloxaliase in Study 206, a multi-center, open-label, single arm Phase 2 basket study of reloxaliase in adults and adolescents with EH or primary hyperoxaluria (PH) with advanced chronic kidney disease (CKD) and elevated plasma oxalate. Patients orally administer 7,500 units of reloxaliase with each meal or snack five times a day, for 12 consecutive weeks. Allena expects to report topline data from Study 206 in the second half of 2019.

- In June 2019, Allena announced interim data from Study 206. EH patients treated with reloxaliase in Study 206 demonstrated a substantial treatment effect. This includes EH patients with advanced CKD, a patient population not previously treated with reloxaliase, who showed reductions in UOx and plasma oxalate (POx). Treatment with reloxaliase was well-tolerated in all patient populations, with no reported treatment-related serious adverse events over the 12-week study, which is the longest duration of treatment to date.
    - All four patients with EH experienced a reduction in POx, with an average reduction of 35% compared to baseline (range 16% to 49%). The two patients not on dialysis also experienced reductions in UOx of 29% and 42%, respectively.
- In June 2019, Allena presented on its reloxaliase development program and the unmet need in patients with EH in four sessions at the Oxalosis & Hyperoxaluria Foundation (OHF) International Hyperoxaluria Workshop in Boston, MA.

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 gastrointestinal tract. Allena is completing its preclinical development of ALLN-346 for the treatment of hyperuricemia in patients with gout in the setting of advanced CKD and also scaling its manufacturing processes to support clinical studies. Allena expects to file an Investigational New Drug (IND) application with the FDA in the second half of 2019 and initiate the first clinical trial of ALLN-346 in the first half of 2020.

Corporate:

- In June 2019, Allena announced a $10.0 million registered direct offering of common stock.

Second Quarter 2019 Financial Results:

- **Cash Position**: As of June 30, 2019, cash and cash equivalents were $48.5 million, as compared to $61.6 million as of December 31, 2018. This decrease was primary due to cash used in operating activities, partially offset by aggregate gross proceeds of approximately $10 million from the Company's registered direct offering of common stock, which closed in June 2019.
- **R&D Expenses**: R&D expenses were $8.6 million for the second quarter of 2019, as compared to $5.9 million for the second quarter of 2018. The increase was primarily due to costs incurred for the URIROX-2 trial, which was initiated during the fourth quarter of 2018, and an increase of formulation and development costs incurred advancing ALLN-346.
- **G&A Expenses**: G&A expenses were $2.7 million for the second quarter of 2019, as compared to $2.3 million for the second quarter of 2018. The increase was primarily due to increases in professional services costs, including public relations, legal, and recruiting activities.
- **Net Loss**: Net loss was $11.3 million for the second quarter of 2019, or a net loss per basic and diluted share of $0.54, as compared to a net loss of $8.6 million for the second quarter of 2018, or a net loss per basic and diluted share of $0.42.

Financial Guidance:

Based on its current plans, Allena expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 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, without limitation, statements regarding Allena's URIROX clinical program and alignment with the FDA, statements regarding the timing of announcement of release of data from its ongoing clinical trials, statements regarding Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements regarding the ability of reloxaliase to provide clinical benefit to patients with hyperoxaluria, statements regarding the results of Study 206 and the clinical and commercial potential of reloxaliase for patients with primary hyperoxaluria or enteric hyperoxaluria and statements regarding development plans for ALLN-346. 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, 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 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 quarter ended June 30, 2019, 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, 2019	As of December 31, 2018
Cash and cash equivalents	$ 48,523	$ 61,643
Working capital (1)	44,565	58,706
Total assets	53,582	65,229

Loan payable, net of current portion and discount	7,984	9,980
Total stockholders' equity	37,673	49,456

(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,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 8,589	$ 5,860	$ 17,717	$ 11,791
General and administrative	2,746	2,275	5,177	4,317
Total operating expenses	11,335	8,135	22,894	16,108
Other income (expense), net	62	(512)	202	(419)
Net loss	$ (11,273)	$ (8,647)	$ (22,692)	$ (16,527)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.54)	$ (0.42)	$ (1.09)	$ (0.80)
Weighted-average common shares outstanding—basic and diluted	20,903,298	20,733,043	20,859,251	20,714,319

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