Allena Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

March 9, 2021

-- Reloxaliase continues to progress through ongoing pivotal Phase 3 URIROX-2 trial for enteric hyperoxaluria --

-- ALLN-346 poised to enter Phase 1 multiple-ascending dose and Phase 2a trials for hyperuricemia and gout --

-- Management team strengthened with addition of David Clark, M.D., M.R.C.P as Chief Medical Officer and Richard Katz, M.D. as Chief Financial Officer --

NEWTON, Mass., March 09, 2021 (GLOBE NEWSWIRE) -- Allena Pharmaceuticals (NASDAQ:ALNA), a late-stage biopharmaceutical company dedicated to discovering, 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 fourth quarter and full year ended December 31, 2020 and provided a business update.

“Building on the significant accomplishments of 2020, we are entering 2021 well-positioned to execute on our mission of delivering novel oral biologic medicines to patients with rare and serious metabolic and kidney diseases,” said Louis Brenner, M.D, President and Chief Executive Officer of Allena Pharmaceuticals. “We successfully reinvigorated our global Phase 3 URIROX-2 clinical trial of reloxaliase for the treatment of enteric hyperoxaluria, a life-threatening disease for which there is no currently approved therapy. In addition, we initiated clinical development of ALLN-346 for the treatment of hyperuricemia and gout, our second oral biologic program, further demonstrating the potential broad applicability of our technology platform."

Dr. Brenner continued, “As a result of the impact of the pandemic on patient enrollment, we now expect to complete the interim analysis in our URIROX-2 trial during the second or third quarter of 2022. Despite the challenges presented by the pandemic, we are grateful for the continued commitment and enthusiasm of our clinical investigators and patients, and are encouraged that both site initiation and recruitment have accelerated significantly in the early months of 2021. With the recent additions to our management team and the available proceeds from financing activities, we are operating from a position of strength, and look forward to delivering reloxaliase as the first potential treatment for patients with enteric hyperoxaluria and advancing ALLN-346 as a potential novel oral agent to treat patients with gout and chronic kidney disease (CKD).”

Clinical-Stage Product Candidate Updates

Reloxaliase: Novel oral biologic for enteric hyperoxaluria

Reloxaliase is a first-in-class, non-absorbed, orally administered enzyme for the treatment of enteric hyperoxaluria. Reloxaliase exerts its effect by breaking down oxalate in the gastrointestinal (GI) tract, reducing the absorption of dietary oxalate. Allena is currently studying reloxaliase in the URIROX-2 trial, the second pivotal Phase 3 clinical trial in its URIROX program, with planned enrollment of 200 patients. The Company plans to conduct an interim analysis after 130 patients have been enrolled in the study for six months, currently expected to occur during the second or third quarter of 2022, with topline data becoming available approximately six months later. The U.S. Food and Drug Administration (FDA) has advised Allena that it agrees with the Company's strategy of pursuing a Biologics License Application (BLA) submission for reloxaliase based upon data from its URIROX program, including the completed URIROX-1 and ongoing URIROX-2 trials, using the accelerated approval regulatory pathway. To support potential accelerated approval, patients will also continue to be followed for a minimum of two years to confirm clinical benefit, including the ability of reloxaliase to reduce the incidence and severity of kidney stone disease and renal impairment. There are currently no approved treatments for enteric hyperoxaluria.

ALLN-346: Novel oral biologic for hyperuricemia and gout

ALLN-346 is a first-in-class, non-absorbed, orally administered enzyme for the treatment of hyperuricemia and gout. ALLN-346 is designed to exert its effect by breaking down urate in the GI tract, which is expected to lead to a concomitant reduction in urine and serum urate levels. Allena recently completed a Phase 1 single ascending dose study of ALLN-346 in healthy volunteers, which demonstrated no safety or tolerability concerns. In addition, an immunoassay of plasma samples demonstrated that ALLN-346 was not absorbed systemically. A Phase 1 multiple ascending dose study is expected to initiate in the second quarter of 2021, with initial results expected in the third quarter. Additionally, pending feedback from the FDA, a Phase 2a program in patients with hyperuricemia is planned for the second half of 2021, with initial efficacy data expected during the fourth quarter. The Company intends to focus its development program for ALLN-346 on the significant population of patients with hyperuricemia and gout who also suffer from CKD, for whom many of the current therapeutics are either dose-limited or contraindicated due to safety and tolerability concerns.

Corporate Update

Appointment of David Clark, M.D., M.R.C.P. as Chief Medical Officer

In December 2020, Allena announced the appointment of David J. Clark, M.D., M.R.C.P. as Chief Medical Officer. Dr. Clark brings more than 20 years of industry experience to the Company, and has led development programs across multiple therapeutic categories, with an emphasis on immune-mediated and rare diseases. Dr. Clark earned his medical degree from the University of Edinburgh Medical School and conducted a research fellowship in respiratory medicine at the University of Dundee.

Appointment of Richard Katz, M.D. as Chief Financial Officer

In February 2021, Allena announced the appointment of Richard D. Katz, M.D. as Chief Financial Officer. Dr. Katz also brings more than 20 years of industry experience to the Company, having served as the chief financial officer for several biopharmaceutical companies after beginning his career in the Healthcare Group at Goldman, Sachs & Company. Dr. Katz earned his AB degree from Harvard University, his medical degree from the Stanford University School of Medicine and his MBA from Harvard Business School. Dr. Katz has succeeded Edward Wholihan, whose planned departure was previously announced.

Fourth Quarter 2020 Financial Results

- **R&D Expense:** R&D expense was $7.0 million for the fourth quarter of 2020, as compared to $8.7 million for the fourth quarter of 2019. The decrease was primarily due to a reduction in costs incurred for the reloxaliase program, including costs for the URIROX-1 and Study 206 trials, both of which were completed during the fourth quarter of 2019, and a reduction in costs incurred for the ALLN-346 program.

- **G&A Expense:** G&A expense was $3.0 million for the fourth quarter of 2020, as compared to $2.0 million for the fourth quarter of 2019. The increase was primarily due to increases in stock-based compensation expense and directors' and officers' insurance costs.

- **Net Loss:** Primarily reflecting the factors noted above, net loss was $10.3 million for the fourth quarter of 2020, as compared to a net loss of $11.4 million for the fourth quarter of 2019.

- **Cash Position:** The cash balance as of December 31, 2020 was $35.0 million. The Company subsequently raised $11.7 million of net proceeds during the first quarter of 2021 through its at-the-market (ATM) equity facility. Additionally, the Company currently has access to up to $15.0 million of convertible debt through its loan and security agreement with Pontifax Medison Finance.

Full Year 2020 Financial Results

- **R&D Expense:** R&D expense was $20.4 million for the year ended December 31, 2020, as compared to $37.2 million for the year ended December 31, 2019. The decrease was primarily due to a reduction of costs incurred for the reloxaliase program, including costs for the URIROX-1 and Study 206 trials, both of which were completed in the fourth quarter of 2019, and a reduction in costs incurred for the ALLN-346 program, including costs for formulation and development relating to the investigational new drug (IND) application incurred during the third quarter of 2019. The Company filed an IND for ALLN-346 with the FDA in the fourth quarter of 2019.

- **G&A Expense:** G&A expense was $11.6 million for the year ended December 31, 2020 as compared to $9.7 million for the year ended December 31, 2019. The increase was primarily due to increases in stock-based compensation expense and directors' and officers' insurance costs.

- **Net Loss:** Primarily reflecting the factors noted above, net loss was $32.8 million for the year ended December 31, 2020 as compared to $47.3 million for the year ended December 31, 2019.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a late-stage 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 and a Phase 2a program planned for 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 concerning the future clinical, regulatory and commercial potential of reloxaliase, statements regarding enrollment and the timing of the planned interim analysis in 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 stone formation rates, statements regarding the Allena's development of ALLN-346 including the timing of planned clinical trials and the announcement of topline date 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; 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 September 30, 2020, 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 December 31,	
	2020	2019
Cash and cash equivalents	$ 35,042	$ 30,007
Working capital (1)	31,127	22,127
Total assets	38,931	34,108
Loan payable, net of current portion and discount	9,853	5,988
Total stockholders' equity	22,569	17,198

(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 December 31,		For the Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 6,977	$ 8,721	$ 20,383	$ 37,244
General and administrative	3,008	1,967	11,603	9,676
Restructuring charges	—	605	—	605
Total operating expenses	9,985	11,293	31,986	47,525
Other income (expense), net	(273)	(66)	(859)	186
Net loss	$ (10,258)	$ (11,359)	$ (32,845)	$ (47,339)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.24)	$ (0.47)	$ (1.01)	$ (2.13)
Weighted-average common shares outstanding—basic and diluted	42,004,030	23,497,048	32,506,679	22,180,868

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