Allena Pharmaceuticals Announces Appointment of Louis Brenner, M.D. as Chief Executive Officer and Confirms Key Milestones for 2019

January 4, 2019

-- Alexey Margolin, Ph.D. to Transition to Chairman of the Board --

-- URIROX-2™ Initiated; URIROX-1™ Topline Data Expected in Second Half of 2019 --

-- Multiple Catalysts Expected Across Pipeline in 2019 --

NEWTON, Mass., Jan. 04, 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 announced that Louis Brenner, M.D., President and Chief Operating Officer at Allena, will be promoted to Chief Executive Officer and appointed to the Board of Directors effective February 1, 2019. Dr. Brenner will succeed Alexey Margolin, Ph.D. as Chief Executive Officer. Dr. Margolin, who co-founded Allena in 2011, will transition to Chairman of the Board effective February 1, 2019. He will continue advising the company in this new role.

"I am honored to succeed Alex as the CEO of Allena. Since the company's founding, Alex has played a key role in shaping our vision and cementing our position as a leader in the development of novel medicines for people living with rare and severe metabolic and kidney disorders. We are grateful for his many contributions," said Louis Brenner, M.D., Chief Executive Officer designate of Allena Pharmaceuticals. "2019 promises to be a transformational year for Allena, following our recent alignment with the FDA on the design of our Phase 3 program for reloxaliase in patients with enteric hyperoxaluria, including our strategy to seek approval using the accelerated approval regulatory pathway, and we anticipate numerous milestones across our broader pipeline throughout the year. I look forward to working with the entire Allena team as we build on our strong foundation and advance our pipeline of first-in-class non-absorbed, oral enzyme therapeutics."

Louis Brenner, M.D. has served as Chief Operating Officer of Allena since April 2015 and as President since February 2017. Dr. Brenner has more than a decade of industry leadership experience, including pharmaceutical development strategy, regulatory affairs, business development and commercialization. Prior to joining Allena, Dr. Brenner served as Chief Medical Officer at Idera Pharmaceuticals, Chief Medical Officer at Radius Health, and Senior Vice President at AMAG Pharmaceuticals. He began his industry career at Genzyme Corporation. In these roles, he led successful product development programs for medicines that are currently marketed in the renal and metabolic areas. He holds an M.D. from Duke University, an M.B.A. from Harvard Business School and a B.S. from Yale University. He completed his residency in internal medicine at Brigham and Women's Hospital and his fellowship in nephrology at Brigham and Women's Hospital and Massachusetts General Hospital. Dr. Brenner holds a clinical appointment at Brigham and Women's Hospital.

"I have worked together with Lou for several years, and cannot think of a better candidate to lead Allena through its next stage of growth. Lou's extensive experience in late-stage clinical development and the pursuit of new regulatory approvals uniquely fits the needs of Allena as we approach our ultimate goal – bringing to patients the first ever drug for enteric hyperoxaluria," said Alexey Margolin, Ph.D., outgoing Chief Executive Officer of Allena Pharmaceuticals. "I feel privileged to have had the opportunity to help build our Company's platform, and I am deeply thankful to all of the stakeholders – including patients, clinicians, investors, business partners, and especially Allena employees – who have enabled this progress to-date."

"I am encouraged by Allena's progress in developing its pipeline of oral enzyme therapies, including the successful advancement of reloxaliase from preclinical studies into the ongoing Phase 3 program in patients with enteric hyperoxaluria," said Gino Santini, who will become Lead Independent Director of Allena Pharmaceuticals in connection with the leadership transition. "I have enjoyed working with Alex since the early days of the Company and look forward to his continued contributions as our new Chairman. I am also eager to work more closely with Lou. Given his expertise in nephrology, his experience in late-stage drug development, and, most importantly, his passion for helping patients, Lou is the ideal choice to lead Allena as it advances its pipeline toward the market."

2019 Corporate Strategy and 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 recently announced that it had reached alignment with the FDA on both the design of URIROX-2 and its strategy to pursue a Biologics License Application submission for reloxaliase using the accelerated approval regulatory pathway. URIROX-1 is currently enrolling patients, and Allena initiated URIROX-2 in the fourth quarter of 2018.

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 primary hyperoxaluria or enteric hyperoxaluria with advanced chronic kidney disease (CKD) and elevated plasma oxalate.

Allena expects to achieve the following key milestones for reloxaliase:

- Report 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 gastrointestinal 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.

Allena expects to achieve the following key milestones for ALLN-346:

- File an Investigational New Drug application with the FDA in 2019; and
- Initiate the first clinical trial in the first half 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 statements regarding Allena's URIROX clinical program and alignment with the FDA, statements regarding Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements regarding the timing of announcement of interim clinical data from Study 206 and topline data from the URIROX-1 trial and Study 206, statements regarding the filing of an IND and the initiation of a clinical trial for ALLN-346, and statements regarding the ability of reloxaliase to provide clinical benefit to patients with hyperoxaluria. 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 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 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 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.

Investor Contact
Hannah Deresiewicz
Stern Investor Relations, Inc.
212-362-1200
hannahd@sternir.com

Media Contact
Adam Daley
Berry & Company Public Relations
212-253-8881
adaley@berrypr.com

Source: Allena Pharmaceuticals, Inc.