Kiniksa Pharmaceuticals Announces Collaboration with the Myocarditis Foundation for the Pericarditis Community

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HAMILTON, Bermuda, Aug. 05, 2019 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients with significant unmet medical need, today announced a collaboration with the Myocarditis Foundation in support of patients affected by pericarditis with heart muscle inflammation.

Kiniksa and the Myocarditis Foundation are working together to raise awareness about pericarditis, an underserved, painful and debilitating autoinflammatory cardiovascular disease. Approximately a third of people with pericarditis will also have heart muscle inflammation, called myocarditis. The Myocarditis Foundation is providing information about pericarditis on its website as an educational reference for patients and caregivers. In addition, the Myocarditis Foundation plans to launch a free online interactive community for pericarditis patients and caregivers to support and connect with each other.

"The Myocarditis Foundation's passion and commitment to patients and families affected by cardiovascular diseases is outstanding," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We are thrilled to partner with them to support patients with heart-related medical conditions and view our relationship as a significant advancement in advocacy for patients with pericarditis."

"The Myocarditis Foundation is a mission-driven organization dedicated to saving the lives of patients with cardiovascular diseases through education and scientific advancement," said Joseph C. Rumore, President and Chairman of the Board of the Myocarditis Foundation. "We are excited to expand our capabilities for patients affected with pericarditis in collaboration with the team at Kiniksa."

Pericarditis, in the acute form, accounts for ≥1% of emergency department (ED) visits among patients with ST-segment elevation[1] and up to 4.4% of ED visits for chest pain.[2]

Kiniksa is currently developing a potential treatment to address the recurrent form of pericarditis. Recurrent pericarditis is a common complication after an initial episode of acute pericarditis and is characterized by the recurrence of chest pain and signs of cardiovascular inflammation. Health plan claims data suggests there are approximately 40,000 recurrent pericarditis patients in the Unites States seeking and receiving medical treatment. There are no currently FDA-approved treatments for pericarditis.

Kiniksa is enrolling RHAPSODY, a global, randomized withdrawal (RW) design, pivotal Phase 3 clinical trial of rilonacept in subjects with recurrent pericarditis. The study is intended to evaluate the efficacy and safety of rilonacept treatment in subjects with recurrent pericarditis. The primary efficacy endpoint is time-to-first pericarditis-recurrence in the RW period. The co-principal investigators are Dr. Allan Klein of Cleveland Clinic and Dr. Massimo Imazio of the University of Torino, Italy. Top-line data are expected in the second half of 2020.

About Kiniksa
Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa has a pipeline of product candidates across various stages of development, focused on autoinflammatory and autoimmune conditions. For more information, please visit www.kiniksa.com.

About the Myocarditis Foundation
The Myocarditis Foundation is a private, 501(c)3 non-profit organization, established in 2005. The organization is dedicated to providing accurate and up-to-date information to medical professionals, patients and their families, and to the scientific advancement of both the diagnosis and treatment of the myocarditis with the goal of saving more lives. For more information, please visit www.myocarditisfoundation.org.

About Rilonacept
Rilonacept is a weekly, subcutaneously-injected, recombinant fusion protein that blocks interleukin-1α (IL-1α) and interleukin 1β (IL-1β) signaling. Rilonacept was discovered and developed by Regeneron Pharmaceuticals, Inc. (Regeneron) and is approved by the FDA under the brand name ARCALYST® for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), which includes Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome. IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking ARCALYST. ARCALYST should be discontinued if a patient develops a serious infection. Taking ARCALYST with TNF inhibitors is not recommended because this may increase the risk of serious infections. Kiniksa exclusively licensed rilonacept from Regeneron for recurrent pericarditis and certain other indications. Rilonacept in recurrent pericarditis is an investigational drug.

About RHAPSODY
RHAPSODY is the ongoing, double-blind, placebo controlled, RW designed, pivotal Phase 3 clinical trial in recurrent pericarditis utilizing rilonacept. Kiniksa expects that up to 50 subjects will be randomized into the RW period. Eligible subjects must present at screening with at least a third pericarditis episode, defined as at least 1 day with pericarditis pain of ≥ 4 on the 11-point NRS and a CRP value ≥ 1 mg/dL within the 7-day period prior to first study drug administration. Subjects included in the study may be receiving concomitant NSAIDs and/or colchicine and/or oral corticosteroid treatment in any combination. The study is comprised of 5 periods: a screening period; a single-blind run-in period during which subjects receive a loading dose of rilonacept 320 mg injected SC followed by 160 mg SC weekly while background pericarditis medications are tapered and discontinued; a double-blind, placebo-controlled 24-week RW period during which clinical responders to rilonacept are randomized 1:1 and receive

160 mg SC weekly rilonacept or placebo for at least 24 weeks; a long-term extension treatment period after trial completion during which all subjects completing the RW period have the option to receive up to 24 weeks of open-label rilonacept 160 mg SC weekly; and a long-term extension follow-up period during which all subjects in the long-term extension period will be followed for 24 weeks for safety and pericarditis recurrences.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding: our execution, pre-commercial activities and investment focus, and potential results therefrom; expected timeframe for funding our operating plan with current cash, cash equivalents and short-term investments; plans and timing for completion of clinical trials; proposed indications for the investigation of our product candidates; our development of rilonacept as potential treatment for recurrent pericarditis; estimated disease prevalence; and plans and timing to report or present top-line clinical trial.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: potential delays or difficulty in enrollment of patients in, and activation of sites for, our clinical trials; potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across a number of jurisdictions for our global clinical trials; potential delays or difficulty in completing our clinical trials; potential undesirable side effects caused by our product candidates; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential for changes between final data and any interim “top-line” and preliminary data we announce; impact of additional data from us or other companies; our potential inability to replicate in later clinical trials positive results from our earlier clinical trials; our reliance on certain third parties as the sole source of supply of the drug substance and drug products used in our product candidates; our reliance on third parties to conduct our research, pre-clinical studies, clinical trials, and other trials for our product candidates; and we face substantial competition.

These and other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on May 7, 2019 and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Every Second Counts!™

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[2] Launbjerg J, Fruergaard P, Hesse B, Jorgensen F, Elsborg L, Petri A. Long-term risk of death, cardiac events and recurrent chest pain in patients with acute chest pain of different origin. *Cardiology.* 1996;87(1):60-66.

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