Kiniksa Pharmaceuticals Logo

Kiniksa to Present Data on the Burden of Disease in Patients with Recurrent Pericarditis at the International Society for Pharmacoeconomics and Outcomes Research

May 16, 2019

HAMILTON, Bermuda, May 16, 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, will present data from a systematic literature review highlighting the burden of illness and unmet medical needs associated with recurrent pericarditis at the International Society for the Pharmacoeconomic and Outcomes Research (ISPOR) in New Orleans, LA.

"Recurrent pericarditis is a debilitating disease for patients who suffer from frequent flares," said Raj Kannan, Chief Commercial Officer at Kiniksa. "Our research suggests that the disorder remains underserved despite the significant impact it has on patients' lives. At Kiniksa, we are working with patients and health care practitioners to further characterize the impact of recurrent pericarditis in order to improve patient outcomes."

Details of the presentation are as follows:

Unmet Needs and Burden of Recurrent Pericarditis: Results of a Systematic Literature Review

- Poster Presentation: Poster Session III, Cardiovascular Disorders (#PCV9) on Tuesday, May 21st, 2019 from 10:30 a.m. to 2:00 p.m. Central Time at the New Orleans Ernest N. Morial Convention Center
- Lead Author: Matt Magestro, Kiniksa Pharmaceuticals Corp., Lexington, Massachusetts, USA

Kiniksa intends to make the materials available through the Investors and Media section of its website (www.kiniksa.com).

Recurrent pericarditis is a painful autoinflammatory cardiovascular disease that is associated with rare but serious complications like constrictive pericarditis and cardiac tamponade. Claims analysis, cross validated with published research estimates, supports a prevalent population of approximately 40,000 patients in the U.S. seeking and receiving medical treatment. Kiniksa is not aware of any U.S. Food and Drug Administration (FDA)-approved therapies for the treatment of recurrent pericarditis.

"There are many unmet needs for patients with autoinflammatory diseases, and for patients with recurrent pericarditis," said Karen Durrant, President of the Autoinflammatory Alliance. "This research is an important step to better understand the burden of recurrent pericarditis in this underserved patient population."

Kiniksa is developing rilonacept, a weekly, subcutaneously-injected, recombinant fusion protein that blocks interleukin-1α (IL-1α) and interleukin-1β (IL-1β) signaling, for the potential treatment of recurrent pericarditis. Clinical data have demonstrated IL-1α and IL-1β play a key role in inflammatory diseases.

Kiniksa is enrolling RHAPSODY, a global, randomized withdrawal (RW) design, pivotal Phase 3 clinical trial. The trial is designed to evaluate the efficacy and safety of rilonacept treatment in subjects with recurrent pericarditis. The primary efficacy endpoint is time-to-first-adjudicated pericarditis-recurrence in the RW period. Secondary endpoints include changes in pain, inflammatory markers, health-related quality of life, and sleep quality. Top-line data are expected in the second half of 2020.

About RHAPSODY
RHAPSODY is the ongoing, double-blind, placebo-controlled, pivotal Phase 3 clinical trial in recurrent pericarditis utilizing rilonacept. 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 subcutaneously (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. 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 pain Numerical Rating Scale (NRS) and a c-reactive protein (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 nonsteroidal anti-inflammatory drugs (NSAIDs) and/or colchicine and/or oral corticosteroid treatment in any combination.

About Rilonacept
Rilonacept is a weekly, subcutaneously-injected, recombinant fusion protein that blocks IL-1α and IL-1β signaling. Rilonacept was discovered and developed by Regeneron and is approved by the FDA under the brand name ARCALYST® for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including 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 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.

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: the potential relevance of data presented at ISPOR from a systemic literature review and data from our other research with respect to recurrent pericarditis, including its burden, prevalence and unmet medical need; statements regarding the size and objectives of the design of our Phase 3 clinical trial for rilonacept; and timing of potential data from the Phase 3 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: changes between data presented at ISPOR or otherwise and any additional data or research disclosed by us or others with respect to recurrent pericarditis, including its burden, prevalence and unmet medical need; our potential inability to replicate in later clinical trials, including our Phase 3 clinical trial, the positive interim data from our Phase 2 and earlier clinical trials; delays or difficulty in activating sites or enrolling subjects in our global Phase 3 clinical trial; potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across a number of jurisdictions for our global Phase 3 clinical trial; impact of additional data from us or other companies; potential undesirable side effects caused by rilonacept; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; our reliance on Regeneron to manufacture rilonacept; drug substance and/or drug product shortages; and our reliance on third parties to conduct research, clinical trials, and/or certain regulatory activities for rilonacept.

These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the period ended March 31, 2019 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!™

Kiniksa Investor and Media Contact
Mark Ragosa
(781) 430-8289
mragosa@kiniksa.com

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