Kiniksa Pharmaceuticals Logo

Kiniksa Announces Breakthrough Therapy Designation for Rilonacept for the Treatment of Recurrent Pericarditis

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HAMILTON, Bermuda, Nov. 20, 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 that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for rilonacept for the treatment of recurrent pericarditis. Rilonacept is a weekly, subcutaneously-injected, recombinant fusion protein that blocks IL-1α and IL-1β signaling.

Kiniksa's Breakthrough Therapy application was based on final data from an open-label Phase 2 clinical trial of rilonacept in a range of pericarditis populations that were included in a poster presentation at the American Heart Association (AHA) Scientific Sessions on November 16, 2019. The materials for the presentation are available through the Science section of Kiniksa's website (www.kiniksa.com).

"We are pleased that the FDA has granted Breakthrough Therapy designation for rilonacept for the treatment of recurrent pericarditis, a painful and debilitating autoinflammatory cardiovascular disease," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "The final Phase 2 data presented at AHA showed rilonacept treatment improved clinically meaningful outcomes associated with unmet need in recurrent pericarditis, including rapid resolution of pericarditis episodes, tapering and discontinuation of corticosteroids without pericarditis recurrence, reduction in recurrences of pericarditis episodes while on treatment, and improvement in quality of life scores. We continue to enroll RHAPSODY, our pivotal Phase 3 clinical trial of rilonacept in recurrent pericarditis, and expect top-line data in the second half of 2020."

Kiniksa is enrolling RHAPSODY, a global, randomized withdrawal (RW) design, pivotal Phase 3 clinical trial of rilonacept in patients with recurrent pericarditis in the U.S., Australia, Israel, and Italy. The primary efficacy endpoint is time-to-first pericarditis-recurrence in the RW period. The Clinical Endpoint Committee will adjudicate all suspected pericarditis recurrences for inclusion in the primary efficacy endpoint analysis. Top-line data are expected in the second half of 2020.

About Breakthrough Therapy Designation
The FDA defines Breakthrough Therapy designation as a process designed to expedite the development and review of drug candidates that are intended to treat a serious condition, and preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over available therapies on a clinically significant endpoint.

About RHAPSODY
RHAPSODY is the ongoing, pivotal Phase 3 clinical trial in recurrent pericarditis utilizing rilonacept. The company expects that at least 50 patients will be randomized into the RW period. Eligible patients 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 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. Patients included in the study may be receiving concomitant nonsteroidal anti-inflammatory drugs (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 patients 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 patients 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 patients in the long-term extension period will be followed for 24 weeks for safety and pericarditis recurrences. The co-principal investigators are Dr. Allan Klein of Cleveland Clinic and Dr. Massimo Imazio of the University of Torino, Italy.

About Rilonacept
Rilonacept is a weekly, subcutaneously-injected, recombinant fusion protein that blocks inflammatory cytokines 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 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 final data from our Phase 2 clinical trial in recurrent pericarditis; statements regarding the expected number of patients randomized in the RW period and objectives of the design of our Phase 3 clinical trial for rilonacept; and timing of potential data from the Phase 3 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: not being eligible for expedited development and review of rilonacept regardless of the FDA having granted Breakthrough Therapy designation for rilonacept for the treatment of recurrent pericarditis; changes between final data from our Phase 2 clinical trial and any additional data or research disclosed by us or others with respect to recurrent pericarditis; our potential inability to replicate in later clinical trials, including our Phase 3 clinical trial, the positive final data from our Phase 2 and earlier clinical trials and other studies; delays or difficulty in activating sites or enrolling patients in our global Phase 3 clinical trial; patients failing to complete the clinical trial; patients failing to experience pre-specified events during the clinical trial within an expected time-frame, if at all; 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 filed with the Securities and Exchange Commission (“SEC”) on November 5, 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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