Kiniksa Announces Breakthrough Therapy Designation Granted to Vixarelimab for the Treatment of Pruritus Associated with Prurigo Nodularis

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HAMILTON, Bermuda, Nov. 16, 2020 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company with a pipeline of assets designed to modulate immunological pathways across a spectrum of diseases, today announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to vixarelimab for the treatment of pruritus associated with prurigo nodularis, a chronic inflammatory skin condition characterized by severely pruritic skin nodules. Vixarelimab is a fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ).

Kiniksa's Breakthrough Therapy application was based on data from the Phase 2a clinical trial of vixarelimab in prurigo nodularis. The Phase 2a trial met its primary efficacy endpoint: there was a statistically significant reduction in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) from baseline at Week 8 in vixarelimab recipients compared to placebo recipients. Additionally, the majority of vixarelimab recipients showed a clinically meaningful greater-than-or-equal-to 4-point weekly-average WI-NRS reduction at Week 8, and a statistically significant percentage of vixarelimab recipients achieved a prurigo nodularis-investigator's global assessment (PN-IGA) score of 0/1 at Week 8 compared to placebo recipients.

"The FDA granting Breakthrough Therapy designation to vixarelimab for the treatment of pruritus associated with prurigo nodularis is an important step forward for patients," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "The Phase 2a study of vixarelimab in prurigo nodularis demonstrated encouraging results in both pruritus and nodule response. We believe vixarelimab has the potential to positively impact the lives of those suffering from prurigo nodularis, a devastating disease for which there are no FDA-approved therapies."

Kiniksa expects to initiate a Phase 2b clinical trial of vixarelimab in prurigo nodularis, evaluating a range of once-monthly dose regimens, by the end of the year.

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 Vixarelimab Phase 2a Trial in Prurigo Nodularis
The Phase 2a trial was a randomized, double-blind, placebo-controlled study designed to investigate the efficacy, safety, tolerability, and pharmacokinetics of vixarelimab in reducing pruritus in subjects with prurigo nodularis. The trial enrolled patients with moderate-to-severe prurigo nodularis experiencing moderate-to-severe pruritus (WI-NRS ≥ 7 at the screening visit and a mean weekly WI-NRS of ≥ 5 for each of the two consecutive weeks immediately prior to randomization). Patients were required to stop antihistamines and topical treatments, including corticosteroids, for at least two weeks prior to dosing. Prurigo nodularis treatments, other than study drug, were not allowed except for rescue. For more information, refer to ClinicalTrials.gov Identifier: NCT03816891.

About Vixarelimab
Vixarelimab is an investigational fully-human monoclonal antibody that targets OSMRβ, which mediates signaling of interleukin-31 (IL-31) and oncostatin M (OSM), two key cytokines implicated in pruritus, inflammation and fibrosis. Kiniksa believes vixarelimab to be the only monoclonal antibody in development that targets both pathways simultaneously. Kiniksa's lead indication for vixarelimab is prurigo nodularis, a chronic inflammatory skin condition characterized by severely pruritic skin nodules. The FDA granted Breakthrough Therapy designation to vixarelimab for the treatment of pruritus associated with prurigo nodularis in 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's product candidates, rilonacept, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions and offer the potential for differentiation. These pipeline assets are designed to modulate immunological pathways across a spectrum of diseases. 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: our beliefs about research, pre-clinical and clinical trial data demonstrating encouraging results; our beliefs about the potential to positively impact the lives of patients with prurigo nodularis and the importance for such patients of vixarelimab having been granted Breakthrough Therapy designation for the treatment of prurigo nodularis; planned clinical trials and timing thereof, including a potential dose-ranging Phase 2b clinical trial of vixarelimab in prurigo nodularis; and our beliefs about the mechanisms of action of our product candidates and potential impact of their approach.

These forward-looking statements are based on management's current plans, estimates or 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: delays or difficulty in enrollment of patients in, and activation or continuation 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 amendments to our clinical trial protocols initiated by us or required by regulatory authorities; delays or difficulty in completing our clinical trials, including as a result of the COVID-19 pandemic; potential for low accrual of events in 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 or otherwise producing negative, inconclusive or commercially uncompetitive results; potential for applicable regulatory authorities to not accept our BLA or sBLA filings or to delay or deny approval of any of our product candidates or to require additional trials to support any such approval; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials conducted by us or third parties, including from investigator initiated studies; impact of additional data from us or other companies; potential inability to replicate in later clinical trials positive results from earlier pre-clinical and clinical trials or studies of our product candidates potential in subsequent clinical trials conducted by us or third parties, including investigator-initiated studies; drug substance and/or drug product shortages; our reliance on 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; substantial existing or new competition; impact of the COVID-19 pandemic, and measures taken in response to the pandemic, on our business and operations as well as the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities; changes in our operating plan and funding requirements; and our ability to attract and retain qualified personnel.

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, 2020 and our other reports subsequently 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 plans, estimates, or expectations 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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