Kiniksa Pharmaceuticals Logo

Kiniksa Presents Preclinical Data Supporting KPL-716 Clinical Development at the 49th Annual Meeting of the European Society of Dermatological Research

September 19, 2019

Data reinforce the scientific evidence supporting the potential treatment of chronic pruritic diseases through OSMRβ inhibition

HAMILTON, Bermuda, Sept. 19, 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 it presented preclinical data supporting the clinical development of KPL-716, an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ). The data were included in a poster presentation at the 49th annual meeting of the European Society of Dermatological Research (ESDR) in Bordeaux, France.

"The preclinical data presented at ESDR, combined with the findings from our longitudinal observational study in prurigo nodularis, affirm the strategy of exploring OSMRβ inhibition for the potential treatment of chronic pruritic diseases," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "Accordingly, the data support the ongoing Phase 2 development of KPL-716 in prurigo nodularis and select chronic pruritic conditions. We look forward to clinical readouts from these trials starting in the first half of 2020."

Kiniksa delivered a poster presentation entitled ***Increased Expression of OSMRβ in Chronic Pruritic Diseases.***

- Increased messenger ribonucleic acid (mRNA) transcript levels and protein levels of OSMRβ, a signaling subunit of the interleukin-31 (IL-31) receptor and oncostatin M (OSM) Type 2 receptors, in formalin-fixed paraffin-embedded biopsies from patients with chronic idiopathic urticaria, chronic idiopathic pruritus, lichen planus and lichen simplex chronicus, relative to healthy control skin samples, suggest the IL-31/OSM signaling axis is associated with these pruritic diseases.
- Elevated levels of OSMRβ mRNA and protein observed in regions of inflammatory infiltrate of all chronic pruritic diseases tested, relative to healthy controls, suggest that the OSMRβ axis may be active in, and contributing to, these skin disorders. Particularly, OSM and IL-31 mRNA and protein are present in each disease evaluated for these cytokines.

KPL-716 is currently being evaluated for the reduction of itch in two Phase 2 clinical trials.

Kiniksa is enrolling a Phase 2a clinical trial of KPL-716 in subjects with prurigo nodularis. The primary efficacy endpoint is percent change from baseline in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) at Week 8. Top-line data are expected in the first half of 2020.

Kiniksa is also enrolling an exploratory Phase 2 clinical trial in diseases characterized by chronic pruritus. The trial is designed to identify chronic pruritic conditions where signaling of OSMRβ may be playing a role and to investigate the efficacy, safety and tolerability of KPL-716 in reducing the moderate-to-severe pruritus experienced by these subjects. Kiniksa expects to provide interim data from this study on a cohort-by-cohort basis throughout 2020.

The materials are available through the Investors and Media section of Kiniksa's website (www.kiniksa.com).

About KPL-716
KPL-716 is an investigational fully-human monoclonal antibody that targets OSMRβ, which mediates signaling of IL-31 and OSM, two key cytokines implicated in pruritus, inflammation and fibrosis. Kiniksa believes KPL-716 to be the only monoclonal antibody in development that targets both pathways simultaneously.

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: potential for treatment of chronic pruritic disease through OSMRβ inhibition with KPL-716; plans and timing to report or present interim or final top-line clinical, pre-clinical and other data; proposed indications for the investigation of our product candidates; and our conclusions from interim or final top-line clinical, pre-clinical and other data for KPL-716.

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: potential delays or difficulty in enrollment of patients in, and activation of sites for, our KPL-716 clinical trials; potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across jurisdictions for our KPL-716 clinical trials; potential amendments to our KPL-716 clinical trial protocols initiated by us or required by regulatory authorities; changes between final data and any preliminary or interim data we present; our potential inability to replicate in later clinical trials, including our Phase 2a clinical trial and exploratory Phase 2 clinical trial of KPL-716, the positive preliminary, interim or final data from our pre-clinical and earlier clinical trials; potential impact

of additional data from us or other companies; potential undesirable side effects caused by KPL-716; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; and our reliance on third parties to manufacture KPL-716 and to conduct research, clinical trials and/or certain regulatory activities for KPL-716.

These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the period ended June 30, 2019, filed with the Securities and Exchange Commission (“SEC”) on August 13, 2019 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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