Kiniksa Announces Interim Data from KPL-716 Repeated-Single-Dose Phase 1b Clinical Trial

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- Rapid and sustained anti-pruritic effect shown throughout the 12-week treatment period -
- No meaningful difference from placebo on other efficacy endpoints specific to atopic dermatitis -
- Data support focused development of KPL-716 in prurigo nodularis and diseases characterized by chronic pruritus -

HAMILTON, Bermuda, Aug. 12, 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 interim repeated-single-dose Phase 1b clinical data for KPL-716, an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ). In this clinical trial, weekly subcutaneous (SC) doses of KPL-716 resulted in a rapid and sustained reduction in pruritus throughout the 12-week treatment period but also a higher rate of atopic dermatitis flares. The results support Kiniksa's ongoing development of KPL-716 in a Phase 2a clinical trial for prurigo nodularis and an exploratory Phase 2 clinical trial in diseases characterized by chronic pruritus.

"Data from the repeated-single-dose Phase 1b study of KPL-716 showed a rapid reduction in pruritus," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "Our focus for KPL-716 continues to be on prurigo nodularis as well as select chronic pruritic conditions, and we have no current plans to invest in atopic dermatitis. Considering the anti-pruritic effect in this repeated-single-dose study, we are pursuing an earlier readout from our Phase 2a prurigo nodularis clinical trial."

The repeated-single-dose Phase 1b clinical trial used a weekly 360 mg SC dose in a randomized, double-blind, placebo-controlled design in order to evaluate safety and exploratory disease response markers. The 360 mg SC dose was intended to replicate and extend exposures from the prior single-ascending-dose Phase 1b clinical trial where an early signal of efficacy was observed in reducing pruritus after a single 7.5 mg/kg intravenous dose.

In the repeated-single-dose Phase 1b clinical trial, 43 subjects with moderate-to-severe atopic dermatitis were enrolled and randomized 1:1 to KPL-716 or placebo once weekly for 12 weeks. There was a seven-day wash out period of all other therapies before treatment, and topical corticosteroids were not allowed throughout the 12-week treatment period. However, rescue medication was available for atopic dermatitis flares throughout the study.

In an interim analysis of the data through the 12-week treatment period, KPL-716 showed a rapid and sustained reduction in Worst-Itch Numeric Rating Scale (WI-NRS) in subjects with moderate-to-severe atopic dermatitis:

- Mean change from baseline in weekly-average WI-NRS at Week 1 was -28.1% in KPL-716 recipients compared to -6.8% in placebo recipients.
- Mean change from baseline in weekly-average WI-NRS at Week 12 was -55.0% in KPL-716 recipients compared to -30.9% in placebo recipients.
- 52.6% of KPL-716 recipients demonstrated a ≥ 4-point reduction in weekly-average WI-NRS at Week 12 compared to 26.3% of placebo recipients.

There was no meaningful benefit of repeated-single-doses of KPL-716 on other efficacy endpoints specific to atopic dermatitis, including Eczema Area and Severity Index (EASI) and Scoring Atopic Dermatitis (SCORAD).

There were no serious adverse events. However, there were more atopic dermatitis flares in the KPL-716-treated population versus placebo (47.6% versus 4.5%) through the 12-week treatment period; all subjects who experienced a flare were successfully managed with topical corticosteroids. KPL-716 was otherwise well-tolerated by all subjects.

"We believe the data from the repeated-single-dose Phase 1b study show that KPL-716 has the potential to treat a spectrum of pruritic diseases which involve signaling through OSMRβ," said John F. Paolini, MD, PhD, Chief Medical Officer of Kiniksa. "The pharmacokinetic data are consistent with our prior modeling and support the testing of lower and less frequent dosing."

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 WI-NRS. Top-line data are expected in the first half of 2020.

Kiniksa is 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.

About KPL-716

KPL-716 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 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: plans and timing to advance our product candidates; plans and timing to report or present interim, final and top-line clinical trial, pre-clinical and other data; proposed indications for the investigation of our product candidates; and our conclusions from interim pre-clinical and clinical trial 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 or interim 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 March 31, 2019, filed with the Securities and Exchange Commission ("SEC") on May 7, 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.

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