Kiniksa Pharmaceuticals Logo

Kiniksa Presents KPL-716 Clinical Data at the 27th European Academy of Dermatology and Venereology

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- Single-doses were well-tolerated and showed reduction in pruritus -

- Data support plans for advancement into multiple chronic pruritic diseases, including prurigo nodularis -

HAMILTON, BERMUDA, Sept. 15, 2018 (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 presented Phase 1a/1b clinical data for KPL-716, an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ), at the 27thEuropean Academy of Dermatology and Venereology (EADV) Congress. In this First-in-Human clinical trial, single intravenous (IV) and subcutaneous (SC) doses of KPL-716 were well-tolerated in both adult healthy volunteers and adult subjects with moderate-to-severe atopic dermatitis experiencing moderate-to-severe pruritus. KPL-716 also demonstrated a reduction in pruritus. The results support Kiniksa's plans for expanding clinical development into multiple chronic pruritic diseases, including prurigo nodularis.

Dr. Zamaneh Mikhak, Senior Director, Clinical Research and Development at Kiniksa, delivered an oral presentation entitled "First-In-Human Study of KPL-716, Anti-Oncostatin M Receptor Beta Monoclonal Antibody, in Healthy Volunteers and Subjects with Atopic Dermatitis" during the Late-Breaking News Session. The materials are available through the Investors and Media section of Kiniksa's website (www.kiniksa.com).

"Data from the single-dose cohorts of the placebo-controlled Phase 1a/1b of KPL-716 achieved the goals established for the study," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "The results provided us with data on the safety and tolerability of KPL-716 as well as the anti-pruritic effect of the drug. We believe KPL-716 has the potential to be an effective treatment option for patients with pruritic diseases where there is unmet medical need."

The Phase 1a/1b clinical trial utilized a double-blind, randomized, placebo-controlled, single-ascending-dose, sequential-group design to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of KPL-716 in healthy volunteers and subjects with atopic dermatitis following IV or SC administration. Atopic dermatitis served as a proxy for IL-31-driven pruritic diseases, including prurigo nodularis.

In total, 50 healthy volunteers and 32 subjects with moderate-to-severe atopic dermatitis experiencing moderate-to-severe pruritus received a single dose of KPL-716 or placebo in the Phase 1a/1b clinical trial, with the top dose of 20 mg/kg IV in healthy volunteers and 7.5 mg/kg IV in subjects with atopic dermatitis. There was a seven-day wash out period of prior therapies for all subjects with atopic dermatitis before treatment, and topical corticosteroids (TCS) were not allowed through Day 28. All subjects were given TCS to use as needed after Day 28 and rescue medication was provided for atopic dermatitis flares throughout the study.

KPL-716 was well-tolerated by all subjects, no dose-limiting toxicities were observed, and there were no serious adverse events.

KPL-716 showed dose-dependent elimination consistent with a target mediated drug disposition profile and was still detectable at least eight weeks after the high dose of 7.5 mg/kg IV in subjects with atopic dermatitis. The available pharmacokinetic and bioavailability data are supportive of SC dosing regimens to be tested in subsequent studies of a single injection once every other week or once monthly.

A single dose of KPL-716 7.5 mg/kg IV in subjects with moderate-to-severe atopic dermatitis (n=10) versus pooled placebo IV recipients (n=10) provided evidence of target engagement and an early signal of efficacy for KPL-716 in reducing pruritus:

- Mean percentage change in weekly-average Worst-Itch Numeric Rating Scale (WI-NRS) decreased by 40.4% in KPL-716 recipients compared to a 17.6% decrease in placebo recipients at Day 28 in the absence of concomitant TCS.
- Mean percentage change in Pruritus Visual Analog Scale (VAS) decreased by 55.4% in KPL-716 recipients compared to a 10.4% decrease in placebo recipients at Day 28 in the absence of concomitant TCS.
- 50% of KPL-716 recipients demonstrated a ≥ 4-point reduction in weekly-average WI-NRS, compared to 10% of placebo recipients at Day 28 in the absence of concomitant TCS.
- The maximum decrease in WI-NRS at Day 28 in the absence of concomitant TCS was ≥ 8-points in KPL-716 recipients compared to a maximum decrease of 4 points in placebo recipients.
- KPL-716 appeared to demonstrate a persistent effect on weekly-average WI-NRS in the period after Day 28 through Day 56, during which concomitant TCS use was permitted.
- Concordant with the effect on pruritus, KPL-716 recipients reported improved sleep, as evidenced by a 59.5% decrease in sleep-loss VAS compared to a 2.3% decrease in placebo recipients at Day 28 in the absence of concomitant TCS.
- The mean percentage change in Eczema Area and Severity Index (EASI; a standardized measure of atopic dermatitis disease severity) decreased by 42.3% in KPL-716 recipients compared to a 25% decrease in placebo recipients at Day 28 in absence of concomitant TCS.

"The KPL-716 Phase 1a/1b results met a high hurdle for success, as the placebo-controlled, single-dose safety and pharmacokinetics study also demonstrated reduction in pruritus," said John F. Paolini, MD, PhD, Chief Medical Officer of Kiniksa. "We are now considering advancement of KPL-716 into multiple chronic pruritic diseases, including prurigo nodularis. Additionally, the observed reduction in EASI scores after only a single dose of KPL-716 is encouraging. Our ongoing repeat-single-dose trial in atopic dermatitis subjects will provide longer-term exposures and data on these inflammatory disease response markers."

About KPL-716

KPL-716 is an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMRβ), which mediates signaling of 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, currently focused on autoinflammatory and autoimmune conditions. For more information, please visit www.kiniksa.com.

Forward-Looking Statements

The information contained in 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 objectives of the design of our Phase 1a/1b clinical trial for KPL-716; our conclusions from the Phase 1a/1b clinical trial data; advancement of KPL-716 into multiple chronic pruritic diseases; planning and initiation of new clinical trials; and indications for investigation of our KPL-716 product candidate.

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: potential for changes between final data and any interim “top-line” and preliminary data we announce; impact of additional data from us or other companies ; our potential inability to replicate in later clinical trials positive results from our Phase 1a/1b clinical trial; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential delays or difficulty in enrollment of patients; potential undesirable side effects caused by our KPL-716 product candidate; our reliance on third parties to manufacture our KPL-716 product candidate; product shortages caused by issues at our third-party manufacturers’ facilities; our reliance on third parties as the sole source of supply of the active ingredient, drug product and drug substance used in our KPL-716 product candidate; and our reliance on third parties to conduct our research, clinical trials, and other trials for our KPL-716 product candidate.

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 August 7, 2018 and our other reports subsequently filed with or furnished to 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.

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