



Kiniksa Presents Clinical and Preclinical Data for KPL-716 at the 77th Annual Meeting of the Society for Investigative Dermatology

May 13, 2019

- Data strengthen the scientific evidence for targeting OSMR β and dual pathway inhibition of IL-31 and OSM via KPL-716 for the potential treatment of chronic pruritic diseases

HAMILTON, Bermuda, May 13, 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 clinical and preclinical data for KPL-716, an investigational fully-human monoclonal antibody that targets oncostatin M receptor beta (OSMR β), the shared receptor subunit for interleukin-31 (IL-31) and oncostatin M (OSM) signaling. The data were included in oral and poster presentations at the 77th Annual Meeting of the Society for Investigative Dermatology in Chicago, IL.

"We are pleased to grow the body of scientific data on the role of IL-31 and OSM in chronic pruritic conditions," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We believe that by simultaneously inhibiting these two key cytokine pathways through targeting a single epitope, OSMR β , KPL-716 may be a differentiated mechanism for the potential treatment of a spectrum of chronic pruritic diseases. We have initiated a global Phase 2a clinical trial of KPL-716 in subjects with prurigo nodularis and plan to initiate an exploratory Phase 2 clinical trial in diseases characterized by chronic pruritus in the first half of 2019."

The data presentations were as follows:

Dr. Zamaneh Mikhak, of Kiniksa Pharmaceuticals Corp., delivered an oral presentation entitled ***KPL-716, Anti-OSMR β Antibody, Reduced Pruritus in Atopic Dermatitis.***

- Data from the adjunctive therapy period (Day 29 to Day 60; topical corticosteroids allowed) of Kiniksa's Phase 1a/1b clinical trial of single-dose KPL-716 7.5 mg/kg intravenous (IV) in subjects with moderate-to-severe atopic dermatitis experiencing moderate-to-severe pruritus versus placebo IV showed a sustained anti-pruritic effect of OSMR β inhibition through at least week 6. The data reinforce and extend the previously-reported findings from the Phase 1a/1b monotherapy period (Day -7 to Day 28; topical corticosteroids not allowed), which provided evidence of target engagement and an early signal of efficacy in reducing pruritus and disease severity.

Dr. John F. Paolini, of Kiniksa Pharmaceuticals Corp., delivered a poster presentation entitled ***The OSMR β Axis Identified in Prurigo Nodularis.***

- Data from Kiniksa's longitudinal observational study in prurigo nodularis (LOTUS-PN) suggest that the OSMR β axis (IL-31, OSM, IL-31 receptor alpha (IL-31R α) and OSMR β) may play a role in the pathogenesis of prurigo nodularis given its prevalent expression in lesional prurigo nodularis. IL-31 messenger ribonucleic acid (mRNA) was expressed in approximately two-thirds of lesional biopsies from prurigo nodularis patients with Worst-Itch Numeric Rating Scale (WI-NRS) ≥ 7 compared to one-tenth in healthy volunteers. Additionally, lesional biopsies from prurigo nodularis patients contained mononuclear cells expressing OSM, OSMR β , IL-31 and IL-31R α protein compared with non-lesional biopsies.

Dr. Carl D. Richards, of McMaster Immunology Research Centre, delivered an e-poster presentation entitled ***OSM Induction of Monocyte Chemoattractant Protein 1 (MCP-1) in Human Epidermal Keratinocytes is Inhibited by Anti-OSMR β Monoclonal Antibody KPL-716.***

- OSM is involved in Type 2 T helper (T_H2) inflammation, epidermal integrity and fibrosis. Data highlight the therapeutic potential of KPL-716, through the inhibition of OSM activity, in T_H2 mediated diseases discrete from inhibition of IL-31. Further, the data show induction of MCP-1 and mRNA by OSM in both cell types tested and significant attenuation by KPL-716 of the cellular MCP-1 response to OSM and the synergistic response to OSM and interleukin-4 (IL-4). Importantly, these data showed that OSM synergizes with IL-4 and interleukin-13 (IL-13), and that leukemia inhibitory factor (LIF) and IL-31 do not.

Dr. Rohan Gandhi, of Kiniksa Pharmaceuticals Corp., delivered a poster presentation entitled ***KPL-716, an OSMR β Monoclonal Antibody, Reduces IL-31-Induced Scratching Behavior in Cynomolgus Monkeys: Establishment and Optimization of Pharmacokinetic/Pharmacodynamic Model.***

- KPL-716 data from a preclinical model exhibited dose- and time-dependent anti-pruritic effects. Pharmacokinetic (PK) and Pharmacodynamic (PD) correlation established an efficacious concentration range of 5 – 8.5 $\mu\text{g/ml}$ in cynomolgus monkeys, at or above which KPL-716 provided protection from pruritus induced by supra-physiologic challenges of IL-31.

The results with single dose KPL-716 IV were corroborated with repeat-dosed KPL-716 subcutaneous in various dosing regimens and were predictive of the reduction in pruritus observed in the Phase 1a/1b clinical trial of single-dose KPL-716 7.5 mg/kg IV in subjects with moderate-to-severe atopic dermatitis experiencing moderate-to-severe pruritis.

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 OSMR β , 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: our belief of the potential for KPL-716 to be a differentiated mechanism for the potential treatment of a spectrum of chronic pruritic diseases; our plans and timing to commence an exploratory Phase 2 clinical trial of KPL-716; and our conclusions from interim pre-clinical and clinical trial data for KPL-716.

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: changes between final data and any interim data we present; our potential inability to replicate in later clinical trials, including our Phase 2a clinical trial and planned exploratory Phase 2 clinical trial of KPL-716, the positive 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 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!*TM**

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