Kiniksa Announces Active U.S. Investigational New Drug Application for Mavrilimumab

January 3, 2019

- Enrollment and dosing of patients with giant cell arteritis commenced in global Phase 2 study

HAMILTON, Bermuda, Jan. 03, 2019 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company with a pipeline of five product candidates across various stages of development, today announced an active investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for a clinical study of mavrilimumab in subjects with giant cell arteritis (GCA). U.S. subjects will be included in the ongoing, global Phase 2 clinical trial, in which dosing has already commenced in multiple countries.

"The active IND for mavrilimumab in GCA and first patients dosed in this global Phase 2 trial are both important milestones for patients and Kiniksa," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "By targeting a key growth factor believed to be involved in the pathology of GCA, mavrilimumab has the potential to be a differentiated treatment for this debilitating disease. At the same time, advancing mavrilimumab into a global Phase 2 study highlights our continued pipeline execution and goal to build a generational company."

The global Phase 2 proof-of-concept clinical trial utilizes a double-blind, randomized, placebo-controlled design to evaluate the efficacy of mavrilimumab in subjects with GCA. The trial is expected to enroll approximately 60 subjects with new-onset and refractory disease. Subjects will be randomized 3:2 to mavrilimumab 150 mg or placebo injected subcutaneously once every 2 weeks co-administered with a corticosteroid taper. Treatment duration will be 26 weeks, and the primary efficacy endpoint is time to first flare.

About Mavrilimumab
Mavrilimumab is an investigational fully-human monoclonal antibody that is designed to antagonize GM-CSF signaling by binding to the alpha subunit of the GM-CSF receptor. Kiniksa's first planned indication for mavrilimumab is giant cell arteritis, an inflammatory disease of blood vessels.

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 five 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," "goal," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "design," 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: corporate goals and objectives; mavrilimumab's design to bind to the alpha subunit of the CM-CSF receptor and first planned indication in GCA; mavrilimumab's potential to be a differentiated treatment solution for GCA; and the global Phase 2 clinical trial design of mavrilimumab in GCA and expected enrollment.

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: our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across a number of jurisdictions for our global Phase 2 clinical trial; follow-up and/or additional information requests from regulatory authorities with respect to our clinical study of mavrilimumab; drug substance and/or drug product shortages; and our reliance on third parties to conduct our research, pre-clinical studies, clinical trials, manufacturing and certain regulatory activities.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended September 30, 2018 filed with the Securities and Exchange Commission ("SEC") on November 6, 2018 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.

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