Kiniksa Pharmaceuticals Logo

Kiniksa Provides Update on U.S. FDA Review of Investigational New Drug Application for Mavrilimumab in Giant Cell Arteritis

December 6, 2018

HAMILTON, Bermuda, Dec. 06, 2018 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company with a pipeline consisting of five product candidates across various stages of development, focused on autoinflammatory and autoimmune conditions, today announced that the U.S. Food and Drug Administration (FDA) requested additional information regarding the delivery device to be used in the company's Phase 2 clinical trial of mavrilimumab in giant cell arteritis. In light of its device-related information request, the FDA placed the company's recently-submitted investigational new drug application (IND) on clinical hold. The device-related information request does not pertain to preclinical toxicology data nor the design of the company's Phase 2 clinical trial. The delivery device is 510(k)-cleared, and the company is providing the requested information.

"Mavrilimumab has the potential to be a differentiated treatment option for giant cell arteritis as we believe it targets the cytokine responsible for the critical pathological steps of the disease," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We are engaged with the FDA to resolve the device-related information request and look forward to having an active IND and initiating in the U.S. as soon as possible."

About Mavrilimumab
Mavrilimumab is an investigational fully-human monoclonal antibody that antagonizes GM-CSF signaling by binding to the alpha subunit of the GM-CSF receptor. Kiniksa's lead 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 sequential pipeline consisting 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," "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: FDA additional device-related information request; actions to resolve the device-related information request and have an active IND; plans and timing for initiating our Phase 2 clinical trial in the U.S.; mavrilimumab's targeting of the cytokine responsible for the critical pathological steps of GCA; and mavrilimumab's potential to be a differentiated treatment option for GCA.

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: delays or difficulty in resolving the FDA's device-related information request; follow-up and/or additional information requests from the FDA with respect to our IND application; delays or difficulty in resolving the clinical hold; potential complications in coordinating among requirements, regulations and guidelines of regulatory authorities across a number of jurisdictions for our global Phase 2 clinical trial; our potential inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; drug substance and/or drug product shortages; 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.

Every Second Counts!™

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