Kiniksa Pharmaceuticals Commences Enrollment in Abiprubart Phase 2b Clinical Trial in Sjögren's Disease

July 9, 2024

– Abiprubart Phase 2b clinical trial in Sjögren's Disease to evaluate treatment response across biweekly and monthly subcutaneous administrations –

– Abiprubart clinical development in Sjögren's Disease fully funded; company expects to remain cash flow positive on an annual basis –

LONDON, July 09, 2024 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals International, plc (Nasdaq: KNSA) (Kiniksa), a commercial-stage biopharmaceutical company with a pipeline of immune-modulating assets designed to target a spectrum of cardiovascular and autoimmune diseases, today announced that it has commenced enrollment of the Phase 2b clinical trial of abiprubart in Sjögren's Disease. Abiprubart is an investigational humanized anti-CD40 monoclonal antibody designed to inhibit CD40-CD154 (CD40 ligand) interaction.

"Sjögren's Disease is a debilitating, chronic autoimmune disorder currently with no FDA-approved therapies. Commencing the next phase of development of abiprubart in Sjögren's Disease is an important step forward for patients," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "This Phase 2b clinical trial builds on external mechanistic proof-of-concept as well as learnings from our own prior clinical data. Additionally, we believe abiprubart has the potential for differentiation in addressing unmet need through convenient subcutaneous administration. Importantly, our current operating plan includes clinical development of abiprubart in Sjögren's Disease, and the company expects to remain cash flow positive on an annual basis."

Phase 2b Clinical Trial of Abiprubart in Sjögren's Disease
The randomized, double-blind, placebo-controlled Phase 2b clinical trial is designed to evaluate the treatment response of chronic subcutaneous (SC) administration of abiprubart in patients with Sjögren's Disease.

The placebo-controlled portion of the trial will randomize approximately 201 patients in a 1:1:1 ratio to receive abiprubart 400 mg SC biweekly, 400 mg SC monthly, or placebo over a period of 24 weeks. The primary endpoint is change from baseline in EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) versus placebo at Week 24. Subsequently, patients will enter a long-term extension in which active treatment will be given in all study arms for an additional 24 weeks.

About Kiniksa
Kiniksa is a commercial-stage biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's immune-modulating assets, ARCALYST ®, abiprubart, and mavrilimumab, are based on strong biologic rationale or validated mechanisms, target a spectrum of underserved cardiovascular and autoimmune conditions, and offer the potential for differentiation. For more information, please visit www.kiniksa.com.

About Abiprubart
Abiprubart is an investigational humanized monoclonal antibody that binds to CD40 and is designed to inhibit the CD40-CD154 (CD40 ligand) interaction, a key T-cell co-stimulatory signal critical for B-cell maturation and immunoglobulin class switching and Type 1 immune responses. Kiniksa believes disrupting the CD40-CD154 co-stimulatory interaction is an attractive approach to addressing multiple autoimmune disease pathologies.

Forward-Looking Statements
This press release contains forward-looking statements. 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 that abiprubart has the potential for differentiation in addressing unmet need through convenient subcutaneous administration; our expectation to remain cash flow positive on an annual basis; and our belief that all of our other product candidates offer the potential for differentiation.

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 enrollment of patients in, and activation or continuation of sites for, our clinical trials; delays or difficulty in completing our clinical trials as originally designed; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials; our inability to replicate results from our earlier clinical trials or studies; impact of additional data from us or other companies, including the potential for our data to produce negative, inconclusive or commercially uncompetitive results; potential undesirable side effects caused by our products and product candidates; our reliance on third parties to conduct research, clinical trials, and/or certain regulatory activities for our product candidates; complications in coordinating requirements, regulations and guidelines of regulatory authorities across jurisdictions for our clinical trials; and changes in our operating plan, business development strategy or funding requirements.

These and other important factors discussed in our filings with the U.S. Securities and Exchange Commission, including under the caption "Risk Factors" contained therein, 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. Except as required by law, we disclaim any intention or obligation to update or revise any forward-looking statements. 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! ®

Kiniksa Investor and Media Contact
Rachel Frank
(339) 970-9437
rfrank@kiniksa.com