Kiniksa Announces Issuance of U.S. Patent for Treatment of Recurrent Pericarditis

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HAMILTON, Bermuda, June 08, 2021 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) ("Kiniksa"), a biopharmaceutical company with a portfolio of assets designed to modulate immunological pathways across a spectrum of diseases, today announced that the U.S Patent and Trademark Office issued a patent covering methods of using ARCALYST® (rilonacept) in the treatment of recurrent pericarditis.

The patent issued as U.S. Patent No. 11,026,997 and will expire on March 11, 2039. Kiniksa has exclusive rights to this patent under the ARCALYST License Agreement.

"We believe this patent continues to strengthen our proprietary position on the FDA-approved use of ARCALYST in recurrent pericarditis and provides protection that extends approximately 11 years beyond orphan drug exclusivity and into 2039," said Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Kiniksa. "We continue to execute on our commercial strategy and look forward to providing our first full quarter ARCALYST sales in our second quarter earnings report."

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's portfolio of assets, ARCALYST, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions and offer the potential for differentiation. These assets are designed to modulate immunological pathways across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About Recurrent Pericarditis
Recurrent pericarditis is a painful and debilitating autoinflammatory cardiovascular disease that typically presents with chest pain and is often associated with changes in electrical conduction and sometimes buildup of fluid around the heart, called pericardial effusion. Patients who have additional pericarditis episodes following a symptom-free period of 4-6 weeks are identified as having recurrent pericarditis. Recurrent pericarditis symptoms have an impact on quality of life, limit physical activities, and lead to frequent emergency department visits and hospitalizations. Data show that approximately 40,000 patients in the U.S. seek and receive treatment for recurrent pericarditis each year. Of that group, approximately 14,000 patients experience a second or subsequent event (recurrence) due to persistent underlying disease or inadequate response to conventional therapies, such as nonsteroidal anti-inflammatory drugs (NSAIDs), colchicine and corticosteroids.

About ARCALYST
ARCALYST is a weekly, subcutaneously-injected recombinant dimeric fusion protein that blocks interleukin-1 alpha and interleukin-1 beta signaling. ARCALYST was discovered by Regeneron and is approved by the FDA for recurrent pericarditis, cryopyrin-associated periodic syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, and deficiency of IL-1 receptor antagonist (DIRA). The FDA granted Breakthrough Therapy designation to ARCALYST for the treatment of recurrent pericarditis in 2019 and Orphan Drug designation to ARCALYST for the treatment of pericarditis in 2020.

About the ARCALYST License Agreement with Regeneron
In 2017, Regeneron granted Kiniksa an exclusive license to develop and commercialize ARCALYST worldwide, excluding Israel, Egypt, Turkey and select countries in the Middle East and North Africa. In the United States and Japan, Kiniksa's license is for all indications other than those involving oncology and local administration to the eye or ear. Upon the approval of the supplemental Biologics License Application (sBLA) for ARCALYST in recurrent pericarditis, the scope of the license granted to Kiniksa expanded to include DIRA and CAPS in the United States and Japan, and Kiniksa assumed the responsibility for sales and distribution of ARCALYST in these additional indications in the United States. Outside the United States and Japan, Kiniksa's license is for all indications other than CAPS and certain periodic fever syndromes, DIRA, oncology, and local application to the eye or ear. Kiniksa and Regeneron will evenly split profits on sales of ARCALYST after deducting certain commercialization expenses, subject to specified limits.

Important information about ARCALYST Injection

- ARCALYST can affect your immune system and can lower the ability of your immune system to fight infections. Serious infections, including life-threatening infections and death have happened in patients taking ARCALYST. You should not begin ARCALYST if you have an infection or have infections that keep coming back. After starting ARCALYST, if you get an infection or show any sign of an infection, including a fever, cough, flu-like symptoms, or have any open sores on your body, call your doctor right away. Treatment with ARCALYST should be stopped if you get a serious infection.
- While taking ARCALYST, do not take other medicines that block interleukin-1, such as Kineret® (anakinra), or medicines that block tumor necrosis factor, such as Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab), as this may increase your risk of getting a serious infection.
- Before starting ARCALYST, tell your doctor if you think you have an infection, are being treated for an infection, have signs of an infection, have any open sores, have a history of infections that keep coming back, have asthma, have diabetes or

an immune system problem, have tuberculosis, or have been in contact with someone who has had tuberculosis, has or has had HIV, hepatitis B or hepatitis C, or takes other medicines that affect your immune system.

- Before you begin treatment with ARCALYST, talk with your healthcare provider about your vaccine history. Ask your healthcare provider whether you should receive any vaccines, including the pneumonia vaccine and flu vaccine, before you begin treatment with ARCALYST.
- ARCALYST can cause serious side effects:
  - Medicines that affect the immune system may increase the risk of getting cancer.
  - Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction (e.g., rash, swollen face, trouble breathing).
  - Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.
- Common side effects of ARCALYST include injection-site reactions, upper respiratory tract infections, joint and muscle aches, rash, ear infection, sore throat, and runny nose.
- Tell your doctor if you are scheduled to receive any vaccines, if you are pregnant or plan to become pregnant, and if you are breastfeeding or plan to breastfeed.
- Tell your doctor if you take other medicines that affect the immune system such as interleukin-1 blockers, tumor necrosis factor blockers, or corticosteroids.

For more information about ARCALYST, talk to your doctor and see the Product Information.

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,” “strategy,” 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 the newly issued patent continues to strengthen our proprietary position and that all of our 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: risks associated with maintaining our intellectual property portfolio, including changes to laws and regulations that may shorten the term that has been lengthened by patent term adjustment of our existing patents; our reliance on third parties as the sole source of supply of the drug substance and drug products used in our products and to manufacture our products; drug substance and/or drug product shortages; the impact of the COVID-19 pandemic and measures taken in response to the pandemic on our business and operations as well as the business and operations of our manufacturers and other third parties with whom we conduct business or otherwise engage; changes in our operating plan and funding requirements; and existing or new competition.

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 May 6, 2021 and our other reports subsequently 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.

ARCALYST is a registered trademark of Regeneron Pharmaceuticals, Inc. All other trademarks are the property of their respective owners.

Every Second Counts!™

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