Kiniksa Pharmaceuticals Reports Preliminary 2024 Net Product Revenue and Provides 2025 Net Product Revenue Guidance

January 13, 2025

– ARCALYST® (rilonacept) 2024 net product revenue of $416.4 million (unaudited), representing ~79% year-over-year growth –
– ARCALYST 2025 net product revenue expected to be $560 - $580 million –
– Kiniksa expects to remain cash flow positive on an annual basis –

LONDON, Jan. 13, 2025 (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 reported preliminary unaudited fourth quarter and full year 2024 ARCALYST net product revenue and provided 2025 ARCALYST net product revenue guidance.

"ARCALYST uptake in recurrent pericarditis continues to grow. As of the end of 2024, approximately 13% of the multiple-recurrence target population was actively on ARCALYST therapy, driving net product revenue to $416.4 million, representing 79% year-over-year growth. Importantly, there is still substantial opportunity ahead for Kiniksa to drive further ARCALYST revenue as we continue executing on our commercial strategy," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "We are also advancing our clinical portfolio as we work to bring new life-changing therapies to patients with unmet medical needs. Lastly, our robust financial profile provides the ability to pursue additional value-creating opportunities."

Commercial Execution
ARCALYST (IL-1α and IL-1β cytokine trap)

- ARCALYST net product revenue was $121.9 million and $416.4 million for the fourth quarter and full year 2024, respectively (unaudited).
- As of the end of the fourth quarter of 2024, approximately 13% of the target 14,000 multiple-recurrence patients were actively on ARCALYST treatment.
- Since launch, more than 2,850 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the fourth quarter of 2024, average total duration of ARCALYST therapy in recurrent pericarditis was approximately 27 months.
- Kiniksa expects 2025 ARCALYST net product revenue of between $560 million and $580 million.

Corporate Update

- As of December 31, 2024, Kiniksa had $243.6 million of cash, cash equivalents, and short-term investments (unaudited).
- Kiniksa expects to remain cash flow positive on an annual basis.

43rd Annual J.P. Morgan Healthcare Conference

- Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa, and Ross Moat, Chief Commercial Officer, will provide a corporate presentation at the 43rd Annual J.P. Morgan Healthcare Conference on January 13, 2025, at 1:30 p.m. Pacific Time (4:30 p.m. Eastern Time). A live webcast of Kiniksa's presentation will be accessible through the Investors & Media section of the company's website at www.kiniksa.com. A replay of the webcast will also be available on Kiniksa's website within approximately 48 hours after the event.

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 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 ARCALYST
ARCALYST is a weekly, subcutaneously injected recombinant dimeric fusion protein that blocks interleukin-1 alpha (IL-1α) and interleukin-1 beta (IL-1β) signaling. ARCALYST was discovered by Regeneron Pharmaceuticals, Inc. (Regeneron) and is approved by the U.S. Food and Drug Administration (FDA) for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older. ARCALYST is also approved by the FDA for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older, and the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more. The FDA granted Orphan Drug Exclusivity to ARCALYST upon its approval for recurrent pericarditis in 2021. The European Commission granted Orphan Drug Designation to

ARCALYST for the treatment of idiopathic pericarditis in 2021.

IMPORTANT SAFETY INFORMATION ABOUT ARCALYST

- ARCALYST may 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. If you have any signs of an infection, call your doctor right away. Treatment with ARCALYST should be stopped if you get a serious infection. You should not begin treatment with ARCALYST if you have an infection or have infections that keep coming back (chronic 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.
- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.
- 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.
- Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.
- Common side effects include injection-site reactions (which may include pain, redness, swelling, itching, bruising, lumps, inflammation, skin rash, blisters, warmth, and bleeding at the injection site), upper respiratory tract infections, joint and muscle aches, rash, ear infection, sore throat, and runny nose.

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

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 expectation that ARCALYST 2025 net product revenue will be between $560 million and $580 million; our expectation to remain cash flow positive on an annual basis; our belief that there is still substantial opportunity ahead for Kiniksa to drive further ARCALYST revenue; our belief that our financial profile provides the ability to pursue additional value-creating opportunities; our beliefs about the mechanisms of our assets and potential impact of their approach; and our belief 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: 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 inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential for applicable regulatory authorities to not accept our filings, delay or deny approval of any of our product candidates or require additional data or trials to support approval; our reliance on third parties as the sole source of supply of the drug substance and drug product used in our products and product candidates; raw material, important ancillary product and drug substance and/or drug product shortages; 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; changes in our operating plan, business development strategy or funding requirements; and existing or new competition.

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 Contact
Jonathan Kirshenbaum
(781) 829-3949
jkirshenbaum@kiniksa.com

Kiniksa Media Contact
Tyler Gagnon
(781) 431-9100
tgagnon@kiniksa.com