



Kiniksa Pharmaceuticals Provides Corporate Update

January 12, 2026

- ARCALYST® (rilonacept) 2025 net product revenue of \$677.5 million (unaudited), representing ~62% year-over-year growth –
 - ARCALYST 2026 net product revenue expected to be \$900 - \$920 million –
 - KPL-387 Phase 2 recurrent pericarditis data expected in 2H 2026 –
 - KPL-1161 Phase 1 trial planned to initiate by year end –
- Cash balance increased by \$170.4 million in 2025 to \$414.1 million (unaudited) –

LONDON, Jan. 12, 2026 (GLOBE NEWSWIRE) -- [Kiniksa Pharmaceuticals International, plc](#) (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company developing and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications, today provided a corporate update.

"IL-1 α & IL-1 β inhibition with ARCALYST is increasingly becoming the preferred second line treatment for patients with recurrent pericarditis. As of the end of 2025, approximately 18% of the multiple recurrence population was actively on ARCALYST therapy. In addition to driving further uptake in this group, we are well-positioned to expand our reach in the broader population of first recurrence patients," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "We are also advancing KPL-387 in recurrent pericarditis, which we believe could expand the IL-1 α & IL-1 β inhibition market by potentially enabling monthly self-administration with a liquid formulation. We are enrolling and dosing patients in the Phase 2 dose-focusing portion of the Phase 2/3 trial, with data expected in the second half of 2026. In addition, we plan to commence a Phase 1 first-in-human trial with KPL-1161, an Fc-modified monoclonal antibody IL-1 receptor antagonist, by the end of this year. Our strong financial position supports these efforts as well as provides the ability to pursue additional value-creating opportunities."

Portfolio Execution

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

- ARCALYST net product revenue was \$677.5 million (unaudited) for the full year 2025, compared to \$417.0 million for the full year 2024, representing approximately 62% year-over-year growth.
 - Gross-to-net was 8.4% (unaudited) for the full year 2025 compared to 9.8% for the full year 2024, due to the impact of the Inflation Reduction Act throughout 2025, as well as prior period reserve adjustments in the fourth quarter of 2025.
- As of the end of the fourth quarter of 2025, approximately 18% of the 14,000 multiple-recurrence patients were actively on ARCALYST treatment.
- Since launch, more than 4,150 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- Average total duration of ARCALYST therapy in recurrent pericarditis continues to grow and is approaching 3 years, in line with the median duration of disease.
- Kiniksa expects 2026 ARCALYST net product revenue of between \$900 million and \$920 million.

KPL-387 (monoclonal antibody IL-1 receptor antagonist)

- Kiniksa is conducting a Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis and expects data from the dose-focusing portion in the second half of 2026.
- Kiniksa is conducting a supplemental Phase 2 Transition to KPL-387 Monotherapy Dosing & Administration Study evaluating the efficacy and safety of the dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy.

KPL-1161 (Fc-modified monoclonal antibody IL-1 receptor antagonist)

- Kiniksa is conducting preclinical development activities with KPL-1161 with a target profile of quarterly subcutaneous (SC) dosing. The company expects to initiate a Phase 1 first-in-human clinical trial by the end of 2026.

Corporate Update

- As of December 31, 2025, Kiniksa had \$414.1 million of cash, cash equivalents, and short-term investments and no debt (unaudited).
- Kiniksa expects its current operating plan to remain cash flow positive on an annual basis.

- Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa and Ross Moat, Chief Corporate and Commercial Officer, will provide a corporate presentation at the 44th Annual J.P. Morgan Healthcare Conference on January 12, 2026, at 2:15 p.m. Pacific Time (5:15 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 biopharmaceutical company dedicated to improving the lives of patients suffering from debilitating diseases by discovering, acquiring, developing, and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications. Kiniksa's portfolio of assets is based on strong biological rationale or validated mechanisms and offers 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-1 α) and interleukin-1 beta (IL-1 β) 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](#).

About KPL-387

KPL-387 is an independently developed, investigational, fully human immunoglobulin G2 (IgG2) monoclonal antibody that binds human interleukin-1 receptor 1 (IL-1R1), inhibiting the signaling of the cytokines IL-1 α and IL-1 β . Kiniksa believes KPL-387 could expand the treatment options for recurrent pericarditis patients by potentially enabling dosing with a single monthly SC self-injection in a liquid formulation. In October 2025, the FDA granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis.

About KPL-1161

KPL-1161 is an independently developed, investigational, Fc-modified IgG2 monoclonal antibody that binds IL-1R1, inhibiting the signaling of the cytokines IL-1 α and IL-1 β , with a target profile of quarterly SC dosing. Kiniksa is currently engaging in preclinical development activities for KPL-1161.

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 2026 net product revenue will be between \$900 million and \$920 million; our belief that data from the dose-focusing portion of our Phase 2 clinical trial of KPL-387 in recurrent pericarditis will be available in the second half of 2026; our plan to initiate a Phase 1 first-in-human clinical trial of KPL-1161 by the end of 2026; our belief that we are well-positioned to expand ARCALYST's reach into the broader population of first recurrence patients; our belief that KPL-387 could expand the IL-1 α & IL-1 β inhibition market by potentially enabling monthly subcutaneous self-administration with a liquid formulation; our target profile of quarterly subcutaneous dosing for KPL-1161; our beliefs about the mechanisms of our assets and potential impact of their approach; statements regarding our belief about the future of our commercial opportunities; and our belief that our portfolio of assets offers 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; business development activities and their impact on our financial performance and strategy; changes in our operating plan, business development strategy or funding requirements; existing or new competition; current and future healthcare reforms, including those affecting the delivery of or payment for healthcare products and services; and the impact of global economic policy, including any uncertainty in national and international markets.

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.

ARCALYST® is a registered trademark of Regeneron Pharmaceuticals, Inc.

Every Second Counts!®

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