Kiniksa Pharmaceuticals Reports First Quarter 2025 Financial Results and Recent Portfolio Execution

April 29, 2025

– ARCALYST® (rilonacept) Q1 2025 net product revenue of $137.8 million, representing 75% year-over-year growth –
– ARCALYST 2025 expected net product revenue increased to $590 - $605 million –
– KPL-387 Phase 2/3 clinical trial in recurrent pericarditis on track to initiate in mid-2025; Phase 2 data expected in 2H 2026 –
– Current operating plan expected to remain cash flow positive on an annual basis –
– Conference call and webcast scheduled for 8:30 am ET today –

LONDON, April 29, 2025 (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 reported first quarter 2025 financial results and recent portfolio execution.

“Kiniksa continues to drive strong growth with ARCALYST. In the first quarter of 2025, our robust commercial execution resulted in a meaningful increase in active commercial patients, driven by increases to the prescriber base, longer average total duration of treatment, and changes to Medicare Part D. As a result of strong first quarter performance, we are increasing our expected 2025 ARCALYST net sales to between $590 and $605 million from our previous guidance of between $560 and $580 million,” said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. “Also, we are excited about the potential of KPL-387 to be an additional treatment option for patients by enabling dosing with a single monthly subcutaneous injection in a liquid formulation. We remain on track to initiate the KPL-387 Phase 2/3 recurrent pericarditis trial in the middle of this year.”

Portfolio Execution

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

- ARCALYST net product revenue was $137.8 million for the first quarter of 2025.
- Since launch, more than 3,150 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the first quarter of 2025, average total duration of ARCALYST therapy in recurrent pericarditis increased to approximately 30 months, compared to approximately 27 months as of the end of the fourth quarter of 2024.

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

- Pharmacokinetic data from the single ascending dose portion of the Phase 1 study support the development plan for KPL-387; Kiniksa plans to initiate a Phase 2/3 clinical trial in mid-2025. The trial will evaluate KPL-387 in recurrent pericarditis, with a target profile of monthly subcutaneous (SC) dosing in a liquid formulation. The company expects data from the Phase 2 portion of the trial in the second half of 2026.

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

- Kiniksa is conducting Investigational New Drug (IND)-enabling development activities with a target profile of quarterly SC dosing.

Financial Results

- Total revenue for the first quarter of 2025 was $137.8 million, compared to $79.9 million for the first quarter of 2024.
  - Kiniksa did not record any license and collaboration revenue for the first quarter of 2025, compared to $1.0 million for the first quarter of 2024.
- Total operating expenses for the first quarter of 2025 were $124.5 million, compared to $96.4 million for the first quarter of 2024.
  - Total operating expenses for the first quarter of 2025 included $43.8 million in collaboration expenses, which are driven by ARCALYST collaboration profitability, compared to $20.8 million for the first quarter of 2024.
  - Total operating expenses for the first quarter of 2025, included $7.7 million in non-cash, share-based compensation expense, compared to $7.2 million for the first quarter of 2024.
- Net income for the first quarter of 2025 was $8.5 million, compared to a net loss of $17.7 million for the first quarter of 2024.
- As of March 31, 2025, Kiniksa had $268.3 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects 2025 ARCALYST net product revenue of between $590 million and $605 million, compared to prior guidance of between $560 million and $580 million.
- Kiniksa expects its current operating plan to remain cash flow positive on an annual basis.
- Kiniksa continues to monitor potential implications of tariffs on pharmaceuticals imported into the United States.
    - ARCALYST is currently manufactured in the United States by Regeneron Pharmaceuticals. Kiniksa has been in the process of transferring drug substance manufacturing to Samsung Biologics in South Korea and believes any future impact to ARCALYST gross margin would be immaterial, limited only to the cost of drug substance imported into the United States.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Tuesday, April 29, 2025, to discuss first quarter 2025 financial results and recent portfolio execution.
- Individuals interested in participating in the call via telephone may register here. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. To access the webcast, please visit the Investors and Media section of Kiniksa's website. A replay of the event 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 biologic 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-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 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 exclusivity to ARCALYST in 2021 for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. 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-1α and IL-1β. Kiniksa believes KPL-387 could expand the treatment options for recurrent pericarditis patients by enabling dosing with a single monthly SC injection in a liquid formulation.

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-1α and IL-1β, with a target profile of quarterly SC dosing. Kiniksa is currently engaging in IND-enabling 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 2025 net product revenue will be between $590 million and $605 million; our plan to initiate a Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis in mid-2025, with Phase 2 data expected in the second half of 2026, and that we remain on track to meeting such plan; our expectation that our current operating plan will remain cash flow positive on an annual basis; our target profile of monthly dosing via a single subcutaneous injection in a liquid formulation for KPL-387; the expected impact of tariff policy on our gross margins; our target profile of quarterly dosing for KPL-1161; our beliefs about the mechanisms of our assets and potential impact of their approach; 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; 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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KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Revenue:		
Product revenue, net	$ 137,785	$ 78,885
License and collaboration revenue	—	973
Total revenue	137,785	79,858
Operating expenses:		
Cost of goods sold	17,868	10,583
Collaboration expenses	43,790	20,801
Research and development	19,325	26,334
Selling, general and administrative	43,530	38,682
Total operating expenses	124,513	96,400
Income (loss) from operations	13,272	(16,542)

Other income	2,293	2,266
Income (loss) before income taxes	15,565	(14,276)
Provision for income taxes	(7,026)	(3,428)
Net income (loss)	$ 8,539	$ (17,704)
Net income (loss) per share attributable to ordinary shareholders—basic	$ 0.12	$ (0.25)
Net income (loss) per share attributable to ordinary shareholders—diluted	$ 0.11	$ (0.25)
Weighted average ordinary shares outstanding—basic	72,647,121	70,633,023
Weighted average ordinary shares outstanding—diluted	76,145,617	70,633,023

KINIKSA PHARMACEUTICALS, LTD.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	As of	
	March 31, 2025	**December 31, 2024**
Cash, cash equivalents, and short-term investments	$ 268,340	$ 243,627
Working capital	258,640	231,178
Total assets	599,326	580,553
Accumulated deficit	(512,604)	(521,143)
Total shareholders' equity	457,489	438,436