Kiniksa Pharmaceuticals Reports Third Quarter 2024 Financial Results and Recent Portfolio Execution

October 29, 2024

– ARCALYST® (rilonacept) Q3 2024 net product revenue of $112.2 million, representing 73% year-over-year growth –
– ARCALYST 2024 expected net product revenue increased to $410 - $420 million –
– Life DisRPted ™ disease awareness campaign for recurrent pericarditis launched in partnership with NHL Hall of Famer, Henrik Lundqvist, and GRAMMY® Award-winning singer-songwriter, Carly Pearce –
– Kiniksa expects to remain cash flow positive on an annual basis –
– Conference call and webcast scheduled for 8:30 am ET today –

LONDON, Oct. 29, 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 reported third quarter 2024 financial results and recent portfolio execution.

"Consistent execution across our commercial organization, including strategic investments in brand and disease awareness, continued to drive ARCALYST growth among new and repeat prescribers. Additionally, we continued to see ARCALYST used as a steroid-sparing agent earlier in the course of disease for patients with recurrent pericarditis. For 2024, we now expect ARCALYST net sales to increase to between $410 and $420 million," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Within our pipeline, we are enrolling and dosing patients in the Phase 2b clinical trial of abiprubart in Sjögren's Disease. We expect to remain cash flow positive on an annual basis while continuing to invest across our business, including commercialization and pipeline advancement."

Corporate Update

- Earlier this month, Kiniksa announced the launch of *Life DisRPted*, an educational campaign aimed at promoting early diagnosis and treatment of recurrent pericarditis, in partnership with NHL Hall-of-Famer, Henrik Lundqvist.
- Yesterday, Kiniksa announced that it had also partnered with GRAMMY Award-winning singer-songwriter, Carly Pearce, to join the *Life DisRPted* campaign.

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

- ARCALYST net product revenue was $112.2 million for the third quarter of 2024.
- Since launch in April 2021, more than 2,550 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the third quarter of 2024, average total duration of ARCALYST therapy in recurrent pericarditis increased to approximately 27 months.

Abiprubart (anti-CD40 monoclonal antibody inhibitor of CD40-CD154 interaction)

- Kiniksa is enrolling and dosing patients in a Phase 2b clinical trial designed to evaluate the efficacy and safety of biweekly and monthly abiprubart administered subcutaneously in patients with Sjögren's Disease.

Financial Results

- Total revenue for the third quarter of 2024 was $112.2 million, compared to $67.0 million for the third quarter of 2023.
  - Kiniksa did not record any license and collaboration revenue for the third quarter of 2024, compared to $2.2 million for the third quarter of 2023.
- Total operating expenses for the third quarter of 2024 were $121.9 million, compared to $78.0 million for the third quarter of 2023.
  - Total operating expenses for the third quarter of 2024 included $29.3 million in collaboration expenses, which are driven by ARCALYST collaboration profitability, compared to $17.3 million for the third quarter of 2023.
  - Total operating expenses for the third quarter of 2024 included $7.8 million in non-cash, share-based compensation expense, compared to $6.8 million for the third quarter of 2023.
- Net loss for the third quarter of 2024 was $12.7 million, compared to a net loss of $13.9 million for the third quarter of 2023.
- As of September 30, 2024, Kiniksa had $223.8 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects 2024 ARCALYST net product revenue of between $410 million and $420 million, compared to prior guidance of between $405 million and $415 million.
- Kiniksa expects to remain cash flow positive on an annual basis.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Tuesday, October 29, 2024, to discuss third quarter 2024 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 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.

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 expectation that ARCALYST 2024 net product revenue will be between $410 million and $420 million; our expectation to remain cash flow positive on an annual basis while continuing to invest in our business; our beliefs about the mechanisms of our product candidates and potential impact of their approach, including that using abiprubart to disrupt the CD40-CD154 co-stimulatory interaction is an

attractive approach to address multiple autoimmune disease pathologies; 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.

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

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

KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
SELECTED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 112,214	$ 64,802	$ 294,493	$ 161,956
License and collaboration revenue	—	2,244	6,210	24,908
Total revenue	112,214	67,046	300,703	186,864
Costs and operating expenses:				
Cost of goods sold	20,109	9,088	43,014	23,823
Collaboration expenses	29,307	17,311	80,122	39,585
Research and development	26,057	17,106	76,408	56,045
Selling, general and administrative	46,399	34,468	127,476	92,688
Total operating expenses	121,872	77,973	327,020	212,141
Loss from operations	(9,658)	(10,927)	(26,317)	(25,277)
Other income	2,457	2,428	7,144	6,175
Loss before income taxes	(7,201)	(8,499)	(19,173)	(19,102)
Benefit (provision) for income taxes	(5,492)	(5,356)	(15,132)	7,949
Net loss	$ (12,693)	$ (13,855)	$ (34,305)	$ (11,153)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (0.18)	$ (0.20)	$ (0.48)	$ (0.16)
Weighted average ordinary shares outstanding—basic and diluted	71,726,685	70,186,016	71,123,658	69,953,591

KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
SELECTED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	As of	
	September 30, 2024	**December 31, 2023**
Cash, cash equivalents, and short-term investments	$ 223,780	$ 206,371
Working capital	215,346	212,631
Total assets	555,298	526,322
Accumulated deficit	(512,255)	(477,950)
Total shareholders' equity	437,006	438,839