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

July 23, 2024

– ARCALYST® (rilonacept) Q2 2024 net product revenue of $103.4 million, representing 90% year-over-year growth –
– ARCALYST 2024 expected net product revenue increased to $405 - $415 million –
– Abiprubart clinical development fully funded; Phase 2b clinical trial in Sjögren's Disease enrolling patients –
– Kiniksa expects to remain cash flow positive on an annual basis –
– Conference call and webcast scheduled for 8:30 am ET today –

LONDON, July 23, 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 second quarter 2024 financial results and recent portfolio execution.

"Kiniksa's work to establish ARCALYST as the standard of care in recurrent pericarditis continues to drive the company's commercial performance. As of the end of the second quarter, ~11% of the 14,000 multiple-recurrence target population were actively on ARCALYST treatment, and total average duration of therapy increased to approximately 26 months. We now expect 2024 ARCALYST net sales to increase to between $405 and $415 million from our previous guidance of between $370 and $390 million," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Within our pipeline, commencing enrollment in the abiprubart Phase 2b trial in Sjögren's Disease, a debilitating, chronic autoimmune disease, which currently has no FDA-approved therapies, represents an exciting growth opportunity for the company. Clinical development of abiprubart in Sjögren's Disease is fully funded in our current operating plan, and we expect to remain cash flow positive on an annual basis."

Portfolio Execution

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

- ARCALYST net product revenue was $103.4 million for the second quarter of 2024.
- Since launch in April 2021, more than 2,300 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the second quarter of 2024, the average total duration of ARCALYST therapy in recurrent pericarditis increased to approximately 26 months, compared to ~23 months as of the end of the first quarter of 2024.
- As of the end of the second quarter of 2024, approximately 11% of the target 14,000 multiple-recurrence patients were actively on ARCALYST treatment, compared to ~9% as of the end of 2023.
- In June 2024, Kiniksa announced its sponsorship of the American Heart Association's *Addressing Recurrent Pericarditis* initiative, a multi-faceted effort aimed at improving access to expert care and quality of care for patients with recurrent pericarditis.
- In June 2024, Kiniksa announced a partnership with National Hockey League Hall-of-Famer, Henrik Lundqvist, to raise awareness in support of patients suffering from recurrent pericarditis.

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

- Kiniksa is enrolling 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 second quarter of 2024 was $108.6 million, compared to $71.5 million for the second quarter of 2023.
  - Total revenue for the second quarter of 2024 included $5.2 million in license and collaboration revenue, compared to $17.0 million for the second quarter of 2023.
- Total operating expenses for the second quarter of 2024 were $108.7 million, compared to $74.6 million for the second quarter of 2023.
  - Total operating expenses for the second quarter of 2024 included $30.0 million in collaboration expenses, which are driven by ARCALYST collaboration profitability, compared to $14.0 million for the second quarter of 2023.
  - Total operating expenses for the second quarter of 2024 included $7.4 million in non-cash, share-based compensation expense, compared to $6.5 million for the second quarter of 2023.
- Net loss for the second quarter of 2024 was $3.9 million, compared to a net income of $15.0 million for the second quarter of 2023.
- As of June 30, 2024, Kiniksa had $218.8 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects 2024 ARCALYST net product revenue of between $405 million and $415 million, compared to prior guidance of between $370 million and $390 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, July 23, 2024, to discuss second 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, ARCALYST, abiprubart, and mavrilimumab, 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 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 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 $405 million and $415 million; our expectation that clinical development of abiprubart in Sjögren's Disease is fully funded in our current operating plan; our expectation to remain cash flow positive on an annual basis; 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.

Every Second Counts! ®

Kiniksa Investor and Media Contact
Rachel Frank
(339) 970-9437
rfrank@kiniksa.com

KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
(FORMERLY KNOWN AS KINIKSA PHARMACEUTICALS, LTD.)
SELECTED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 103,394	$ 54,495	$ 182,279	$ 97,154
License and collaboration revenue	5,237	16,978	6,210	22,664
Total revenue	108,631	71,473	188,489	119,818
Costs and operating expenses:				
Cost of goods sold	12,322	7,699	22,905	14,735
Collaboration expenses	30,014	13,986	50,815	22,274
Research and development	24,017	23,767	50,351	38,939
Selling, general and administrative	42,395	29,175	81,077	58,220
Total operating expenses	108,748	74,627	205,148	134,168
Loss from operations	(117)	(3,154)	(16,659)	(14,350)
Other income	2,421	1,915	4,687	3,747
Income (loss) before income taxes	2,304	(1,239)	(11,972)	(10,603)
Benefit (provision) for income taxes	(6,212)	16,211	(9,640)	13,305
Net income (loss)	$ (3,908)	$ 14,972	$ (21,612)	$ 2,702
Net income (loss) per share attributable to ordinary shareholders—basic	$ (0.06)	$ 0.21	$ (0.31)	$ 0.04
Net income (loss) per share attributable to ordinary shareholders—diluted	$ (0.06)	$ 0.21	$ (0.31)	$ 0.04
Weighted average ordinary shares outstanding—basic	71,004,640	69,918,287	70,818,831	69,835,452
Weighted average ordinary shares outstanding—diluted	71,004,640	71,634,729	70,818,831	71,420,026

KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
(FORMERLY KNOWN AS KINIKSA PHARMACEUTICALS, LTD.)
SELECTED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	As of	
	June 30, 2024	**December 31, 2023**
Cash, cash equivalents, and short-term investments	$ 218,758	$ 206,371
Working capital	216,730	212,631
Total assets	542,428	526,322
Accumulated deficit	(499,562)	(477,950)
Total shareholders' equity	435,095	438,839