Kiniksa Pharmaceuticals Reports Fourth Quarter and Full-Year 2023 Financial Results and Recent Portfolio Execution

February 28, 2024

– ARCALYST® (rilonacept) Q4 2023 and full-year 2023 net product revenue of $71.2 million and $233.2 million, respectively –

– ARCALYST 2024 net product revenue expected to be $360 - $380 million, representing ~59% year-over-year growth at the midpoint –
– Abiprubart Phase 2 rheumatoid arthritis data from Cohort 4 and a new development indication expected in April 2024 –
– Cash reserves of $206.4 million expected to fund operations into at least 2027 –
– Conference call and webcast scheduled for 8:30 am ET today –

HAMILTON, Bermuda, Feb. 28, 2024 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (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 fourth quarter and full-year 2023 financial results and recent portfolio execution.

"Kiniksa meaningfully advanced its business in 2023, primarily through robust ARCALYST net product revenue and collaboration profit growth. Significant growth remains with ARCALYST in recurrent pericarditis, and we expect to help an increasing number of patients in the years ahead. Importantly, we anticipate our robust commercial performance to contribute to our strong financial position and ability to drive growth across our business," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Additionally, abiprubart recently showed clinical effect in the first three cohorts of the Phase 2 trial in rheumatoid arthritis. We now expect to advance the asset into a Phase 2b trial in a new indication, funding for which is included in our current cash runway guidance. Data from the fourth cohort of the abiprubart Phase 2 trial are intended to inform trial design and are expected in April."

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

- ARCALYST net product revenue was $71.2 million and $233.2 million for the fourth quarter and full-year 2023, respectively.
- Since launch in April 2021, more than 1,700 prescribers have written ARCALYST prescriptions for recurrent pericarditis.
- As of the end of the fourth quarter of 2023, average total duration of ARCALYST therapy in recurrent pericarditis had increased to approximately 23 months.
- As of the end of the fourth quarter of 2023, approximately 9% of the target 14,000 multiple-recurrence patients were actively on ARCALYST treatment.
- A poster entitled *Rilonacept Utilization in a Steroid-Sparing Paradigm for Recurrent Pericarditis: Real-World Evidence Demonstrating Increased Adoption* is planned to be presented at the upcoming American College of Cardiology Scientific Session (ACC.24) in April 2024.

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

- Kiniksa previously announced topline data from the Phase 2 clinical trial of abiprubart in rheumatoid arthritis, showing that the trial met its primary efficacy endpoint: change from baseline in Disease Activity Score of 28 Joints Using C-reactive Protein (DAS28-CRP) versus placebo.
    - In Cohorts 1 and 2 (pharmacokinetic lead-in), multiple doses of abiprubart were well-tolerated.
    - In Cohort 3, the abiprubart 5 mg/kg subcutaneous (SC) weekly dose level achieved statistical significance. The 5 mg/kg SC biweekly dose level did not achieve statistical significance. Across both dose levels abiprubart reduced Rheumatoid Factor, a clinical marker of disease activity and an autoantibody pharmacodynamic marker of CD40 target engagement. Abiprubart was well-tolerated, with no dose-related adverse experiences observed.
- Kiniksa expects data from the fourth cohort (Cohort 4) of the Phase 2 clinical trial in April 2024. Cohort 4 will evaluate a fixed dose level administered as a single subcutaneous injection once monthly.

Mavrilimumab (monoclonal antibody inhibitor targeting GM-CSFRα)

- Kiniksa is evaluating potential partnership opportunities to advance development of mavrilimumab, which has generated positive data in mid-stage clinical trials across multiple indications.

Vixarelimab (monoclonal antibody inhibitor of signaling through OSMRβ)

- In the fourth quarter of 2023, Kiniksa recognized a $10.0 million development milestone related to a second new indication under its global license agreement with Genentech, a member of the Roche Group.

Financial Results

- Total revenue for the fourth quarter of 2023 was $83.4 million, compared to $61.9 million for the fourth quarter of 2022. Total revenue for the full-year 2023 was $270.3 million, compared to $220.2 million for the full-year 2022.
    - Total revenue for the fourth quarter of 2023 included $12.2 million in license and collaboration revenue, compared to $21.9 million for the fourth quarter of 2022.
    - Total revenue for the full-year 2023 included $37.1 million in license and collaboration revenue, compared to $97.7 million for the full-year 2022.
- Total operating expenses for the fourth quarter of 2023 were $83.3 million, compared to $55.8 million for the fourth quarter of 2022. Total operating expenses for the full-year 2023 were $295.5 million, compared to $210.4 million for the full-year 2022.
    - Total operating expenses for the fourth quarter of 2023 included $16.9 million in collaboration expenses, which are driven by ARCALYST collaboration profitability, compared to $7.5 million for the fourth quarter of 2022. Total operating expenses for the full-year 2023 included $56.5 million in collaboration expenses, compared to $24.1 million for the full-year 2022.
    - Total operating expenses for the fourth quarter of 2023 included $7.8 million in non-cash, share-based compensation expense, compared to $6.4 million for the fourth quarter of 2022. Total operating expense for the full-year 2023 included $27.1 million in non-cash, share-based compensation expense, compared to $25.1 million for the full-year 2022.
- Net income for the fourth quarter of 2023 was $25.2 million, compared to net income of $4.5 million for the fourth quarter of 2022. Net income for the full-year 2023 was $14.1 million, compared to net income of $183.4 million for the full-year 2022.
    - Net income for the fourth quarter of 2023 included a tax benefit of $22.8 million, primarily due to the treatment of non-cash deferred tax assets, compared to a tax expense of $2.4 million for the fourth quarter of 2022.
    - Net income for the full-year 2023 included a tax benefit of $30.7 million, compared to a tax benefit of $172.3 million for the full-year 2022, both primarily due to the treatment of non-cash deferred tax assets.
- As of December 31, 2023, Kiniksa had $206.4 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects 2024 ARCALYST net product revenue of between $360 million and $380 million.
- Kiniksa expects that its cash, cash equivalents, and short-term investments will fund its current operating plan into at least 2027.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Wednesday, February 28, 2024, to discuss fourth quarter and full-year 2023 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.

About Mavrilimumab
Mavrilimumab is an investigational fully human monoclonal antibody that blocks activity of GM-CSF by specifically binding to the alpha subunit of the GM-CSF receptor (GM-CSFRα). Phase 2 clinical trials of mavrilimumab in rheumatoid arthritis and giant cell arteritis achieved their primary and secondary endpoints with statistical significance. Kiniksa is evaluating potential partnership opportunities for mavrilimumab.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 $360 million and $380 million; our plan to report data from Cohort 4 of our Phase 2 clinical trial of abiprubart in rheumatoid arthritis and a new development indication for abiprubart in April 2024; our expectation about our cash reserves funding our current operating plan into at least 2027; our expectation that we will help an increasing number of patients in the future; our plan to develop abiprubart in an additional indication; our plan to present a poster at the upcoming American College of Cardiology Scientific Session in April 2024; 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; inability to successfully execute on our commercial strategy for ARCALYST; 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; our reliance on Regeneron as the current sole manufacturer of ARCALYST; risks arising from our ongoing technology transfer of ARCALYST drug substance manufacturing; 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! ®

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KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Product revenue, net	$ 71,220	$ 39,939	$ 233,176	$ 122,524
License and collaboration revenue	12,175	21,945	37,083	97,656
Total revenue	83,395	61,884	270,259	220,180
Operating expenses:				
Cost of goods sold	9,584	6,710	33,407	22,895
Collaboration expenses	16,939	7,522	56,524	24,071
Research and development	20,052	14,390	76,097	65,490
Selling, general and administrative	36,739	27,215	129,427	97,951
Total operating expenses	83,314	55,837	295,455	210,407
Income (loss) from operations	81	6,047	(25,196)	9,773
Other income	2,369	794	8,544	1,253
Income (loss) before income taxes	2,450	6,841	(16,652)	11,026
Benefit (provision) for income taxes	22,787	(2,380)	30,736	172,337
Net income	$ 25,237	$ 4,461	$ 14,084	$ 183,363
Net income per share attributable to common shareholders—basic	$ 0.36	$ 0.06	$ 0.20	$ 2.64
Net income per share attributable to common shareholders—diluted	0.35	0.06	0.20	2.60
Weighted average common shares outstanding—basic	70,371,601	69,609,342	70,058,952	69,382,275
Weighted average common shares outstanding—diluted	72,660,171	71,369,394	71,922,915	70,421,322

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

	As of	
	December 31, 2023	**December 31, 2022**
Cash, cash equivalents, and short-term investments	$ 206,371	$ 190,608
Working capital	212,631	195,994
Total assets	526,322	459,672
Accumulated deficit	(477,950)	(492,034)
Total shareholders' equity	438,839	396,149