Kiniksa Pharmaceuticals Reports Fourth Quarter and Full-Year 2022 Financial Results and Recent Portfolio Execution

February 28, 2023

– ARCALYST® (rilonacept) Q4 2022 and full-year 2022 net product revenue of $39.9 million and $122.5 million, respectively –

– ARCALYST full-year 2023 net product revenue expected to be $190 - $205 million, representing >60% year-over-year growth at the midpoint –

– ARCALYST average total duration of therapy as of the end of Q4 2022 was ~18 months after accounting for patient restarts –

– Cash reserves expected to fund operations into at least 2025 –

HAMILTON, Bermuda, Feb. 28, 2023 (GLOBE NEWSWIRE) -- Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (Kiniksa), a 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 2022 financial results and recent portfolio execution.

"Kiniksa executed across its cardiovascular and emerging autoimmune franchises in 2022," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "Within the cardiovascular franchise, we are focused on increasing brand awareness of ARCALYST, the only FDA-approved treatment for recurrent pericarditis, and pursuing collaborative study agreements for mavrilimumab in rare cardiovascular diseases. In our emerging autoimmune franchise, we believe KPL-404, our CD40 antagonist, has significant potential for differentiation in targeting chronic autoimmune diseases. We are advancing the Phase 2 trial of KPL-404 in rheumatoid arthritis into the efficacy portion and expect data in the first half of 2024. Additionally, our profitable ARCALYST collaboration, non-dilutive capital from strategic out-licensing transactions, and continued financial discipline support these efforts while providing cash runway into at least 2025."

Portfolio Execution

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

- ARCALYST net product revenue was $39.9 million and $122.5 million for the fourth quarter and full-year 2022, respectively.
- Since launch, greater than 800 prescribers have written ARCALYST prescriptions for recurrent pericarditis, with 22% having written prescriptions for 2 or more patients.
- As of the end of the fourth quarter of 2022, there was a greater than 90% payer approval rate of completed patient cases for recurrent pericarditis.
- As of the end of the fourth quarter of 2022, ARCALYST average total duration of therapy was approximately 18 months after accounting for the approximately 45% of recurrent pericarditis patients who had discontinued therapy and restarted treatment.
    - ARCALYST average initial duration of therapy remained approximately 12 months as of the end of the fourth quarter of 2022.
- As of the end of the fourth quarter of 2022, approximately 5% of the target 14,000 multiple-recurrence pericarditis patients were actively on ARCALYST treatment.

KPL-404 (monoclonal antibody inhibitor of CD40-CD154 interaction)

- Kiniksa has completed enrollment of the second and final cohort of the multiple ascending dose portion of the Phase 2 clinical trial of KPL-404 in rheumatoid arthritis. Following completion of this portion of the trial, the proof-of-concept portion will begin. The company expects data from the trial in the first half of 2024.

Mavrilimumab (monoclonal antibody inhibitor targeting GM-CSFRα)

- Kiniksa is pursuing collaborative study agreements to evaluate the potential of mavrilimumab in rare cardiovascular diseases where the granulocyte macrophage colony stimulating factor (GM-CSF) mechanism has been implicated.

Financial Results

- Total revenue for the fourth quarter of 2022 was $61.9 million, compared to $18.7 million for the fourth quarter of 2021. Total revenue for the full-year 2022 was $220.2 million, compared to $38.5 million for the full-year 2021.

    - Total revenue for the fourth quarter of 2022 included $39.9 million in ARCALYST net product revenue and $21.9 million in license and collaboration revenue from Roche and Genentech, a member of the Roche Group (Genentech). Kiniksa did not report license and collaboration revenue in the fourth quarter of 2021.
    - Total revenue for the full-year 2022 included $122.5 million in ARCALYST net product revenue and $97.7 million in license and collaboration revenue from Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd and Genentech. Kiniksa did not report license and collaboration revenue in 2021.
- Total operating expenses for the fourth quarter of 2022 were $55.8 million, compared to $54.9 million for the fourth quarter of 2021. Total operating expenses for the full-year 2022 were $210.4 million, compared to $195.2 million for the full-year 2021.
    - Total operating expenses for the fourth quarter of 2022 included $6.4 million in non-cash, share-based compensation expense, compared to $6.1 million for the fourth quarter of 2021.
    - Total operating expenses for the full-year 2022 included $25.1 million in non-cash, share-based compensation expense, compared to $25.2 million for the full-year 2021.
- Net income for the fourth quarter of 2022 was $4.5 million, compared to a net loss of $36.3 million for the fourth quarter of 2021. Net income for the full-year 2022 was $183.4 million, compared to a net loss of $157.9 million for the full-year 2021.
    - Net income for the full-year 2022 included a $172.3 million tax benefit primarily due to the release of a valuation allowance on non-cash deferred tax assets.
- As of December 31, 2022, Kiniksa had $190.6 million of cash, cash equivalents, and short-term investments and no debt.

Financial Guidance

- Kiniksa expects ARCALYST net product revenue for the full-year 2023 of between $190 million and $205 million.
- Kiniksa expects that its cash and cash equivalents will fund its current operating plan into at least 2025.

Conference Call Information

- Kiniksa will host a conference call and webcast at 8:30 a.m. Eastern Time on Tuesday, February 28, 2023, to discuss fourth quarter and full-year 2022 financial results and to provide a corporate update.
- 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 focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's portfolio of immune-modulating assets, ARCALYST, KPL-404, 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 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 designation to ARCALYST for the treatment of pericarditis in 2020. 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-404
KPL-404 is an investigational humanized monoclonal antibody that is designed to inhibit 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 interaction is an attractive approach to address 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 the development of mavrilimumab in rare cardiovascular diseases where the GM-CSF mechanism has been implicated.

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 (i) that the proof-of-concept portion of the Phase 2 clinical trial of KPL-404 in rheumatoid arthritis will begin after completion of the multiple ascending dose portion of such trial, and (ii) that we will report data from such trial in the first half of 2024; our pursuit of collaborative study agreements to evaluate the potential of mavrilimumab in rare cardiovascular diseases where the GM-CSF mechanism has been implicated; our expectation that ARCALYST full-year 2023 net product revenue will be between $190 million and $205 million; our expectation about our cash reserves funding our current operating plan into at least 2025; our beliefs about the mechanisms of action of our product candidates and potential impact of their approach, including (i) that KPL-404 has significant potential for differentiation in targeting chronic autoimmune diseases and (ii) that using KPL-404 to disrupt the CD40-CD154 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 sole manufacturer of ARCALYST; 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; the impact of the COVID-19 pandemic and any subsequent pandemic and measures taken in response to such pandemics on our business and operations as well as the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities; changes in our operating plan and 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.

ARCALYST® is a registered trademark of Regeneron Pharmaceuticals, Inc. All other trademarks are the property of their respective owners.

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,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	$ 39,939	$ 18,745	$ 122,524	$ 38,544
License and collaboration revenue	21,945	—	97,656	—
Total revenue	61,884	18,745	220,180	38,544
Operating expenses:				
Cost of goods sold	6,710	3,867	22,895	9,100
Collaboration expenses	7,522	835	24,071	835
Research and development	14,390	27,433	65,490	99,297
Selling, general and administrative	27,215	22,741	97,951	85,948
Total operating expenses	55,837	54,876	210,407	195,180
Income (loss) from operations	6,047	(36,131)	9,773	(156,636)
Other income	794	77	1,253	97
Income (loss) before income taxes	6,841	(36,054)	11,026	(156,539)
Benefit (provision) for income taxes	(2,380)	(279)	172,337	(1,385)
Net income (loss)	$ 4,461	$ (36,333)	$ 183,363	$ (157,924)
Net income (loss) per share attributable to common shareholders—basic	$ 0.06	$ (0.53)	$ 2.64	$ (2.30)
Net income (loss) per share attributable to common shareholders—diluted	$ 0.06	$ (0.53)	$ 2.60	$ (2.30)
Weighted average common shares outstanding—basic	69,609,342	68,970,730	69,382,275	68,576,810
Weighted average common shares outstanding—diluted	71,369,394	68,970,730	70,421,322	68,576,810

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

	As of	
	December 31, 2022	December 31, 2021
Cash, cash equivalents, and short-term investments	$ 190,608	$ 182,201
Working capital	195,994	151,622
Total assets	459,672	232,800
Accumulated deficit	(492,034)	(675,397)
Total shareholders' equity	396,149	185,037