OnKure Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Business Highlights

March 10, 2025

— PIKture-01 trial update including additional PK data, mature single agent and initial combination data expected in the second half of 2025; reported encouraging preliminary data in December 2024

— Expansion of PI3Kα franchise to include a pan-mutant selective program; development candidate expected to be announced in Q2 2025

— $111M in cash and cash equivalents expected to be sufficient to fund operations through multiple PIKture-01 clinical readouts and anticipated milestones into Q4 2026

BOULDER, Colo., March 10, 2025 (GLOBE NEWSWIRE) -- OnKure Therapeutics, Inc. (Nasdaq: OKUR), a clinical-stage biopharmaceutical company focused on developing novel precision medicines in oncology, today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided recent business highlights.

“I am extremely pleased with the progress we made last year. With three PI3Ka inhibitor programs, including one in clinical development and a second development candidate expected next quarter, we are committed to developing product candidates that address the needs of patients who suffer from diseases implicated by PI3Ka, which is a key mediator in cancer growth signaling,” said Nicholas Saccomano, Ph.D., President and Chief Executive Officer of OnKure.

“The extensive expertise of our research and development team in discovering development candidates with favorable drug properties is our strength, and the entire OnKure team is contributing to the execution of our strategy. This year, we expect to report additional OKI-219 data from PIKture-01, announce our pan-mutant inhibitor program, and declare plans to initiate additional clinical trials,” concluded Dr. Saccomano.

Recent Business Highlights and Upcoming Anticipated Milestones

- **PIKture-01 trial Part A Monotherapy** – In December 2024, OnKure announced encouraging preliminary safety, tolerability, and pharmacokinetic (“PK”) data from the part A single-agent arm of PIKture-01 with a data cut-off of October 28, 2024. These preliminary data showed OKI-219 was well tolerated across all dose levels, with no hyperglycemia, stomatitis, or rash observed. Additionally, only grade 1 treatment-related adverse events (“TRAEs”) were reported with no dose interruptions, delays, reductions, or discontinuations reported for any adverse events. To date, OnKure has completed the enrollment of patients in the Part A monotherapy arm of PIKture-01 through the 1200 mg BID cohort level with no dose limiting toxicities observed in the completed cohorts. OnKure is currently enrolling the last cohort with a top dose of 1500 mg BID and enrollment in Part A is almost complete. OnKure expects to provide a clinical update in the second half of 2025.

- **PIKture-01 Part B Fulvestrant Combination** – In the fourth quarter of 2024, OnKure initiated patient dosing in Part B of the PIKture-01 trial, evaluating OKI-219 in combination with fulvestrant in patients with PI3Kα^{H1047R} mutated HR+/HER2- metastatic breast cancer. To date, OnKure has enrolled patients in the Part B fulvestrant combination arm of PIKTure-01 through the 900 mg BID cohort with no dose limiting toxicities observed for all completed cohorts through 600 mg BID and enrollment in the dose escalation portion of Part B is almost complete. OnKure expects to report initial combination data with fulvestrant in the second half of 2025.

- **Pan-mutant Program** – OnKure believes a PI3Kα “pan-mutant” inhibitor will need to demonstrate approximately 10-fold selectivity against each of the most common mutations (PI3Kα^{H1047X}, PI3Kα^{E542K}, and PI3Kα^{E545K}) over wild type. OnKure expects to announce its pan-mutant development candidate in the second quarter of 2025.

- **Merger and Financing** – As previously announced, the merger between OnKure, Inc. and Reneo Pharmaceuticals, Inc. closed on October 4, 2024. Concurrent with the closing of the merger, the company closed a $65 million financing, changed its name to OnKure Therapeutics, Inc. and began trading on the Nasdaq Global Market on October 7, 2024 under the new ticker symbol “OKUR”.

Fourth Quarter 2024 Financial Results

Cash and cash equivalents were approximately $110.8 million as of December 31, 2024.

Research and development (R&D) expenses were $14.4 million for the fourth quarter of 2024, compared to $8.8 million for the fourth quarter of 2023. The increase of $5.6 million was primarily driven by an increase of $3.4 million in clinical trial and

manufacturing related expenses in addition to $2.1 million of higher personnel-related costs, including share-based compensation charges.

General and Administrative (G&A) expenses were $4.3 million for the fourth quarter of 2024, compared to $1.1 million for the fourth quarter of 2023. The increase of $3.2 million was primarily driven by an increase in personnel-related costs of $2.0 million and an increase in consulting and professional service expenses of $1.2 million including, audit, tax, insurance, board of director compensation and other consulting expenses.

Net loss and net loss per share for the fourth quarter of 2024 were $17.4 million or $1.37 per share, compared to $9.5 million, or $30.14 per share, for the fourth quarter of 2023.

About OnKure Therapeutics

OnKure Therapeutics (Nasdaq: OKUR) is a clinical-stage biopharmaceutical company focused on the discovery and development of best-in-class precision medicines that target biologically validated drivers of cancers that are underserved by available therapies. Using a structure-based drug design platform, OnKure is building a pipeline of tumor-agnostic candidates that are designed to achieve optimal efficacy and tolerability. OnKure is currently developing OKI-219, a selective PI3Kα^{H1047R} inhibitor, as its lead program. OnKure aims to become a leader in targeting oncogenic PI3Kα and has multiple programs designed to enable best-in-class targeting of this key oncogene.

For more information about OnKure, visit us at www.onkure.com and follow us on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the potential of, and expectations regarding, OnKure's product candidates and programs, including OKI-219; the pan-mutant program; OnKure's ability to advance additional programs; the expected milestones and timing of such milestones, including additional data for OKI-219 from the PIKture-01 trial, anticipated development candidate announcements and OnKure's discovery stage programs; and statements regarding OnKure's financial position, including its liquidity, cash runway and the sufficiency of its cash resources. In some cases, you can identify forward-looking statements by terminology such as "estimate," "intend," "may," "plan," "potentially" "will" or the negative of these terms or other similar expressions.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things, OnKure's limited operating history; the significant net losses incurred since inception; the ability to raise additional capital to finance operations; the risk that actual uses of cash and cash equivalents differ from the assumptions underlying our expected cash runway; the ability to advance product candidates through preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, OnKure's product candidates; the outcome of preclinical testing and early clinical trials for OnKure's product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements and the potential that the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials; OnKure's limited resources; the risk of adverse events, toxicities or other undesirable side effects; potential delays or difficulties in the enrollment or maintenance of patients in clinical trials; the decision to develop or seek strategic collaborations to develop OnKure's current or future product candidates in combination with other therapies and the cost of combination therapies; OnKure's limited experience in designing clinical trials and lack of experience in conducting clinical trials; the substantial competition OnKure faces in discovering, developing, or commercializing products; OnKure's ability to protect its intellectual property and proprietary technologies; developments relating to OnKure's competitors and its industry, including competing product candidates and therapies; reliance on third parties, contract manufacturers, and contract research organizations; legislative, regulatory, political and economic developments and general market conditions; and those risks described in the section entitled "Risk Factors" in documents that OnKure files from time to time with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K filed with the SEC on March 10, 2025 and any subsequent filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this press release.

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ONKURE THERAPEUTICS, INC.
Consolidated Condensed Balance Sheets
(In thousands, unaudited)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 110,761	$ 29,876
Prepaid expenses and other current assets	2,242	3,890
Total current assets	113,003	33,766
Property and equipment, net	1,025	1,432
Operating lease, right-of-use asset	770	478
Other assets	109	58
Total assets	$ 114,907	$ 35,734
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable, accrued expenses, and other liabilities	$ 9,994	$ 7,077
Operating lease liabilities, current portion	536	208
Total current liabilities	10,530	7,285
Long-term operating lease liabilities	549	466
Total liabilities	11,079	7,751
Convertible preferred stock	—	129,825
Stockholders' equity (deficit)	103,828	(101,842)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 114,907	$ 35,734

ONKURE THERAPEUTICS, INC.
Consolidated Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data, unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 14,361	$ 8,825	$ 43,795	$ 32,115
General and administrative	4,338	1,067	10,591	4,819
Total operating expenses	18,699	9,892	54,386	36,934
Loss from operations	(18,699)	(9,892)	(54,386)	(36,934)
Total other income and (expense), net	1,257	437	1,713	1,623
Net loss and comprehensive loss	$ (17,442)	$ (9,455)	$ (52,673)	$ (35,311)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (1.37)	$ (30.14)	$ (15.28)	$ (124.41)
Weighted average shares outstanding:				
Basic and diluted	12,774,553	313,652	3,447,071	283,817