OnKure Announces Closing of Merger with Reneo Pharmaceuticals and Concurrent Private Placement of $65 Million

October 4, 2024

-- OnKure is focused on advancing a pipeline of candidates targeting oncogenic mutations in phosphoinositide 3-kinase alpha (PI3Kα), initially in breast cancer

-- On track to announce early clinical data for its lead program, OKI-219, in Q4-2024

-- Post-transaction cash, cash equivalents, and short-term investments of approximately $139 million expected to provide funding through multiple clinical readouts and runway into Q4-2026

-- Shares to trade on Nasdaq under the new ticker symbol "OKUR" commencing on October 7, 2024

BOULDER, Colo., Oct. 04, 2024 (GLOBE NEWSWIRE) -- OnKure Therapeutics, Inc. (Nasdaq: OKUR) ("OnKure"), a clinical-stage biopharmaceutical company focused on the development of novel precision medicines in oncology, today announced the completion of its previously announced merger of OnKure, Inc. and Reneo Pharmaceuticals, Inc. ("Reneo"). The combined company will operate under the name OnKure Therapeutics, Inc., and its shares are expected to begin trading on the Nasdaq Global Market on October 7, 2024 under the ticker symbol "OKUR".

Concurrent with the closing of the merger, the company completed a $65 million private placement with a group of new and existing investors, including Acorn Bioventures, Cormorant Asset Management, Deep Track Capital, Perceptive Advisors, Samsara BioCapital, Surveyor Capital (a Citadel company), Vestal Point Capital, and other undisclosed investors. Following the transactions, OnKure is expected to have a cash runway through multiple clinical readouts and into Q4-2026.

"We are ecstatic to finalize this merger, and move to accelerate the development of our mutant-specific PI3Kα inhibitor portfolio. Combined with our unique expertise in PI3K-mutated cancers, we aim to fully target and exploit the vulnerabilities of this oncogenic menace for the benefit of patients suffering needlessly," said Nicholas Saccomano, Ph.D., President and Chief Executive Officer of OnKure. "Our lead program OKI-219, a highly selective inhibitor of PI3Kα^{H1047R}, has the potential to provide benefit to breast cancer patients. With the PIKture-01 trial of OKI-219 well underway, we look forward to releasing early clinical data in the fourth quarter of 2024 and initiating planned combination arms of the PIKture-01 trial."

Transaction Details

In connection with the closing of the merger, Reneo effected a 1-for-10 reverse stock split of its common stock. Following the reverse stock split and based on the final exchange ratios of 0.0236 shares of Reneo common stock for each share of OnKure common stock and 0.1448 shares of Reneo common stock for each share of OnKure preferred stock, at the closing of the merger there were approximately 13.3 million shares of common stock outstanding, with prior Reneo stockholders owning approximately 31.8% and prior OnKure, Inc. stockholders holding approximately 68.2% of the combined company's outstanding common stock before the concurrent financing. Following the consummation of the private placement of $65.0 million of newly issued common stock, prior OnKure, Inc. stockholders own approximately 53.6%, prior Reneo stockholders own approximately 25.1%, and the private placement investors own approximately 21.3% of the combined company's outstanding stock.

Leerink Partners served as exclusive financial advisor for Reneo. Jones Day and Cooley LLP served as legal counsel for Reneo for the transactions. Leerink Partners, Evercore ISI and LifeSci Capital served as the placement agents for the private placement financing. Covington & Burling LLP served as legal counsel to the placement agents in connection with the private placement financing. Oppenheimer & Co. served as capital markets advisor to OnKure, Inc., and Wilson Sonsini Goodrich & Rosati, P.C. served as legal counsel to OnKure, Inc.

Leadership Team and Board of Directors Updates

The combined company will be led by Nicholas A. Saccomano, Ph.D. as President and Chief Executive Officer of OnKure. In addition to Dr. Saccomano, the OnKure leadership team includes Samuel Agresta, M.D., as Chief Medical Officer, Dylan Hartley, Ph.D., as Chief Scientific Officer, and Jason Leverone, as Chief Financial Officer.

The Board of Directors of OnKure will be composed of Dr. Saccomano, Isaac Manke, Ph.D., R. Michael Carruthers, Andrew Philips, Ph.D., who join from OnKure, Inc.'s Board of Directors, Michael Grey and Edward T. Mathers, who continue from Reneo's Board of Directors, and Valerie M. Jansen, who joined the Board at the closing of the merger.

About PI3Kα and OKI-219

PI3Kα is the most frequently mutated oncogene in cancers, and PI3Kα^{H1047R} is the most common mutation in this gene, being found in 15% of breast cancer and 4% of cancers overall. While novel drugs targeting PI3Kα have been approved for treatment, the lack of mutant selectivity of these therapeutics drives considerable on-target toxicity by inhibiting the normal version of this protein in various tissues.

OnKure is discovering and developing a portfolio of highly mutant-selective PI3Kα inhibitors with the goal of improving efficacy and safety with molecules that fully inhibit the mutant oncogene while sparing the wild-type enzyme in normal tissues. OnKure's lead product candidate, OKI-219, is an orally bioavailable, highly selective inhibitor of PI3Kα^{H1047R} with approximately 80-fold selectivity for the mutated form of the enzyme compared to wild-type. OnKure believes that the wild-type-sparing properties of OKI-219 should significantly improve the activity and safety relative to currently approved PI3Kα inhibitors. Currently, OKI-219 is being evaluated in a Phase 1 clinical trial in solid tumor patients with PI3Kα^{H1047R} mutations, including breast cancer.

About OnKure

OnKure 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 robust 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.

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; OnKure's ability to advance additional programs; the expected milestones and timing of such milestones, including for OKI-219 and its discovery 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.

The company 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, 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 Reneo's Quarterly Report on Form 10-Q filed with the SEC on August 13, 2024 and the final 424B3 proxy statement/prospectus filed with the SEC on August 26, 2024. 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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