Olema Oncology Announces FDA Clearance of Investigational New Drug Application for OP-3136, a Potent KAT6 Inhibitor

December 9, 2024

- *Phase 1 clinical trial for OP-3136 to initiate in early 2025*

SAN FRANCISCO, Dec. 09, 2024 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. (“Olema” or “Olema Oncology”, Nasdaq: OLMA), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of targeted therapies for breast cancer and beyond, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for OP-3136, a novel small molecule that potently and selectively inhibits KAT6, a validated epigenetic target that is dysregulated in breast and other cancers.

"We are very pleased to have received notification from the FDA that OP-3136 may proceed into the clinic,” said David C. Myles, Ph.D., Chief Discovery and Non-Clinical Development Officer of Olema Oncology. “The compelling activity demonstrated by OP-3136 in preclinical models both as a single agent and in combination with palazestrant has generated strong investigator interest in OP-3136. We expect to initiate the Phase 1 clinical trial early next year and are excited by OP-3136’s potential in breast cancer and beyond.”

About Olema Oncology
Olema Oncology is a clinical-stage biopharmaceutical company committed to transforming the standard of care and improving outcomes for patients living with breast cancer and beyond. Olema is advancing a pipeline of novel therapies by leveraging our deep understanding of endocrine-driven cancers, nuclear receptors, and mechanisms of acquired resistance. Our lead product candidate, palazestrant (OP-1250), is a proprietary, orally available complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), currently in a Phase 3 clinical trial called OPERA-01. In addition, Olema is developing a potent KAT6 inhibitor (OP-3136). Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit us at www.olema.com.

Forward Looking Statements
Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Words such as “anticipate,” “believe,” “could,” “expect,” “goal,” “may,” “potential,” “upcoming,” “will” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements include those related to the advancement of OP-3136 into clinical development, including timelines for initiation and enrollment, the combinability of OP-3136 with other drugs and potential beneficial characteristics of OP-3136 as a monotherapy and in combination with other drugs. Because such statements deal with future events and are based on Olema’s current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of Olema could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, those discussed in the section titled “Risk Factors” in Olema’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, and other filings and reports that Olema makes from time to time with the U.S. Securities and Exchange Commission. Except as required by law, Olema assumes no obligation to update these forward-looking statements, including in the event that actual results differ materially from those anticipated in the forward-looking statements.

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