Olema Oncology Receives FDA Fast Track Designation for OP-1250 for the Treatment of ER+ / HER2- Metastatic Breast Cancer

July 21, 2022

SAN FRANCISCO, July 21, 2022 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. (“Olema” or “Olema Oncology,” Nasdaq: OLMA) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to OP-1250, the Company's novel, oral complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD), for the treatment of ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a cyclin-dependent kinase (CDK) 4/6 inhibitor. OP-1250 is currently being evaluated as a single agent in an ongoing Phase 1/2 clinical trial and in Phase 1b combination with palbociclib in patients with recurrent, locally advanced, or metastatic ER+/HER2- breast cancer.

“Receiving Fast Track designation from the FDA for OP-1250 is an important milestone for the development program and underscores OP-1250’s potential clinical utility to address a significant unmet medical need in women living with advanced ER+/HER2- breast cancer,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “We look forward to working closely with the FDA to optimize and expedite the development program, with the goal of making OP-1250 available to patients sooner.”

Fast Track is an FDA process designed to facilitate the development and expedite the review of potential therapies that seek to treat serious conditions and fill an unmet medical need. A drug candidate that receives Fast Track designation is eligible for more frequent communication with the FDA throughout the drug development process for the purpose of expediting the drug's development, review, and potential approval. Additionally, the designation allows for eligibility for and a rolling and/or priority review of its marketing application if relevant criteria are met.

About Olema Oncology

Olema Oncology is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted therapies for women’s cancers. Olema’s lead product candidate, OP-1250, is an orally-available small molecule with combined activity as both a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD). It is currently being evaluated as a single agent in an ongoing Phase 1/2 clinical trial, and in Phase 1b combination with palbociclib, in patients with recurrent, locally advanced, or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts.

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,” “expect,” “intend,” “will,” “may,” “goal,” “estimate,” “potential” 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 development of OP-1250, including the timeline to develop OP-1250, the clinical utility of OP-1250, and the expected benefits of FDA Fast Track designation. 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, the risk that Olema’s ongoing or future clinical studies in humans may show that OP-1250 is not a tolerable and effective treatment for breast cancer and other risks and uncertainties affecting Olema, as well as those discussed in the section titled “Risk Factors” in Olema’s Annual Report on Form 10-Q for the quarter ended March 31, 2022 and filed on May 9, 2022 and future filings and reports that Olema makes from time to time with the United States Securities and Exchange Commission. Except as required by law, Olema assumes no obligation to update these forward-looking statements or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

Contact:
Eva Stroynowski
Vice President, Communications and Investor Relations
eva@olema.com