Olema Oncology Announces Expansion of Collaboration Agreement with Novartis

October 10, 2023

Amended clinical collaboration and supply agreement increases the palazestrant/ribociclib combination Phase 1/2 clinical study size to approximately 60 patients

Expanded study supports the potential late-stage development of palazestrant in first-line advanced or metastatic breast cancer in combination with ribociclib

SAN FRANCISCO, Oct. 10, 2023 (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 women's cancers, today announced an amendment to our existing clinical collaboration and supply agreement with Novartis Institutes for BioMedical Research, Inc. ("Novartis") to increase the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib to approximately 60 patients.

"The amendment announced today significantly increases the size of our ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib, in collaboration with Novartis," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "With the Phase 1b dose escalation portion now successfully completed, we are currently in Phase 2 dose expansion at the 120 mg dose of palazestrant in combination with 600 mg of ribociclib. We believe that this expanded study now has the potential to generate a clinical dataset sufficient to support the regulatory pathway for a first-line pivotal trial."

Olema first signed a clinical collaboration and supply agreement with Novartis in July 2020, the agreement was amended and restated in January 2022, and focuses on the evaluation of the safety, tolerability and efficacy of palazestrant in combination with Novartis' proprietary cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor ribociclib and/or Novartis' proprietary phosphatidylinositol 3-kinase (PI3Ka) inhibitor alpelisib in patients with metastatic ER+ breast cancer. The amendment adds approximately 30 patients to be enrolled in the cohort expansion phase of the palazestrant clinical study in combination with ribociclib.

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, palazestrant (OP-1250), is a proprietary, orally-available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD). It is currently being evaluated both as a single agent in an ongoing Phase 2 clinical trial, and in combination with CDK4/6 inhibitors (palbociclib and ribociclib) and a PI3Ka inhibitor (alpelisib), in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. Palazestrant has been granted FDA Fast Track designation for the treatment of ER+/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 CDK4/6 inhibitor. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit us at www.olema.com, or follow us on Twitter and LinkedIn.

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," "will," "may," "goal," "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 timelines for potential clinical trials of palazestrant (OP-1250) in combination trials, the potential impact and sufficiency of clinical trial results for clinical trial timelines for palazestrant in combination trials, palazestrant's combinability with other drugs, patient enrollment, and statements regarding Olema's partnerships and collaborations. 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 June 30, 2023, and future 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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