Olema Oncology Announces New Clinical Trial Agreement with Pfizer to Combine Palazestrant with Atirmociclib in ER+/HER2- Metastatic Breast Cancer

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- *Study to explore the palazestrant-atirmociclib combination in approximately 35 patients with initiation anticipated in H2 2025*
- *Results to inform potential pivotal Phase 3 trial of novel combination in frontline metastatic breast cancer setting*

SAN FRANCISCO, Sept. 02, 2025 (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 a new clinical trial collaboration and supply agreement with Pfizer Inc. (NYSE: PFE) in metastatic breast cancer. The companies will evaluate in a Phase 1b/2 study the safety and combinability of palazestrant plus atirmociclib, Pfizer’s investigational, highly selective-CDK4 inhibitor, in patients with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) metastatic breast cancer.

"We are excited to assess this combination in the clinic as we seek to establish palazestrant as a potential backbone endocrine therapy for metastatic breast cancer,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “Based on the promising profiles of palazestrant and atirmociclib to date, we look forward to evaluating the potential of this novel combination and, if successful, advancing to a pivotal trial in the frontline setting. With OPERA-01, our first pivotal study of palazestrant, underway and our OPERA-02 ribociclib combination trial in frontline metastatic breast cancer anticipated to initiate this quarter, we remain focused on achieving our goal of transforming the metastatic breast cancer treatment paradigm.”

Under the terms of the agreement, Pfizer will supply atirmociclib for use in the Phase 1b/2 study and Olema will lead the conduct of the study. All clinical data and inventions relating to the combined use of atirmociclib and palazestrant resulting from the study will be jointly owned, with Olema maintaining full global commercial and marketing rights to palazestrant.

This announcement represents Olema’s second clinical trial agreement with Pfizer. The companies’ previous agreement was established in November 2020 to evaluate palazestrant in combination with palbociclib (IBRANCE®) in patients with recurrent, locally advanced or metastatic ER+/HER2- breast cancer.

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 OP-3136, a potent lysine acetyltransferase 6 (KAT6) inhibitor, now in a Phase 1 clinical study. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit www.olema.com.

About Palazestrant (OP-1250)
Palazestrant (OP-1250) is a novel, orally available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD). It is currently being investigated in patients with recurrent, locally advanced or metastatic ER-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. In clinical studies, palazestrant completely blocks ER-driven transcriptional activity in both wild-type and mutant forms of metastatic ER+ breast cancer and has demonstrated anti-tumor efficacy along with attractive pharmacokinetics and exposure, favorable tolerability, central nervous system penetration, and combinability with cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. Palazestrant has been granted U.S. Food and Drug Administration (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. It is being evaluated as a single agent in the ongoing pivotal Phase 3 clinical trial, OPERA-01 and is anticipated to be evaluated in combination with ribociclib in the planned pivotal Phase 3 clinical trial, OPERA-02. Learn more at www.opera01study.com. Palazestrant has also been evaluated in multiple Phase 1/2 studies in combination with ribociclib, palbociclib, alpelisib, and everolimus.

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,” “plan,” “potential,” “seek,” “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 potential of palazestrant to become a backbone endocrine therapy for

metastatic breast cancer, Olema's potential to transform the metastatic breast cancer treatment paradigm, the timing for initiation, enrollment, and results of Olema's existing and planned clinical trials, including OPERA-01 and OPERA-02, the potential beneficial characteristics, safety, tolerability, efficacy, and therapeutic effects of palazestrant as a single agent or in combination therapy, and the ownership of clinical data, commercial rights, marketing rights and inventions relating to the combined use of palazestrant and atirmociclib. 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, 2025, 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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