



Olema Oncology Announces Palazestrant Dose Selection and Trial-in-Progress Poster at ASCO 2025 Annual Meeting

May 28, 2025

- 90 mg once-daily palazestrant dose selected for Part 2 of the Phase 3 OPERA-01 monotherapy trial and for the Phase 3 OPERA-02 combination trial with ribociclib
- OPERA-01 trial-in-progress poster to be presented on Monday, June 2 between 9:00am–12:00pm CT / 10:00am–1:00pm ET

SAN FRANCISCO, May 28, 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 it has aligned with the U.S. Food and Drug Administration (FDA) to select 90 mg of palazestrant as the dose for Part 2 of the ongoing registrational Phase 3 OPERA-01 trial in second- and third-line estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) metastatic breast cancer. This update will be presented as part of the OPERA-01 trial-in-progress poster at the American Society of Clinical Oncology (ASCO) Annual Meeting taking place May 30-June 3 in Chicago, Illinois. The FDA also selected 90 mg of palazestrant in combination with the approved dose of CDK4/6 inhibitor ribociclib for the pivotal Phase 3 OPERA-02 trial in frontline ER+/HER2- metastatic breast cancer.

"Metastatic breast cancer treatment continues to be challenged by resistance mechanisms resulting in a clear need for innovative new therapies. We believe the clinical results we have achieved to date for palazestrant across *ESR1* mutant and wild-type ER+/HER2- tumors, both in the monotherapy and combination treatment settings, support palazestrant's potential to have a significant positive impact on breast cancer patients," said Naseem Zojwalla, M.D., Chief Medical Officer of Olema Oncology. "We remain steadfast in our commitment to these patients, and with 90 mg of palazestrant confirmed as the selected dose, we are focused on rapidly advancing our OPERA-01 and OPERA-02 pivotal trials with top-line data from OPERA-01 anticipated in 2026 and a potential commercial launch in 2027."

Poster Presentation Details

Title: OPERA-01: A randomized, open-label, phase 3 study of palazestrant (OP-1250) monotherapy vs standard-of-care endocrine therapy for patients with ER+, HER2- advanced breast cancer after endocrine and CDK4/6 inhibitor therapy

Abstract Number: TPS1131

Poster Number: 104b

Poster Session: Breast Cancer – Metastatic

Date/Time: June 2, 2025 from 9:00am–12:00pm CT / 10:00am–1:00pm ET

Additional information can be found on the ASCO [Annual Meeting website](#), including abstracts. A copy of the poster will be made available on the [Publications](#) page of Olema's website in alignment with ASCO's embargo policy.

About Palazestrant (OP-1250)

Palazestrant (OP-1250) is a novel, orally available small molecule with dual activity as both a complete estrogen receptor antagonist (CERAN) and selective estrogen receptor 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. Learn more at www.opera01study.com. Palazestrant is also being evaluated in multiple Phase 1/2 trials in combination with ribociclib, palbociclib, alpelisib, and everolimus. It will also be evaluated in combination with ribociclib in the planned pivotal Phase 3 trial, OPERA-02.

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 trial. Olema is headquartered in San Francisco and has operations in Cambridge, Massachusetts. For more information, please visit 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 potential of palazestrant to have a significant positive impact on breast cancer patients, the timing for initiation, enrollment, and results of Olema’s clinical trials, the timing of a potential commercial launch for palazestrant, and the potential beneficial characteristics, safety, tolerability, efficacy, and therapeutic effects of palazestrant. 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 March 31, 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.

Media and Investor Relations Contact

Courtney O’Konek
Vice President, Corporate Communications
Olema Oncology
media@olema.com