



Olema Oncology Announces Encouraging Initial Clinical Data from the Phase 1 Study of OP-3136, a KAT6 Inhibitor, at 2026 ASCO Annual Meeting

May 21, 2026

- *OP-3136 monotherapy was well-tolerated with no dose-limiting toxicities observed and no discontinuations due to treatment-related adverse events*
- *OP-3136 shows evidence of anti-tumor activity across multiple solid tumor types*
- *Data support the ongoing Phase 1 evaluation of OP-3136 as a monotherapy and in combination with fulvestrant and palazestrant*

SAN FRANCISCO, May 21, 2026 (GLOBE NEWSWIRE) -- [Olema Pharmaceuticals, Inc.](#) ("Olema" or "Olema Oncology", Nasdaq: OLM), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of targeted therapies for breast cancer and beyond, today announced preliminary clinical data from the Phase 1 study of OP-3136, a potent lysine acetyltransferase 6 (KAT6) inhibitor. The data will be presented in a poster presentation on May 30, 2026 at the American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, Illinois. Olema will also present a trial-in-progress poster for the Phase 3 OPERA-02 trial of palazestrant in combination with ribociclib in frontline estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) metastatic breast cancer.

"We are pleased to share the initial Phase 1 data for OP-3136, which demonstrated acceptable tolerability and promising anti-tumor activity as a monotherapy across multiple dose levels in various advanced solid tumor types," said Sean P. Bohlen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "The decreases in tumor size observed in over two-thirds of evaluable patients and evidence of on-target engagement reinforce our confidence in OP-3136 as a potential best-in-class KAT6 inhibitor and a potentially differentiated option for difficult-to-treat cancers. We look forward to progressing OP-3136 in development, particularly in combination with palazestrant in metastatic breast cancer."

The Phase 1 study evaluates dose escalation followed by dose expansion of OP-3136 in patients with ER+/HER2- advanced breast cancer (ABC), metastatic castration-resistant prostate cancer (mCRPC), and metastatic non-small cell lung cancer (mNSCLC). In Part 1A, OP-3136 monotherapy was administered orally once daily in 28-day cycles across dose levels from 2 mg to 45 mg. As of the March 2, 2026 data cut-off, 32 heavily pretreated patients who became resistant or intolerant to standard of care treatments were enrolled in this cohort.

Key Findings

Safety and Tolerability

- OP-3136 monotherapy was well-tolerated with no dose-limiting toxicities observed across the evaluated daily dose range up to 45 mg per day orally.
- Most treatment-related adverse events (TRAEs) were grade 1 or 2; no grade 4 or 5 TRAEs were observed. TRAEs were manageable with dose modifications; no treatment discontinuations occurred due to TRAEs.
- The most common TRAEs were dysgeusia (81% any grade; 56% grade 1, 25% grade 2), anemia (38% any grade; 6% grade 3), and neutropenia (34% any grade; 28% grade 3).

Efficacy and Target Engagement

- Among 19 response-evaluable patients across dose levels and tumor types, tumor shrinkage was observed in 13 patients; partial responses (PR) were observed in 3 patients with measurable disease, with 2 confirmed PRs and 1 unconfirmed PR.
- The longest duration of treatment is 62 weeks.
- 11 patients remain on treatment, including 9 with ABC and 2 with mCRPC.
- Across all doses tested, OP-3136 demonstrated rapid, sustained, and significant reduction in levels of lysine 23 of histone H3, a direct target of KAT6, consistent with on-target KAT6 inhibition.

Pharmacokinetics

- OP-3136 exhibited predictable, dose-proportional plasma exposure across all doses tested.
- At doses of 6 mg and above, steady-state concentrations exceeded efficacy targets based on preclinical models.

"These initial results from the Phase 1 study of OP-3136, including confirmed and durable responses and a manageable safety profile in a heavily pretreated population, underscore the potential of KAT6 inhibition as a therapeutic strategy in different solid

tumor types,” said Amita Patnaik, MD, FRCPC, Principal Investigator, Co-Founder, and Co-Director of Clinical Research at the START Center for Cancer Research. “Supported by evidence of target engagement and predictable pharmacokinetics across all doses evaluated to date, I am excited to further evaluate this novel therapy, both as a monotherapy and in combination with multiple agents, as Phase 1 development continues.”

OP-3136 Poster Presentation Details

Title: A phase 1, first-in-human study of OP-3136, a novel oral selective KAT6A/B inhibitor, as monotherapy in advanced solid tumors and in combination with endocrine therapy in ER+, HER2- advanced breast cancer: preliminary results

Abstract Number: 3088

Poster Number: 225

Date/Time: May 30, 2026 from 1:30pm-4:30pm CT / 2:30pm-5:30pm ET

OPERA-02 Trial-in-Progress Poster Presentation Details

Olema will also present a trial-in-progress poster for the Phase 3 OPERA-02 trial of palazestrant in combination with ribociclib in frontline ER+/HER2- metastatic breast cancer.

Title: OPERA-02: A phase 3 study of palazestrant plus ribociclib as first-line treatment of ER+, HER2- advanced breast cancer

Abstract Number: TPS1152

Poster Number: 261b

Date/Time: June 1, 2026 from 1:30pm-4:30pm CT / 2:30pm-5:30pm ET

Copies of these posters will be available on the [Publications](#) page of Olema’s website in alignment with the ASCO embargo. Additional information, including abstracts, is available on the ASCO Annual Meeting [website](#).

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 antagonist (CERAN) and a selective estrogen receptor degrader (SERD), currently in two Phase 3 clinical trials. 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 OP-3136

OP-3136 is a novel, orally available small molecule that potently and selectively inhibits lysine acetyltransferase 6 (KAT6), an epigenetic target that is dysregulated in breast and other cancers. In preclinical studies, OP-3136 has demonstrated significant anti-proliferative activity in ER+ breast cancer models and is combinable and synergistic with endocrine therapies, including palazestrant and cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. The Investigational New Drug (IND) application for OP-3136 was cleared by the U.S. Food and Drug Administration (FDA) in December 2024 and patients are currently enrolling in the Phase 1 clinical study.

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,” “intend,” “may,” “on track,” “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 beneficial characteristics including but not limited to safety, tolerability, activity, efficacy and therapeutic effects of OP-3136 and the combinability of OP-3136 with other therapies, including palazestrant and fulvestrant; the potential of OP-3136 to be a best-in-class KAT6 inhibitor and differentiated therapy for difficult-to-treat cancers; and the continued development and advancement of OP-3136, including in combination with other therapies such as fulvestrant and 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, 2026, 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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