Olema Oncology Provides Clinical Update Reflecting Strong Progress Across OP-1250 Development Program

June 9, 2022

- *Favorable tolerability with no grade 3/4 neutropenia and encouraging anti-tumor activity across Phase 1b monotherapy expansion*
- *Combinability with CDK4/6i palbociclib demonstrated across initial dose escalation cohorts, including no dose limiting toxicities and no induced metabolism of palbociclib*
- *Rapidly advancing the development of OP-1250 for ER+ / HER2- breast cancer with pivotal monotherapy study planned for 2023 initiation*

SAN FRANCISCO, June 09, 2022 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. ("Olema" or "Olema Oncology," Nasdaq: OLMA) today announced clinical development progress for OP-1250, a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD) in development for the treatment of metastatic breast cancer.

"We are extremely pleased with the emerging clinical profile of OP-1250 and the encouraging progress achieved over the last six months. High investigator enthusiasm has led to rapid enrollment across the development program. In our Phase 1b monotherapy dose expansion, we have seen favorable tolerability and encouraging early anti-tumor activity. In the Phase 1b combination trial with palbociclib, two initial cohorts have completed the dose limiting toxicity evaluation period and we have demonstrated combinability for OP-1250 with no induced metabolism of palbociclib," said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. "We are entering an exciting period with the selection of our Recommended Phase 2 Dose later this month, followed by enrollment in our Phase 2 cohorts and plans to initiate an additional Phase 1b combination trial with each of ribociclib and alpelisib. We expect these datasets will further validate OP-1250's clinical profile and lay the foundation for our planned pivotal monotherapy study to begin next year."

Olema continues to be well capitalized with sufficient cash to fund our planned research and development operations into the second half of 2024. As of June 1, 2022, Olema reported the following clinical updates and anticipated milestones for the OP-1250 development program:

Phase 1b Monotherapy Expansion

- Successfully achieved 30 patient targeted enrollment (N=15 each for 60 and 120 mg dose cohorts).
- Favorable tolerability demonstrated, with no grade 3/4 neutropenia and no adverse events that led to discontinuation.
- Encouraging anti-tumor activity observed, including unconfirmed partial responses (uPRs) in the initial group of patients eligible for efficacy evaluation.

Phase 1b Combination with Palbociclib (a CDK4/6 inhibitor)

- Dose escalation progressing as planned. Two initial cohorts have completed the dose limiting toxicity (DLT) evaluation period (30 and 60 mg cohorts), and the 90 mg dose cohort is ongoing.
- Combinability demonstrated in initial cohorts, including no DLTs, tolerability consistent with the expected profile of palbociclib plus endocrine therapy, and no induced metabolism of palbociclib.

Anticipated Milestones

- Select the Recommended Phase 2 Dose (RP2D) for OP-1250 in June 2022, followed by enrollment in the Phase 2 portion of the trial. Phase 2 will include enrollment across three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15) and patients with CNS metastasis (N=15).
- Initiate a Phase 1b combination study with each of ribociclib, a CDK4/6 inhibitor, and alpelisib, a PI3Kα inhibitor, in Q3 2022.
- Present updated monotherapy and initial combination data for OP-1250 in 2H 2022.
- Initiate a pivotal monotherapy study for OP-1250 in 2023.

Dr. Bohen will discuss these developments in further detail during a fireside chat today, Thursday, June 9, 2022, at the Jefferies Healthcare Conference at 8:30 a.m. ET. A live webcast of this presentation may be accessed under the Investors & Media section of Olema's website (www.olema.com) and will be archived for 14 days.

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 potential beneficial characteristics, safety, tolerability, efficacy and therapeutic effects of OP-1250, the development of OP-1250, OP-1250's combinability with other drugs, and the timelines for clinical trials of OP-1250 as a monotherapy and in combination trials. 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 year quarter March 31, 2022, 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.

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