Olema Oncology Advances OP-1250 into Phase 2 Monotherapy Expansion in Patients with ER+/HER2- Advanced Breast Cancer

August 9, 2022

SAN FRANCISCO, Aug. 09, 2022 (GLOBE NEWSWIRE) -- Olema Pharmaceuticals, Inc. ("Olema" or "Olema Oncology," Nasdaq: OLMA), today announced the advancement of OP-1250, a complete estrogen receptor (ER) antagonist (CERAN) and a selective ER degrader (SERD), into Phase 2 clinical development for the treatment of ER+/HER2- metastatic breast cancer.

"We are excited about the potential of OP-1250 and are expeditiously advancing the development program as we work to further position OP-1250 as a differentiated CERAN and potential endocrine therapy of choice for ER+ breast cancer." said Naseem Zojwalla, M.D., Chief Medical Officer of Olema Oncology. "Enrollment is underway in Phase 2 monotherapy, and we look forward to further evaluating OP-1250's benefit in treating ER+/HER2- breast cancer patients."

Selection of the recommended Phase 2 dose (RP2D) of 120 mg OP-1250 once-daily was based on pharmacokinetics, safety and tolerability, and encouraging early anti-tumor activity from Phase 1b expansion, which evaluated both 60 mg and 120 mg dose cohorts. As of July 1, 2022, a total of 50 patients had been treated in Phase 1b expansion (N=25 for each cohort).

- Pharmacokinetic analyses demonstrated dose-proportional exposure of OP-1250, high oral bioavailability, and steady-state plasma levels with minimal peak-to-trough variability.
- The majority of reported adverse events were Grade 1 or 2 at both dose levels, and the most common treatment-emergent adverse events occurring in ≥10% of patients were nausea, vomiting, fatigue, and headache, which were similar across both doses.
- Two cases of Grade 4 and one case of Grade 3 neutropenia have been observed in patients in the 120 mg cohort of the Phase 1b expansion. One patient with Grade 4 neutropenia paused treatment for one week, restarted at a lower dose and subsequently had an unconfirmed partial response at the first scan. A second patient had Grade 4 febrile neutropenia with no evidence of infection. The patient discontinued treatment and remains off-study. Concurrent with disease progression at 8 weeks, a third patient had Grade 3 neutropenia, which has since resolved.
- Encouraging early anti-tumor activity continued to be observed, with a total of 4 partial responses in 31 efficacy-evaluable patients in the Phase 1b expansion as of July 1, 2022 (1 confirmed partial response at 60 mg and 3 unconfirmed partial responses, pending confirmation at a subsequent scan, at 120 mg).

Phase 2 enrollment continues and will include three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15), and patients with CNS metastasis (N=15). Olema plans to initiate a pivotal monotherapy trial in mid-2023.

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 a Phase 1b combination trial 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 development of OP-1250, including timelines related to data presentation, trial initiation and advancement, and enrollment, and the beneficial characteristics, safety, efficacy and therapeutic effects of OP-1250. 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, the risk that Olema's ongoing or future clinical studies in humans may show that OP-1250 is not a tolerable and effective treatment for breast cancer and other risks and uncertainties affecting Olema, as well as those discussed in the section titled "Risk Factors" in Olema's Annual Report on Form 10-Q for the quarter ended June 30, 2022 to be filed on August 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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