



New Data from Interim Analysis of Verastem Oncology's RAMP 201 Trial Evaluating Avutometinib and Defactinib in Recurrent Low-Grade Serous Ovarian Cancer to be Presented at the American Society of Clinical Oncology Annual Meeting

April 26, 2023

Registration-Directed RAMP-201 Trial Designed to Address High Unmet Need in Low-Grade Serous Ovarian Cancer, a Unique and Distinct Type of Ovarian Cancer with Limited Treatment Options

BOSTON--(BUSINESS WIRE)--Apr. 26, 2023-- Verastem Oncology, (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today announced that an abstract highlighting updated interim results from Part A of the ongoing Phase 2, registration-directed RAMP 201 trial evaluating avutometinib (VS-6766) and defactinib in patients with low-grade serous ovarian cancer (LGSOC) has been selected for a presentation in a Poster Discussion Session at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 2–6, 2023 in Chicago, IL.

The objective of Part A (selection Phase) of the RAMP201 LGSOC study was to determine the go forward regimen between avutometinib monotherapy or the combination of avutometinib and defactinib to be studied in Part B (expansion Phase) of the study. The efficacy and safety of each regimen were assessed in both KRAS mutant and KRAS wild-type recurrent LGSOC. The ongoing expansion Phase of the trial, which is fully enrolled, will evaluate the efficacy and safety of the regimen selected.

"Building on our breakthrough therapy designation, we are pleased with the continued progress of our LGSOC program and look forward to the presentation of these updated results from the RAMP 201 trial at ASCO 2023," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "LGSOC is a difficult disease to treat and one in need of improved therapies to address this unique ovarian cancer. We are working to bring forward what may be the first therapy specifically approved for patients with LGSOC as quickly as possible."

The Company is in ongoing discussions with the U.S. Food and Drug Administration (FDA) on confirmatory study plans and intends to provide an update after agreement with the FDA. Continued enrollment in the combination arm of RAMP 201 is planned to expand the clinical experience in anticipation of initiation of a confirmatory study.

Details for the ASCO 2023 Annual Meeting presentation are as follows:

Title: Initial efficacy and safety results from ENGOT-ov60/GOG-3052/RAMP 201: A phase 2 study of avutometinib (VS-6766) ± defactinib in recurrent low-grade serous ovarian cancer (LGSOC).

Lead author: Susana Banerjee, Institute of Cancer Research and The Royal Marsden

Abstract #: 5515

Session: Gynecologic Cancer

Poster Session Display Date and Time: 6/5/2023, 1:15 PM-4:15 PM

Poster Discussion Session Date and Time: 6/5/2023, 4:30 PM-6:00 PM

Poster Board Number: 210

About Low-Grade Serous Ovarian Cancer (LGSOC)

Low-grade serous ovarian cancer (LGSOC) is a highly recurrent, chemotherapy-resistant cancer, associated with slow tumor growth and high mortality rate. Approximately 6,000 women in the U.S. and 80,000 worldwide are living with this disease. Mutations in the KRAS gene are present in 30% of cases of LGSOC. LGSOC is most often diagnosed in women between the ages of 45-55 years and has a median survival of approximately ten years. The majority of patients experience severe pain and complications as the disease progresses. Chemotherapy is the standard of care for this disease, with limited treatment options currently available.

About Avutometinib (VS-6766)

Avutometinib is a RAF/MEK clamp that induces inactive complexes of MEK with ARAF, BRAF and CRAF potentially creating a more complete and durable anti-tumor response through maximal RAS pathway inhibition. Avutometinib is currently in late-stage development.

In contrast to other MEK inhibitors, avutometinib blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows avutometinib to block MEK signaling without the compensatory activation of MEK that appears to limit the efficacy of other inhibitors. The U.S. Food and Drug Administration granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK clamp avutometinib, with defactinib, its FAK inhibitor, for the treatment of all patients with recurrent low-grade serous ovarian cancer (LGSOC) regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.

Verastem Oncology is currently conducting clinical trials with its RAF/MEK clamp avutometinib in RAS- driven tumors as part of its (Raf And Mek Program). RAMP 201 is a registration-directed trial of avutometinib in combination with defactinib in patients with recurrent LGSOC. Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS® (sotorasib) and KRAZATI® (adagrasib) in combination with avutometinib in KRAS G12C mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively. As part of the "Therapeutic Accelerator Award" Verastem Oncology received from PanCAN, Verastem Oncology is conducting RAMP 205, a Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a development-stage biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. Our pipeline is focused on novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and focal adhesion kinase (FAK) inhibition. For more information, please visit www.verastem.com.

Forward-Looking Statements Notice

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements related to the potential clinical value of various of its clinical trials and planned interactions with regulators involving Verastem Oncology's lead compound. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "promising" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement.

Applicable risks and uncertainties include the risks and uncertainties, among other things, regarding: the success in the development and potential commercialization of our product candidates, including avutometinib in combination with other compounds, including defactinib, LUMAKRAS and others; the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis or result in unmanageable safety profiles as compared to their levels of efficacy; our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding trial design, labeling and other matters that could affect the timing, availability or commercial potential of our product candidates; whether preclinical testing of our product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for our product candidates is uncertain; that third-party payors (including government agencies) may not reimburse; that there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that our product candidates will experience manufacturing or supply interruptions or failures; that we will be unable to successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned, including as a result of conducting additional studies; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that we or our other collaboration partners may fail to perform under our collaboration agreements; that we may not have sufficient cash to fund our contemplated operations; that we may be unable to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that Secura Bio, Inc. will achieve the milestones that result in payments to us under our asset purchase agreement with Secura Bio, Inc.; that we will be unable to execute on our partnering strategies for avutometinib in combination with other compounds; and that we will not pursue or submit regulatory filings for our product candidates; that our product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients.

Other risks and uncertainties include those identified under the heading "Risk Factors" in Verastem Oncology's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission (SEC) on March 14, 2023 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology's views as of the date hereof, and Verastem Oncology does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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