Verastem Oncology Announces Updated Phase 1/2 FRAME Study Data in Low Grade Serous Ovarian Cancer Selected for a Mini Oral Presentation at the European Society of Medical Oncology Congress 2021

July 27, 2021 at 7:00 AM EDT

BOSTON--(BUSINESS WIRE)--Jul. 27, 2021-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients battling cancer, today announced that an abstract detailing updated results from the ongoing Phase 1/2 FRAME study investigating VS-6766, the Company's RAF/MEK inhibitor, in combination with defactinib, its FAK inhibitor, in patients with low grade serous ovarian cancer (LGSOC) has been selected for a mini oral presentation at the upcoming European Society of Medical Oncology (ESMO) Congress 2021, taking place virtually September 16-21, 2021.

"The investigator-sponsored FRAME study has been instrumental in providing the foundational knowledge regarding the safety, efficacy and durability of the VS-6766/defactinib combination as well as the basis for the breakthrough therapy designation recently granted by the FDA. We are pleased this abstract has been selected for a mini oral presentation at ESMO 2021, and we look forward to further engaging with the medical community regarding these important data," said Jonathan Pachter, Ph.D., Chief Scientific Officer of Verastem Oncology. "Patients with low-grade serous ovarian cancer urgently need better solutions due to low response rates and tolerability issues associated with other therapeutic approaches. The company-sponsored, registration-directed Phase 2 RAMP 201 study is well underway, with top-line results from the selection phase expected during the first half of 2022."

Verastem Oncology is currently evaluating the efficacy and safety of VS-6766 alone and in combination with defactinib in the registration-directed Phase 2 RAMP 201 (**R**af **A**nd **M**ek **P**rogram) (ENGOTov60/GOG3052) trial in patients with recurrent LGSOC.[1]

Details for the ESMO 2021 mini oral presentation are as follows:

Title: Phase I study of the combination of the dual RAF/MEK inhibitor VS-6766 and the FAK inhibitor defactinib: Results of efficacy in low grade serous ovarian cancer
Speaker: Susana Banerjee, *Royal Marsden NHS Foundation Trust*
Presentation #: 725MO
Session: Mini oral – Gynaecological cancers
Date and Time: Sunday, September 19, 2021; 17:50-17:55 CEST

About the VS-6766/Defactinib Combination

The combination of VS-6766 and defactinib has been found to be clinically active in patients with KRAS mutant tumors. In an ongoing investigator-initiated Phase 1/2 FRAME study, the combination of VS-6766 and defactinib is being evaluated in patients with LGSOC, KRAS mutant NSCLC and colorectal cancer (CRC). The FRAME study was expanded to include new cohorts in pancreatic cancer, KRAS mutant endometrioid cancer and KRAS-G12V NSCLC. Verastem Oncology is also supporting an investigator-initiated Phase 2 trial evaluating VS-6766 with defactinib in patients with metastatic uveal melanoma. Verastem Oncology has initiated Phase 2 registration-directed trials of VS-6766 with defactinib in patients with recurrent LGSOC and in patients with recurrent KRAS-G12V mutant NSCLC as part of its RAMP (**R**af **A**nd **M**ek **P**rogram).

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK inhibitor VS-6766, 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.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) (Verastem, Inc.) 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 the RAF/MEK/FAK combination, the potential benefits of Breakthrough Therapy designation and the timing of commencing and completing registration-directed trials for the RAF/MEK/FAK combination. 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 defactinib in combination with VS-6766; 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 labeling and other matters that could affect the 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; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the VS-6766 license agreement; 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 we will be unable to execute on our partnering strategies for defactinib in combination with VS-6766; that we will not pursue or submit regulatory filings for our product candidates; that we do not receive additional proceeds from the contingent payments negotiated in the sale of COPIKTRA; and 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 the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (SEC) on March 18, 2021 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 the Company 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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[1] Clinicaltrials.gov. A Study of VS-6766 v. VS-6766 + Defactinib in Recurrent Low-Grade Serous Ovarian Cancer With and Without a KRAS Mutation. Available at: https://clinicaltrials.gov/ct2/show/NCT04625270?cond=vs6766&draw=2&rank=1. Accessed April 9, 2021.

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Source: Verastem Oncology