Verastem Oncology Announces Investor Conference Call to Discuss Clinical Data from Investigator-initiated RAF/MEK and FAK Combination Study in KRAS Mutant Solid Tumors

April 20, 2020

Conference Call to Discuss Preliminary Clinical Data Being Presented at the American Association for Cancer Research 2020 Virtual Annual Meeting I

Conference Call Scheduled for Monday, April 27, 2020 at 8:00 AM ET

BOSTON--(BUSINESS WIRE)--Apr. 20, 2020-- Verastem, Inc. (Nasdaq:VSTM) (also known as Verastem Oncology), a biopharmaceutical company committed to developing and commercializing new medicines for patients battling cancer, today announced that management will host an investor conference call to discuss the clinical data from the ongoing investigator-initiated study investigating VS-6766, its RAF/MEK inhibitor, in combination with defactinib, its FAK inhibitor, in patients with KRAS mutant advanced solid tumors. The conference call coincides with the presentation of this data at the upcoming American Association for Cancer Research (AACR) 2020 Virtual Annual Meeting I. The investor conference call is scheduled for Monday, April 27, 2020 at 8:00 a.m. ET.

The call will feature members of the Company's management team and Udai Banerji, MBBS, MD, DNB, PhD, FRCP, NIHR Professor of Molecular Cancer Pharmacology at The Institute of Cancer Research and Honorary Consultant in Medical Oncology at The Royal Marsden NHS Foundation Trust, and lead investigator of the clinical study. This is an ongoing investigator-initiated open label, dose escalation and expansion study. Expansion cohorts are currently ongoing in patients with KRAS mutant advanced solid tumors, including low grade serous ovarian cancer (LGSOC), non-small cell lung cancer (NSCLC) and colorectal cancer (CRC).

Verastem Oncology plans to initiate discussions with regulatory authorities during the first half of 2020, with the goal of commencing a registration-directed trial investigating the VS-6766/defactinib combination as soon as possible.

Details for the AACR 2020 Virtual Meeting I presentation are as follows:

Title: Phase 1 study of the combination of a RAF-MEK inhibitor CH5126766 and FAK inhibitor defactinib in an intermittent dosing schedule with expansions in KRAS mutant cancers
Lead author: Udai Banerji, Institute of Cancer Research and The Royal Marsden
Poster #: CT143
Session: VPO.CT01 - Phase I Clinical Trials
Date and Time: Monday, April 27, 2020; 9:00 a.m. to 6:00 p.m. ET
URL: https://www.abstractsonline.com/pp8/#!/9045/presentation/10642

Conference Call and Webcast Information

The Verastem Oncology management team will host a conference call and webcast on Monday, April 27, 2020, at 8:00 AM ET to discuss the Phase 1 RAF/MEK/FAK combination data. The call can be accessed by dialing (877) 341-5660 (U.S. and Canada) or (315) 625-3226 (international), five minutes prior to the start of the call and providing the passcode 8390795.

The live, listen-only webcast of the conference call can be accessed by visiting the investors section of the Company's website at www.verastem.com. A replay of the webcast will be archived on the Company's website for 90 days following the call.

About VS-6766

VS-6766 (formerly known as CH5126766, CKI27 and RO5126766) is a unique inhibitor of the RAF/MEK signaling pathway. In contrast to other MEK inhibitors in development, VS-6766 blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows VS-6766 to block MEK signaling without the compensatory activation of MEK that appears to limit the efficacy of other inhibitors. The combination of VS-6766 and the focal adhesion kinase (FAK) inhibitor defactinib is currently being investigated in a Phase 1 dose escalation and expansion study. The expansion cohorts are currently ongoing in patients with KRAS mutant advanced solid tumors, including low grade serous ovarian cancer (LGSOC), non-small cell lung cancer (NSCLC) and colorectal cancer (CRC).[1] The ongoing clinical study of the VS-6766/defactinib combination is supported by single-agent Phase 2 studies which investigated defactinib in KRAS mutant NSCLC[2] and VS-6766 in KRAS mutant NSCLC and LGSOC.[3]

About Defactinib

Defactinib is an oral small molecule inhibitor of FAK and PYK2 that is currently being evaluated as a potential combination therapy for various solid tumors. The Company has received Orphan Drug designation for defactinib in ovarian cancer and mesothelioma in the US, EU and Australia. Preclinical research by Verastem Oncology scientists and collaborators at world-renowned research institutions has described the effect of FAK inhibition to enhance immune response by decreasing immuno-suppressive cells, increasing cytotoxic T cells, and reducing stromal density, which allows tumor-killing immune cells to enter the tumor.[4,5] Additionally, in both preclinical and clinical studies, FAK activation has been shown to occur as a potential resistance mechanism in response to MEK inhibitor treatment, and synergy of a FAK inhibitor with a RAF/MEK inhibitor has been shown in several preclinical models. The combination of defactinib and VS-6766 is currently being investigated in a Phase 1 dose escalation and expansion study. The expansion cohorts are currently ongoing in patients with KRAS mutant advanced solid tumors, including low grade serous ovarian cancer (LGSOC), non-small cell lung cancer (NSCLC) and colorectal cancer (CRC).[1] The ongoing clinical study of the VS-6766/defactinib combination is

supported by single-agent Phase 2 studies which investigated defactinib in KRAS mutant NSCLC[2] and VS-6766 in KRAS mutant NSCLC and LGSOC.[3] Defactinib is also in clinical testing in combination with pembrolizumab for treatment of patients with pancreatic cancer, NSCLC and mesothelioma.[6]

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a commercial 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 phosphoinositide 3-kinase (PI3K), focal adhesion kinase (FAK) and RAF/MEK inhibition.

Our first FDA approved product is available for the treatment of patients with certain types of indolent non-Hodgkin's lymphoma (iNHL).

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 opportunity to rapidly advance the development of clinical programs through Verastem Oncology's expanded development pipeline and strengthened balance sheet, the timing of top-line results for clinical trials, anticipated reductions in operating expenses from Verastem Oncology's strategic realignment, the timing of commencing a registration-directed trial for CH5126766 (VS-6766) and financial guidance estimates. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," 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.

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 CH5126766 (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 CH5126766 (VS-6766) license agreement; that we may not have sufficient cash to fund our contemplated operations; that we may be unable to make additional draws under our debt facility or 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 CH5126766 (VS-6766); that we will not pursue or submit regulatory filings for our product candidates, 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019, as filed with the Securities and Exchange Commission (SEC) on October 30, 2019, its Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the SEC on March 12, 2019 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.

References

[1] https://clinicaltrials.gov, NCT03875820

[2] Gerber D. et al. Phase 2 study of the focal adhesion kinase inhibitor defactinib (VS-6063) in previously treated advanced KRAS mutant non-small cell lung cancer. Lung Cancer 2020: 139:60-67.

[3] Chénard-Poirier, M. et al. Results from the biomarker-driven basket trial of RO5126766 (CH5127566), a potent RAF/MEK inhibitor, in RAS- or RAF-mutated malignancies including multiple myeloma. Journal of Clinical Oncology 2017: 35. 10.1200/JCO.2017.35.15_suppl.2506.

[4] Jiang H et al. Targeting focal adhesion kinase renders pancreatic cancers responsive to checkpoint immunotherapy. Nat Med 2016: Aug 22(8) 851-60.

[5] Sulzmaier F.J. et al. FAK in cancer: mechanistic findings and clinical applications. Nature Rev Cancer. 2014 14: 598-610.

[6] www.clinicaltrials.gov, NCT02758587

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