Verastem Oncology Outlines Key 2022 Strategic Priorities and Upcoming Catalysts for Advancing VS-6766 as a Backbone of Therapy for RAS Pathway-Driven Cancers

January 11, 2022

Report Selection Phase (Part A) Results from RAMP 201 and RAMP 202 Evaluating VS-6766 Alone and in Combination with Defactinib in Low-Grade Serous Ovarian Cancer (LGSOC) and KRAS-Mutant Non-Small Cell Lung Cancer (NSCLC), Respectively

Report Preliminary Data from Phase 1/2 Trial Evaluating LUMAKRAS™ (sotorasib) and VS-6766 and Initiate Phase 1/2 Trial Evaluating adagrasib and VS-6766; Both in KRAS G12C-Mutant Non-Small Cell Lung Cancer

Expand Ongoing Investigator-Initiated Trial Program to Explore Combination Potential with VS-6766 in Additional Areas of High Unmet Need; Data Read-Outs Expected Throughout 2022

BOSTON--(BUSINESS WIRE)--Jan. 11, 2022-- Verastem Oncology (Nasdaq:VSTM), a biopharmaceutical company committed to advancing new medicines for patients battling cancer, today outlined key strategic priorities and upcoming catalysts to support its lead compound VS-6766 in 2022. VS-6766 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. VS-6766 is currently in late-stage development.

“Building on the Breakthrough Therapy designation for VS-6766 with defactinib in recurrent low-grade serous ovarian cancer, the significant progress of our RAMP program in both low-grade serous ovarian cancer and KRAS G12V-mutant non-small cell lung cancer, our clinical collaborations in KRAS G12C-mutant non-small cell lung cancer as well as our ongoing investigator-initiated trials program, we expect to see tremendous progress on behalf of patients in 2022,” said Brian Stuglik, CEO of Verastem Oncology. “We plan to efficiently advance our development strategy, report multiple data readouts and further highlight the differentiated potential of VS-6766 across tumor types and mutations.”

2022 Strategic Priorities

Gynecologic Oncology Program

- Fully enroll Part B of the RAMP 201 trial (LGSOC VS-6766 +/- defactinib).
- Expand development program into other RAS pathway-driven gynecologic cancers.

Non-Small Cell Lung Cancer (NSCLC) Program

- Select regimen for Part B of the RAMP 202 trial (KRAS G12V NSCLC VS-6766 +/- defactinib).
- Initiate and complete dose-finding portions of RAMP 203 (KRAS G12C NSCLC VS-6766 + LUMAKRAS™ (sotorasib)) and RAMP 204 (KRAS G12C NSCLC VS-6766 + *adagrasib)* combination trials.
- Provide signal read-out of investigator-sponsored trial of VS-6766 and everolimus in KRAS- mutant NSCLC.

Other Programs

- Expand investigator-initiated trial program to include signal-finding studies in other tumor types, including melanoma, breast and colorectal cancers.
- Expand clinical combinations with VS-6766.

Anticipated 2022 Development Milestones and Catalysts

1Q-2022

- Having completed target enrollment (n=64) in the selection phase (Part A) of the Phase 2 RAMP 201 trial (LGSOC VS-6766 +/- defactinib), the enrollment phase (Part B) is now ongoing with both treatment arms currently advancing.
- Complete enrollment in the selection phase (Part A) of the Phase 2 RAMP 202 trial (KRAS G12V NSCLC VS-6766 +/- defactinib).
- Initiate RAMP 203 trial (KRAS G12C NSCLC VS-6766 + LUMAKRAS™ (sotorasib)) with Amgen.

Q2-2022

- Report topline results from Part A of the RAMP 201 trial (LGSOC VS-6766 +/- defactinib), following discussions with regulatory authorities.
- Initiate RAMP 204 trial (KRAS G12C VS-6766 + *adagrasib)* with Mirati.
- Present topline results of investigator-initiated trial of VS-6766 and everolimus in KRAS-mutant NSCLC.
- Present investigator-initiated FRAME LGSOC translational data.

2H-2022

- Complete enrollment in the RAMP 201 trial (LGSOC VS-6766 +/- defactinib).
- Report topline results from RAMP 202 trial (KRAS G12V NSCLC VS-6766 +/- defactinib) and initiate the expansion phase (Part B), following discussions with regulatory authorities.
- Report initial readout of the RAMP 203 trial (KRAS G12C NSCLC VS-6766 + LUMAKRAS™ (sotorasib)) with Amgen.

“We are pleased with the progress of our scientific collaborations and the high level of interest of leading investigators to advance the preclinical synergy data towards clinical evaluation of VS-6766 in combinations across multiple tumor types, including melanoma, colorectal and breast cancers,” said Louis Denis, CMO of Verastem Oncology. “These clinical research efforts complement our company-sponsored development program and help to expediently advance our efforts to address an even broader scope of significant unmet medical needs.”

About VS-6766

VS-6766 (formerly known as CH5126766 and RO5126766) 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. VS-6766 is currently in late-stage development.

In contrast to other MEK inhibitors, 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 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.[1]

Verastem Oncology is conducting Phase 2 registration-directed trials of VS-6766 alone and 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) clinical trials, RAMP 201 and RAMP 202, respectively. Verastem Oncology has also established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS™ (sotorasib) and *adagrasib* in combination with VS-6766 in KRAS G12C-mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively.

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, the timing of commencing and completing trials, including topline data reports, and potential for additional development programs 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 VS-6766 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 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 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 we will be unable to execute on our partnering strategies for VS-6766 in combination with other compounds; 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 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.

[1] Verastem Oncology Press Release. Verastem Oncology Receives Breakthrough Therapy Designation for VS-6766 with Defactinib in Recurrent Low-Grade Serous Ovarian Cancer. May 24, 2021. Available at: https://investor.verastem.com/news-releases/news-release-details/verastem-oncology-receives-breakthrough-therapy-designation-vs. Accessed October 2021.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220111005415/en/

Investors:
Ajay Munshi
Vice President, Corporate Development
+1 781-469-1579
amunshi@verastem.com

Sherri Spear
Argot Partners
+1 212-600-1902
sherri@argotpartners.com

Media:
Lisa Buffington
Corporate Communications
+1 781-292-4205
lbuffington@verastem.com

Source: Verastem Oncology