Verastem Oncology Announces Multiple Data Presentations at Society of Gynecologic Oncology 2025 Annual Meeting on Women's Cancer

February 20, 2025 at 4:05 PM EST

Oral presentation of RAMP 201 trial results including updated subgroup analyses in recurrent low-grade serous ovarian cancer

Oral presentation of investigator-sponsored study of avutometinib plus defactinib in gynecologic mesonephric cancer, a rare grouping of cancers that generally harbor KRAS mutations

BOSTON--(BUSINESS WIRE)--Feb. 20, 2025-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with RAS/MAPK pathway-driven cancers, today announced multiple oral and poster presentations, including an oral presentation of additional analyses from the ongoing Phase 2 RAMP 201 (ENGOT-ov60/GOG-3052) trial evaluating the investigational combination of avutometinib plus defactinib in patients with recurrent low-grade serous ovarian cancer (LGSOC), at the Society of Gynecologic Oncology (SGO) 2025 Annual Meeting on Women's Cancer, to be held on March 14-17 in Seattle, Washington. Verastem will also have an exhibition booth (#622) at the meeting where it will be available to discuss its ongoing cancer research.

"The presentation of the RAMP 201 primary analysis, which served as the basis of the acceptance of our NDA that is under Priority Review with the FDA, includes additional subgroup analysis by KRAS mutational status," said Dan Paterson, president, and chief executive officer of Verastem Oncology. "We look forward to sharing these learnings with many of the world's leading gynecologic oncologists at SGO as part of our continued commitment to people living with recurrent low-grade serous ovarian cancer. We also recognize the importance of these findings to the broader cancer community as part of our growing pool of data reinforcing the potential to change expectations in managing RAS/MAPK pathway-driven cancers."

Oral Presentation:

- **Abstract Title:** Avutometinib + Defactinib in Recurrent Low-Grade Serous Ovarian Cancer (ENGOT-ov60/GOG-3052/RAMP 201): Dose Intensity and Subgroup Analysis
- **Presenter**: Rachel Grisham, M.D.
- **Session:** Focused Forum XV: Ongoing IMPACT
- **Date/Time:** Monday, March 17, 2025, 9:15 am PST

Oral Presentation – Investigator-Sponsored Trial:

- **Abstract Title:** A Phase II Study of Avutometinib and Defactinib in Advanced or Recurrent Gynecologic Mesonephric Cancer: Interim Results
- **Presenter**: Rachel Grisham, M.D.
- **Session:** Focused Forum IV: Finding IMPACT: The Needle in the Haystack
- **Date and Time:** Saturday, March 15, 2025, 4:15 pm PST

Preclinical Virtual Poster:

- **Abstract Title:** Preclinical Efficacy of the Estrogen Receptor Degrader Fulvestrant in Combination with RAF/MEK clamp Avutometinib and FAK Inhibitor in Low-Grade Serous Ovarian Cancer with Acquired Resistance to Chemotherapy and Aromatase Inhibitor
- **Study Author:** Cem Demirkiran, M.D.

nAbout the Avutometinib and Defactinib Combinatio

Avutometinib is an oral RAF/MEK clamp that potently inhibits MEK1/2 kinase activities and induces inactive complexes of MEK with ARAF, BRAF, and CRAF, potentially creating a more complete and durable anti-tumor response through maximal RAS/MAPK pathway inhibition. In contrast to currently available MEK-only 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 the MEK-only inhibitors.

Defactinib is an oral, selective inhibitor of focal adhesion kinase (FAK) and proline-rich tyrosine kinase-2 (Pyk2), the two members of the focal adhesion kinase family of non-receptor protein tyrosine kinases. FAK and Pyk2 integrate signals from integrin and growth factor receptors to regulate cell proliferation, survival, migration, and invasion. FAK activation has been shown to mediate resistance to multiple anti-cancer agents, including RAF and MEK inhibitors.

Verastem Oncology is currently conducting clinical trials with avutometinib with and without defactinib in RAS/MAPK-driven tumors as part of its Raf And Mek Program or RAMP. Verastem is currently enrolling patients and activating sites for RAMP 301 (GOG-3097/ENGOT-ov81/NCRI) (NCT06072781), an international Phase 3 confirmatory trial evaluating the combination of avutometinib and defactinib versus standard chemotherapy

or hormonal therapy for the treatment of recurrent low-grade serous ovarian cancer (LGSOC).

Verastem was granted Priority Review and a Prescription Drug User Fee Act (PDUFA) date of June 30, 2025, for its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), for the investigational combination of avutometinib and defactinib in adults with recurrent KRAS mutant LGSOC who received at least one prior systemic therapy. Verastem initiated a rolling NDA in May 2024 to the FDA and completed its NDA submission in October 2024. The FDA granted Breakthrough Therapy Designation for the treatment of patients with recurrent LGSOC after one or more prior lines of therapy, including platinum-based chemotherapy, in May 2021. Avutometinib alone or in combination with defactinib was also granted Orphan Drug Designation by the FDA for the treatment of LGSOC.

Verastem Oncology has established a clinical collaboration with Amgen to evaluate LUMAKRAS™ (sotorasib) in combination with avutometinib and defactinib in both treatment-naïve patients and in patients whose KRAS G12C mutant non-small cell lung cancer progressed on a G12C inhibitor as part of the RAMP 203 trial (NCT05074810). Verastem has received Fast Track Designation from the FDA for the triplet combination in April 2024. RAMP 205 (NCT05669482), a Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer, is supported by the PanCAN Therapeutic Accelerator Award. FDA granted Orphan Drug Designation to the avutometinib and defactinib combination for the treatment of pancreatic cancer.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a late-stage development biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with RAS/MAPK pathway-driven cancers. 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, FAK inhibition and KRAS G12D inhibition. For more information, please visit www.verastem.com and follow us on LinkedIn.

Forward-Looking Statements

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “plan,” “could,” “may,” “believe,” “estimate,” “forecast,” “goal,” “project,” and other words of similar meaning. Such forward-looking statements address various matters about, among other things, Verastem Oncology’s programs and product candidates, strategy, future plans and prospects, including statements related to the potential for and timing of commercialization of product candidates, the anticipated timing for the IND application for VS-7375/GFH375, the expected outcome and benefits of the Company’s collaboration with GenFleet Therapeutics (Shanghai), Inc., the timing of commencing and completing trials and compiling data, the expected timing of the presentation of data by the Company and the potential clinical value of various of the Company’s clinical trials. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: the uncertainties inherent in research and development, such as the possibility of negative or unexpected results of clinical trials; that we may not see a return on investment on the payments we have and may continue to make pursuant to the collaboration and option agreement with GenFleet, or that GenFleet may fail to fully perform under the agreement; that the development and commercialization of our product candidates may take longer or cost more than planned, including as a result of conducting additional studies or our decisions regarding execution of such commercialization; that data may not be available when expected; risks associated with preliminary and interim data, which may not be representative of more mature data; that our product candidates may not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients; and the risks identified under the heading "Risk Factors" the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (SEC) on March 14, 2024, as well as the other information we file with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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For Investor and Media Inquiries:
Julissa Viana
Vice President, Corporate Communications, Investor Relations and Patient Advocacy
investors@verastem.com or
media@verastem.com

Source: Verastem Oncology