Verastem Oncology Reports First Quarter 2025 Financial Results and Highlights Recent Business Updates

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AVMAPKI™ FAKZYNJA™ CO-PACK launch underway following accelerated approval on May 8, 2025, for adult patients with KRAS-mutated recurrent LGSOC

U.S. IND cleared for VS-7375, oral KRAS G12D (ON/OFF) inhibitor; expect to initiate Phase 1/2a study in mid-2025

Initial safety and efficacy results from the trial of VS-7375 by partner GenFleet Therapeutics to be presented at the 2025 ASCO Annual Meeting

Updated safety and efficacy results from the RAMP 205 trial of avutometinib and defactinib in combination with current standard of care in first-line metastatic pancreatic cancer to be announced at the 2025 ASCO Annual Meeting

Ended Q1 2025 with $117.6 million in cash and cash equivalents; pro-forma $192.6 million including the equity issuance in the private placement in April 2025

BOSTON--(BUSINESS WIRE)--May 13, 2025-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with RAS/MAPK pathway-driven cancers, today announced business updates and reported financial results for the first quarter ended March 31, 2025.

"In the first quarter of 2025, we continued to make progress with our pipeline programs by exercising our option early to license VS-7375 from our partner GenFleet Therapeutics, completing enrollment in the initial cohorts in our RAMP 205 clinical trial in first-line metastatic pancreatic cancer, and continuing enrollment in the triplet combination in our RAMP 203 clinical trial in advanced KRAS G12C mutant non-small cell lung cancer," said Dan Paterson, president and chief executive officer of Verastem Oncology. "With a strengthened financial position, we are looking forward to a transformational second quarter with the FDA approval and launch of AVMAPKI FAKZYNJA CO-PACK for KRAS-mutated recurrent low-grade serous ovarian cancer, our plans to initiate a Phase 1/2a study in the U.S. for VS-7375, our potential best-in-class oral KRAS G12D (ON/OFF) inhibitor, in mid-2025, and share updated data for both VS-7375 and RAMP 205 at ASCO."

First Quarter 2025 and Recent Updates

Avutometinib and Defactinib Combination in Low-Grade Serous Ovarian Cancer (LGSOC)

- Announced the U.S. Food and Drug Administration (FDA) approved AVMAPKI™ FAKZYNJA™ CO-PACK (avutometinib capsules; defactinib tablets) for the treatment of adult patients with KRAS-mutated recurrent LGSOC who have received prior systemic therapy on May 8, 2025, in advance of PDUFA action date of June 30, 2025.
- Initiation of the commercial execution of the AVMAPKI FAKZYNJA CO-PACK launch in the U.S.
- AVMAPKI FAKZYNJA CO-PACK is now available through a specialty distribution network in the U.S.
- A support program for patients prescribed AVMAPKI FAKZYNJA CO-PACK, called Verastem Cares™, is now available.
- Submitted request for NCCN guideline inclusion.
- Shared multiple oral and poster presentations at the American Association of Cancer Research (AACR) Annual Meeting 2025 on April 25-30, highlighting the exploration of the mechanisms by which the Company's FAK inhibitor increases the anti-tumor efficacy of avutometinib.
- Multiple abstracts were selected for oral and poster presentations at the Society of Gynecologic Oncology (SGO) 2025 Annual Meeting on Women's Cancer on March 14-17 in Seattle. These presentations included an oral presentation of additional analyses from the Phase 2 RAMP 201 trial of avutometinib and defactinib combination with recurrent LGSOC and an oral presentation of interim results from a Phase 2 Investigator-Sponsored Trial evaluating avutometinib plus defactinib in advanced or recurrent gynecologic mesonephric cancer.

Key Milestones Expected for 2025:

- Primary analysis from both the FRAME and RAMP 201 clinical trials anticipated to be published in H1 2025.
- Complete enrollment for the international Phase 3 confirmatory RAMP 301 clinical trial for patients with recurrent LGSOC regardless of KRAS mutation status by the end of 2025.
- Report initial data from the RAMP 201J Phase 2 clinical trial being conducted in Japan with JGOG in H2 2025.
- Continue to advance the regulatory pathway in Japan and Europe.

RAMP 205: Avutometinib Plus Defactinib in Combination with Chemotherapy in First-Line Metastatic Pancreatic Cancer

- Completed enrollment of 60 patients in the dose-level evaluation phase of RAMP 205 study in Q1; follow-up continues.
- In March 2025, announced several updates to the trial, including the addition of a new dose level “0” to evaluate the doses of avutometinib and defactinib used in LGSOC and expanding all dose levels to 12 patients each, including six additional patients to dose level “1”, where 5/6 patients reported an objective response (83% cORR) at the ASCO 2024 annual meeting.

Key Milestones Expected for 2025:

- Plan to report additional data when ASCO abstracts are live on May 22, 2025.
- Select the recommended Phase 2 Dose (RP2D) for trial expansion in H1 2025.

RAMP 203: Avutometinib Plus Defactinib in Combination with a KRAS G12C Inhibitor in Non-Small Cell Lung Cancer (NSCLC)

- Completed enrollment in the KRAS G12C inhibitor prior-treated Stage 1 Part B doublet cohort in Q1 2025.
- Completed enrollment in the planned dose level evaluation cohorts for the triplet combination in Q1 2025.

Key Milestones Expected for 2025:

- Present an interim update of both doublet and triplet data at a medical meeting in H2 2025.

VS-7375, an Oral KRAS G12D (ON/OFF) Inhibitor, in Advanced Solid Tumors

- Verastem announced in April 2025 that the FDA had cleared the Company’s Investigational New Drug (IND) application for VS-7375, enabling a Phase 1/2a trial in advanced solid tumors in the U.S.
- Shared a presentation at the AACR Annual Meeting 2025, highlighting that VS-7375 was found to be more potent than other KRAS G12D inhibitors in preclinical models.
- GenFleet announced on Feb. 28, 2025, that it had dosed the first patient in the Phase 2 portion of the trial in China.
- Verastem announced on January 14, 2025, that it had exercised its option early to license GFH375 (VS-7375) from partner GenFleet Therapeutics. In addition, the Company announced preliminary clinical data from the Phase 1 dose-escalation study conducted by GenFleet in China. In the study, VS-7375 demonstrated oral bioavailability, with no DLTs across six dose levels, and partial responses were achieved among multiple patients with both pancreatic and lung cancers.

Key Milestones Expected for 2025:

- Initiate a Phase 1/2a trial in the U.S. by mid-2025.
- GenFleet to share clinical data from the Phase 1 study of VS-7375 in an oral presentation at ASCO on Monday, June 2, 2025.

Upcoming Presentations

ASCO Annual Meeting
The meeting will be held from May 30 to June 3, 2025, in Chicago, IL, and abstracts are under embargo until May 22, 2025, at 5:00 pm EDT.

Title: A First-in-Human Phase I/II Study of GFH375, a Highly Selective and Potent Oral KRAS G12D Inhibitor in Patients with KRAS G12D Mutant Advanced Solid Tumors

- **Abstract Number:** 3013
- **Session:** Rapid Oral Abstract Sessions: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
- **Date/Time:** Monday, June 2, 2025 from 8:00 am to 9:30 am CDT

Title: Avutometinib/defactinib and gemcitabine/nab-paclitaxel combination in first-line metastatic pancreatic ductal adenocarcinoma: Updated safety and efficacy of a phase 1b/2 study (RAMP 205)

- **Abstract Number:** e16043
- Accepted for inclusion in the 2025 ASCO Annual Meeting Proceedings, *Journal of Clinical Oncology* supplement. The abstract is under embargo until May 22, and the Company will be reporting additional data then.

ESMO Gynaecological Cancers Congress 2025
The meeting will be held from June 19 to 21, 2025, in Vienna, Austria, and the abstract is under embargo until June 16, 2025.

- **Title:** Blood ctDNA vs tumor tissue screening for the detection of KRAS mutations in low-grade serous ovarian cancer
- **Abstract Number:** 276
- **Date/Time:** Thursday, June 19, from 2:00 to 3:30 pm EDT

Corporate Updates

- In April 2025, Verastem strengthened its balance sheet by raising gross proceeds of approximately $75 million in a private

placement of 3.4 million shares of its common stock and 7.3 million pre-funded warrants to purchase 7.3 million shares of its common stock.

First Quarter 2025 Financial Results

Verastem Oncology ended the first quarter of 2025 with cash, cash equivalents and investments of $117.6 million. On a pro forma basis, taking into account the $75 million of gross proceeds raised in a private placement in April, cash and cash equivalents were $192.6 million as of March 31, 2025.

Total operating expenses for the three months ended March 31, 2025 (the "2025 Quarter") were $44.2 million, inclusive of $6.8 million of one-time charges, compared to $28.1 million for the three months ended March 31, 2024 (the "2024 Quarter").

Research & development expenses for the 2025 Quarter were $29.2 million, compared to $17.7 million for the 2024 Quarter. The increase of $11.5 million, or 65.0%, was primarily related to the option exercise fee related to the GenFleet G12D program, increased contract research organization costs, and increased drug substance and drug product costs.

Selling, general & administrative expenses for the 2025 Quarter were $15.0 million, compared to $10.4 million for the 2024 Quarter. The increase of $4.6 million, or 44.2%, was primarily related to additional costs in anticipation of a potential launch of avutometinib and defactinib in KRAS mt LGSOC, increased personnel costs, including non-cash stock compensation, and one-time financing costs associated with the note purchase agreement.

Net loss for the 2025 Quarter was $52.1 million, or $0.96 per share (basic and diluted), compared to $33.9 million, or $1.26 per share for the 2024 Quarter.

For the 2025 Quarter, non-GAAP adjusted net loss was $42.9 million, or $0.79 per share (diluted) compared to non-GAAP adjusted net loss of $26.2 million, or $0.98 per share (diluted), for the 2024 Quarter. Please refer to the GAAP to non-GAAP Reconciliation attached to this press release.

Use of Non-GAAP Financial Measures

To supplement Verastem Oncology's condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), the Company uses the following non-GAAP financial measures in this press release: non-GAAP adjusted net loss and non-GAAP net loss per share. These non-GAAP financial measures exclude certain amounts or expenses from the corresponding financial measures determined in accordance with GAAP. Management believes this non-GAAP information is useful for investors, taken in conjunction with the Company's GAAP financial statements, because it provides greater transparency and period-over- period comparability with respect to the Company's operating performance and can enhance investors' ability to identify operating trends in the Company's business. Management uses these measures, among other factors, to assess and analyze operational results and trends and to make financial and operational decisions. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of the Company's operating results as reported under GAAP, not in isolation or as a substitute for, or superior to, financial information prepared and presented in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. The determination of the amounts that are excluded from non-GAAP financial measures is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Reconciliations between these non-GAAP financial measures and the most comparable GAAP financial measures for the three months ended March 31, 2025 and 2024 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About AVMAPKI and FAKZYNJA Combination Therapy

AVMAPKI (avutometinib) inhibits MEK kinase activity while also blocking the compensatory reactivation of MEK by upstream RAF. RAF and MEK proteins are regulators of the RAS/RAF/MEK/ERK (MAPK) pathway. Blocking RAF and/or MEK activates FAK, a key mediator of drug resistance. FAKZYNJA (defactinib) is a FAK inhibitor and together, the avutometinib and defactinib combination was designed to provide a more complete blockade of the signaling that drives the growth and drug resistance of RAS/MAPK pathway-dependent tumors.

The U.S. Food and Drug Administration (FDA) approved AVMAPKI™ FAKZYNJA™ CO-PACK (avutometinib capsules; defactinib tablets) for the treatment of adult patients with KRAS-mutated recurrent LGSOC who have received prior systemic therapy on May 8, 2025. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Verastem is also evaluating avutometinib in combination with defactinib and other agents as a potential treatment for patients with advanced pancreatic cancer (RAMP 205; NCT05669482) and advanced KRAS G12C mutant non-small cell lung cancer (RAMP 203; NCT05074810). Avutometinib and defactinib are not approved by the FDA or any other regulatory authority, either in combination or with other therapies, for any of these investigative uses. Neither avutometinib nor defactinib are approved by the FDA or any other regulatory authority on a stand-alone basis for any use.

AVMAPKI FAKZYNJA CO-PACK U.S. Indication

Indication
AVMAPKI FAKZYNJA CO-PACK is indicated for the treatment of adult patients with *KRAS*-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information

Warnings and Precautions

- **Ocular Toxicities:** Ocular toxicities, including visual impairment and vitreoretinal disorders, occurred. Perform comprehensive ophthalmic evaluation at baseline, prior to cycle 2, every three cycles thereafter, and as clinically indicated. Withhold AVMAPKI FAKZYNJA CO-PACK for ocular toxicities until improvement at the same or reduced dose. Permanently discontinue AVMAPKI FAKZYNJA CO-PACK for any grade 4 toxicity.

- **Serious Skin Toxicities:** Skin toxicities, including photosensitivity and severe cutaneous adverse reactions (SCARSs) occurred. Adhere to concomitant medications. Monitor for skin toxicities and interrupt, reduce or permanently discontinue AVMAPKI FAKZYNJA CO-PACK based on severity, tolerability and duration.
- **Hepatotoxicity:** Monitor liver function tests prior to each cycle, on day 15 of the first 4 cycles, and as clinically indicated. Withhold, reduce or discontinue AVMAPKI FAKZYNJA CO-PACK based on severity and persistence of abnormality.
- **Rhabdomyolysis:** Monitor creatine phosphokinase prior to the start of each cycle, on day 15 of the first four cycles, and as clinically indicated. If increased CPK occurs, evaluate patients for rhabdomyolysis or other causes. Withhold, reduce or permanently discontinue AVMAPKI FAKZYNJA CO-PACK based on severity and duration of the adverse reaction.
- **Embryo-Fetal Toxicity:** AVMAPKI FAKZYNJA CO-PACK can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Adverse Reactions
The most common (≥ 25%) adverse reactions, including laboratory abnormalities, were increased creatine phosphokinase, nausea, fatigue, increased aspartate aminotransferase, rash, diarrhea, musculoskeletal pain, edema, decreased hemoglobin, increased alanine aminotransferase, vomiting, increased blood bilirubin, increased triglycerides, decreased lymphocyte count, abdominal pain, dyspepsia, dermatitis acneiform, vitreoretinal disorders, increased alkaline phosphatase, stomatitis, pruritus, visual impairment, decreased platelet count, constipation, dry skin, dyspnea, cough, urinary tract infection, and decreased neutrophil count.

Drug Interactions

- **Strong and moderate CYP3A4 inhibitors**: Avoid concomitant use with AVMAPKI FAKZYNJA CO-PACK.
- **Strong and moderate CYP3A4 inducers**: Avoid concomitant use with AVMAPKI FAKZYNJA CO-PACK.
- **Warfarin:** Avoid concomitant use of AVMAPKI FAKZYNJA CO-PACK with warfarin and use an alternative to warfarin.
- **Gastric acid reducing agents**: Avoid concomitant use of AVMAPKI FAKZYNJA CO-PACK with proton pump inhibitors (PPIs) or H2 receptor antagonists. If use of an acid-reducing agent cannot be avoided, administer FAKZYNJA 2 hours before or 2 hours after the administration of a locally acting antacid.

Use in Specific Populations

- **Lactation**: Advise not to breastfeed.
- **Fertility:** May impair fertility in males and females.

Click here for full Prescribing Information.

About VS-7375, an Oral KRAS G12D (ON/OFF) Inhibitor

VS-7375 is a potential best-in-class, potent, and selective oral KRAS G12D dual ON/OFF inhibitor. VS-7375 is the lead program from the Verastem Oncology discovery and development collaboration with GenFleet Therapeutics. Verastem announced in April 2025 that the U.S. Investigational New Drug (IND) application for VS-7375 was cleared and plans to initiate a Phase 1/2a clinical trial in mid-2025. GenFleet's IND for VS-7375 (known as GFH375 in China) was approved in China in June 2024, and the first patient was dosed in a Phase 1/2 study in July 2024.

About the GenFleet Therapeutics Collaboration

The collaboration with GenFleet Therapeutics aims to advance three oncology discovery programs related to RAS/MAPK pathway-driven cancers. The collaboration provides Verastem with an exclusive option to obtain a license for each of the three compounds in the collaboration after the successful completion of pre-determined milestones in a Phase 1 trial. Verastem selected VS-7375 (also known as GFH375), an oral KRAS G12D (ON/OFF) inhibitor, as its lead program in December 2023 and the license for VS-7375 that was exercised in January 2025 is the first one from this collaboration. The licenses would give Verastem development and commercialization rights outside the GenFleet markets of mainland China, Hong Kong, Macau, and Taiwan.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a biopharmaceutical company committed to developing and commercializing new medicines to improve the lives of patients diagnosed with RAS/MAPK pathway-driven cancers. Verastem markets AVMAPKI™ FAKZYNJA™ CO-PACK in the U.S. 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 Notice

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 initiation of the Phase 1/2a study 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 we may not be successful in our launch or commercialization of AVMAPKI FAKZYNJA CO-PACK; 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; risks associated with the recent changes in administration policy or actions that may create regulatory uncertainty that may adversely affect our business; 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" as detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission (SEC) on March 20, 2025, as well as the other information we file with the SEC, are possibly realized. 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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Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	March 31, 2025	**December 31, 2024**
Cash & cash equivalents	$ 117,569	$ 88,818
Grant receivable	200	200
Prepaid expenses and other current assets	6,930	5,943
Property and equipment, net	22	32
Right-of-use asset, net	1,188	1,405
Restricted cash and other assets	5,789	5,140
Total assets	**$ 131,698**	**$ 101,538**
Current Liabilities	$ 35,619	$ 30,973
Long term debt	71,476	40,724
Vendor financing arrangement, long-term	2,019	—
Lease liability, long-term	271	535
Warrant liability	54,746	58,199
Stockholders' (deficit) equity	(32,433)	(28,893)
Total liabilities, and stockholders' (deficit) equity	**$ 131,698**	**$ 101,538**

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Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 29,152	$ 17,707
Selling, general and administrative	15,022	10,352
Total operating expenses	44,174	28,059
Loss from operations	(44,174)	(28,059)
Other expense	(40)	(30)
Interest income	960	1,367
Interest expense	(192)	(1,130)
Loss on debt extinguishment	(1,826)	—
Change in fair value of preferred stock tranche liability	—	(6,011)
Change in fair value of warrant liability	(2,416)	—
Change in fair value of Notes	(4,415)	—
Net loss	$ (52,103)	$ (33,863)
Net loss per share—basic and diluted	$ (0.96)	$ (1.26)
Weighted average common shares outstanding used in computing:		
Net loss per share – basic and diluted	$ 54,173	$ 26,832

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Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2025	**2024**
Net loss reconciliation		
Net loss (GAAP basis)	$ (52,103)	$ (33,863)

Adjust:		
Stock-based compensation expense	1,788	1,483
Non-cash interest, net	30	(419)
Change in fair value of preferred stock tranche liability	—	6,011
Loss on debt extinguishment	1,826	—
Change in fair value of warrant liability	2,416	—
Non-cash change in fair value of Notes	3,115	—
Severance and other	—	553
Adjusted net loss (non-GAAP basis)	$ (42,928)	$ (26,235)
Reconciliation of net loss per share		
Net loss per share – diluted (GAAP Basis)	$ (0.96)	$ (1.26)
Adjust per diluted share:		
Stock-based compensation expense	0.03	0.06
Non-cash interest, net	—	(0.02)
Change in fair value of preferred stock tranche liability	—	0.22
Loss on debt extinguishment	0.05	—
Change in fair value of warrant liability	0.06	—
Non-cash change in fair value of Notes	0.03	—
Severance and other	—	0.02
Adjusted net loss per share – diluted (non-GAAP basis)	$ (0.79)	$ (0.98)
Weighted average common shares outstanding used in computing net loss per share—diluted	$ 54,173	$ 26,832

View source version on businesswire.com: https://www.businesswire.com/news/home/20250513753037/en/

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