Verastem Oncology Reports First Quarter 2024 Financial Results and Highlights Recent Business Updates

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Plan to announce topline RAMP 201 data with the start of planned rolling NDA submission for avutometinib and defactinib combination in recurrent low-grade serous ovarian cancer in Q2 2024

FDA Fast Track Designation granted for avutometinib in combination with adagrasib for the treatment of KRAS G12C-mutated metastatic non-small cell lung cancer

FDA Fast Track Designation granted for avutometinib plus defactinib in combination with sotorasib for the treatment of KRAS G12C-mutated metastatic non-small cell lung cancer

Initial 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 presented at the 2024 ASCO Annual Meeting

BOSTON--(BUSINESS WIRE)--May 9, 2024-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today announced business updates and reported financial results for the first quarter ended March 31, 2024.

“In the first quarter of 2024, we received FDA Orphan Drug Designation for avutometinib and defactinib combination in recurrent low-grade serous ovarian cancer, which recognizes this rare cancer as different and distinct from other forms of ovarian cancer and reinforces the need for new treatment options,” said Dan Paterson, president and chief executive officer of Verastem Oncology. “We look forward to starting our planned rolling NDA submission and sharing topline data for avutometinib and defactinib combination in recurrent low-grade serous ovarian cancer. We also plan to announce initial data from the RAMP 205 trial in first-line metastatic pancreatic cancer at ASCO and plan to provide updates across our other clinical programs in the second half of 2024.”

First Quarter 2024 and Recent Updates

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

- Enrollment and site activations are underway in the U.S., Australia, and the UK, for the international confirmatory Phase 3 RAMP 301 trial evaluating the avutometinib and defactinib combination versus standard of care chemotherapy or hormonal therapy for the treatment of recurrent LGSOC.
- Granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for avutometinib alone or in combination with defactinib for the treatment of all patients with recurrent LGSOC, in March 2024.
- Multiple abstracts were selected for oral and poster presentations at the Society of Gynecologic Oncology (SGO) 2024 Annual Meeting on Women’s Cancer on March 16-18 in San Diego. These presentations included a late-breaking oral presentation on a planned subgroup analysis of Part A of the Phase 2 RAMP 201 trial of avutometinib and defactinib combination of heavily pretreated patients with LGSOC and a plenary oral presentation of preclinical efficacy data of avutometinib in combination with a focal adhesion kinase (FAK) inhibitor in recurrent LGSOC as well as a trials-in-progress poster about the Phase 3 RAMP 301 trial.
- Plan to announce updated topline data from the RAMP 201 trial in LGSOC to coincide with the start of our planned rolling New Drug Application (NDA) submission for Accelerated Approval for the avutometinib and defactinib combination in recurrent LGSOC in Q2 2024.
- Preparations for a potential U.S. commercial launch in 2025 are ongoing and plans to initiate discussions with European and Japanese regulatory authorities to address patient needs outside the U.S. continue to advance.

Avutometinib in Combination with KRAS G12C Inhibitors in Non-Small Cell Lung Cancer (NSCLC)

- Verastem Oncology announced today it has received Fast Track Designation from the FDA for avutometinib in combination with Mirati’s (BMS) G12C inhibitor, KRAZATI™ (adagrasib) for the treatment of patients with KRAS G12C-mutated metastatic NSCLC who have received at least one prior systemic therapy and have not been previously treated with a KRAS G12C inhibitor, in April 2024.
- Verastem Oncology announced today it has received Fast Track Designation from the FDA for the combination of avutometinib plus defactinib with Amgen’s G12C inhibitor, LUMAKRAS™ (sotorasib) for the treatment of patients with KRAS G12C-mutated metastatic NSCLC who have received at least one prior systemic therapy, in April 2024.
- The FDA granted Fast Track Designation for avutometinib in combination with Amgen’s G12C inhibitor, LUMAKRAS™ (sotorasib), for the treatment of patients with KRAS G12C-mutant metastatic NSCLC who have received at least one prior systemic therapy and have not been previously treated with a KRAS G12C inhibitor, in January 2024.

- Data updates from patients with KRAS G12C-mutant NSCLC in the Phase 1/2 RAMP 203 trial evaluating avutometinib plus defactinib and sotorasib are planned for H2 2024.
- Data from patients with KRAS G12C-mutant NSCLC in the Phase 1/2 RAMP 204 trial evaluating avutometinib and adagrasib are planned for H2 2024.

Avutometinib and Defactinib Combination in First-Line Metastatic Pancreatic Cancer

- Verastem Oncology today announced the acceptance of an abstract that will include initial safety and efficacy results from the RAMP 205 trial of avutometinib and defactinib in combination with current standard of care gemcitabine and nab-paclitaxel in first-line metastatic pancreatic cancer at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting.

GFH375 (VS-7375): Oral KRAS G12D (ON/OFF) Inhibitor

- GenFleet Therapeutics investigational new drug (IND) application for GFH375 (VS-7375) was submitted in China and accepted for review. Expect to begin a Phase 1 trial in China in H2 2024.
- Discovery/lead optimization continues for second and third programs with GenFleet collaboration.

Upcoming Presentations

Verastem Oncology today announced the acceptance of an abstract for poster presentation at the ASCO Annual Meeting being held from May 31 to June 4, 2024, in Chicago, IL.

- **Title:** Avutometinib/defactinib and gemcitabine/nab-paclitaxel combination in first-line metastatic pancreatic ductal adenocarcinoma: Initial safety and efficacy of phase 1b/2 study (RAMP 205).
- **Abstract Number:** 4140
- **Date/Time:** Saturday, June 1, 2024, 1:30 to 4:30 pm CDT

Corporate Updates

- Strengthened the executive leadership team with the appointment of John Hayslip, M.D., to chief medical officer in April 2024.

First Quarter 2024 Financial Results

Verastem Oncology ended the first quarter of 2024 with cash, cash equivalents and investments of $110.1 million.

Total operating expenses for the three months ended March 31, 2024 (the “2024 Quarter”) were $28.1 million, compared to $19.3 million for the three months ended March 31, 2023 (the “2023 Quarter”).

Research & development expenses for the 2024 Quarter were $17.7 million, compared to $12.0 million for the 2023 Quarter. The increase of $5.7 million, or 47.5%, was primarily related to increased contract research organization costs, increased investigator fees and increased personnel costs, including non-cash stock compensation.

Selling, general & administrative expenses for the 2024 Quarter were $10.4 million, compared to $7.3 million for the 2023 Quarter. The increase of $3.1 million, or 42.5%, was primarily related to additional costs in anticipation of a potential launch of avutometinib and defactinib in LGSOC, increased personnel costs, including non-cash stock compensation, and increased consulting and professional fees.

Net loss for the 2024 Quarter was $33.9 million, or $1.26 per share (basic and diluted), compared to $15.7 million, or $0.94 per share (basic and diluted, each as adjusted for the Company’s reverse stock split) for the 2023 Quarter.

For the 2024 Quarter, non-GAAP adjusted net loss was $26.2 million, or $0.98 per share (diluted) compared to non-GAAP adjusted net loss of $17.8 million, or $1.07 per share (diluted, as adjusted for the Company’s reverse stock split), for the 2023 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, 2024 and 2023 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About the Avutometinib and Defactinib Combination

Avutometinib 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/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 other MEK-only inhibitors. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation of the investigational combination of avutometinib and defactinib, a selective 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. Avutometinib alone or in combination with defactinib was also granted Orphan Drug Designation by the FDA for the treatment of LGSOC.

Verastem Oncology is currently conducting clinical trials with avutometinib in RAS/MAPK driven tumors as part of its **R**af **A**nd **M**ek **P**rogram or RAMP. RAMP 301 (NCT06072781) is an international Phase 3 confirmatory trial evaluating the combination of avutometinib and defactinib versus standard chemotherapy or hormonal therapy for the treatment of recurrent LGSOC. RAMP 201 (NCT04625270) is a Phase 2 registration-directed trial of avutometinib in combination with defactinib in patients with recurrent LGSOC and enrollment has been completed in each of the dose optimization and expansion phases and the low-dose evaluation.

Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS™ (sotorasib) in combination with avutometinib and defactinib and KRAZATI™ (adagrasib) in combination with avutometinib in KRAS G12C mutant NSCLC as part of the RAMP 203 (NCT05074810) and RAMP 204 (NCT05375994) trials, respectively. The 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.

About GFH375 (VS-7375)

GFH375 (VS-7375) is a potential best-in-class, potent and selective oral KRAS G12D (ON/OFF) inhibitor, identified as the lead program from the Verastem Oncology discovery and development collaboration with GenFleet Therapeutics. Upon approval of the investigational new drug (IND) application in China (which is currently under review), GenFleet is expected to initiate a Phase 1 trial in China in the second half of 2024. The collaboration includes three discovery programs, the first being the KRAS G12D inhibitor, and will provide Verastem Oncology with exclusive options to obtain licenses to each of the three compounds in the collaboration after successful completion of pre-determined milestones in Phase 1 trials. The licenses would give Verastem Oncology development and commercialization rights outside of the GenFleet territories of mainland China, Hong Kong, Macau, and Taiwan.

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 cancer. Our pipeline is focused on RAS/MAPK-driven cancers, specifically novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and FAK 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 about Verastem Oncology's strategy, future plans and prospects, including statements related to the expected timing of the planned rolling New Drug Application (NDA) submission for the avutometinib and defactinib combination in low-grade serous ovarian cancer, the outcome and benefits of the collaboration with GenFleet, including the approval of the IND in China, the potential clinical value of various of the Company's clinical trials, the timing of commencing and completing trials, including topline data reports, interactions with regulators, the potential for and timing of commercialization of product candidates 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. Forward-looking statements are not guarantees of future performance and are 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 avutometinib in combination with other compounds, including defactinib, LUMAKRAS™ and others; the uncertainties inherent in research and development, such as negative or unexpected results of clinical trials, the occurrence or timing of applications for our product candidates that may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications that may be filed for our product candidates, and, if approved, whether our product candidates will be commercially successful in such jurisdictions; 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 trial design, labeling and other matters that could affect the timing, 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 cause adverse safety events and/or unexpected concerns may arise from additional data or analysis, or result in unmanageable safety profiles as compared to their levels of efficacy; that our product candidates may experience manufacturing or supply interruptions or failures; that any of our third party contract research organizations, contract manufacturing organizations, clinical sites, or contractors, among others, who we rely on fail to fully perform; that we face substantial competition, which may result in others developing or commercializing products before or more successfully than we do which could result in reduced market share or market potential for our product candidates; 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, including as a result of conducting additional studies; that we may not have sufficient cash to fund our contemplated operations; that we may not attract and retain high quality personnel; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that our target market for our product candidates might be smaller than we are presently estimating; that Secura Bio, Inc. will fail to fully perform under the asset purchase agreement with Secura Bio, Inc., including in relation to milestone payments; that we will 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 will fail to fully perform under the agreement; 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 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, 2023 as filed with the Securities and Exchange Commission (SEC) on March 14, 2024 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.

Verastem Oncology
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	March 31, 2024	**December 31, 2023**
Cash, cash equivalents, & investments	$ 110,125	$ 137,129
Grant receivable	226	—
Prepaid expenses and other current assets	7,323	6,553
Property and equipment, net	52	37
Right-of-use asset, net	997	1,171
Restricted cash and other assets	4,816	4,828
Total assets	**$ 123,539**	**$ 149,718**
Current Liabilities	$ 26,725	$ 26,380
Long term debt	40,123	40,086
Lease liability, long-term	270	530
Preferred stock tranche liability	10,200	4,189
Convertible preferred stock	21,159	21,159
Stockholders’ equity	25,062	57,374
Total liabilities, convertible preferred stock and stockholders’ equity	**$ 123,539**	**$ 149,718**

Verastem Oncology
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 17,707	$ 12,015
Selling, general and administrative	10,352	7,329
Total operating expenses	28,059	19,344
Loss from operations	(28,059)	(19,344)
Other income (expense)	(30)	(7)
Interest income	1,367	976
Interest expense	(1,130)	(769)
Change in fair value of preferred stock tranche liability	(6,011)	3,430
Net loss	$ (33,863)	$ (15,714)
Net loss per share—basic and diluted	$ (1.26)	$ (0.94)[1]
Weighted average common shares outstanding used in computing:		
Net loss per share – basic and diluted	$ 26,832	$ 16,723[1]

(1) Amounts have been retroactively restated to reflect the 1-for-12 reverse stock split effected on May 31, 2023

Verastem Oncology
Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31,	
	2024	2023
Net loss reconciliation		
Net loss (GAAP basis)	$ (33,863)	$ (15,714)
Adjust:		
Stock-based compensation expense	1,483	1,313
Non-cash interest, net	(419)	(36)
Change in fair value of preferred stock tranche liability	6,011	(3,430)

Severance and other	553	38
Adjusted net loss (non-GAAP basis)	$ (26,235)	$ (17,829)
Reconciliation of net loss per share		
Net loss per share – diluted (GAAP Basis)	$ (1.26)	$ (0.94)[1]
Adjust per diluted share:		
Stock-based compensation expense	0.06	0.08[1]
Non-cash interest, net	(0.02)	—
Change in fair value of preferred stock tranche liability	0.22	(0.21)[1]
Severance and other	0.02	—
Adjusted net loss per share – diluted (non-GAAP basis)	$ (0.98)	$ (1.07)[1]
Weighted average common shares outstanding used in computing net loss per share—diluted	$ 26,832	$ 16,723[1]

(1) Amounts have been retroactively restated to reflect the 1-for-12 reverse stock split effected on May 31, 2023

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