Verastem Oncology Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights Recent Business Updates

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Initiated confirmatory Phase 3 RAMP 301 trial evaluating avutometinib and defactinib combination in recurrent low-grade serous ovarian cancer; on track to submit rolling NDA for accelerated approval in H1 2024; preparations underway for potential commercial launch in 2025

Granted FDA Fast Track designation for avutometinib and sotorasib combination for the treatment of KRAS G12C-mutant non-small cell lung cancer

Announced oral KRAS G12D inhibitor GFH375 (VS-7375) as lead program in discovery and development collaboration with GenFleet Therapeutics

Multiple data readouts evaluating combination therapies in low-grade serous ovarian cancer, non-small cell lung cancer and pancreatic cancer anticipated in 2024

BOSTON--(BUSINESS WIRE)--Mar. 14, 2024-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today reported financial results for the three months and full year ended December 31, 2023, and highlighted recent progress.

“In 2023, we made significant progress toward expanding the opportunities for avutometinib combination therapies across RAS/MAPK driven cancers and I am extremely proud of the team’s accomplishments,” said Dan Paterson, president and chief executive officer of Verastem Oncology. “2024 is expected to be a pivotal year with the planned NDA submission for our avutometinib and defactinib combination in recurrent LGSOC, and multiple clinical data readouts across our programs including initial data from the RAMP 205 trial in metastatic pancreatic cancer and data from the combination with G12C inhibitors in NSCLC. We look forward to continuing to deliver results across our programs.”

Fourth Quarter 2023 and Recent Highlights

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

- Initiated 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 in December 2023 to support potential full approval.
- Reported results of a planned subgroup analysis of Part A of the Phase 2 RAMP 201 trial evaluating avutometinib and defactinib combination in recurrent LGSOC, which demonstrated promising efficacy in patients regardless of number and class of prior therapies including after poor response to prior therapy at the Annual Global Meeting of the International Gynecologic Cancer Society meeting in November 2023.
- Launched patient and healthcare professional programs, including *Let’s Talk About LGSOC* , to support clinicians in the diagnosis and management of LGSOC and provide information and resources to patients.
- Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in March 2024 for avutometinib alone or in combination with defactinib for the treatment of all patients with recurrent LGSOC.

Verastem anticipates the following milestones for avutometinib and defactinib combination in LGSOC in 2024:

- On track to submit a rolling New Drug Application (NDA) for Accelerated Approval for the avutometinib and defactinib combination in LGSOC in H1 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.
- Plan to announce updated topline data from RAMP 201 trial in LGSOC in H1 2024.

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

- Received Fast Track designation from the FDA 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.
- Presented initial results from Phase 1/2 RAMP 203 trial evaluating the efficacy and safety of avutometinib and sotorasib in patients with KRAS G12C-mutant NSCLC who have or have not been previously treated with a KRAS G12C inhibitor at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2023. The confirmed objective rate of response (ORR) was 25% with responses observed in both KRAS G12C inhibitor resistant and naïve patients, and a recommended Phase 2 dose was selected.
- Added defactinib to RAMP 203 trial of avutometinib with sotorasib based on stronger tumor regressions in KRAS G12C-mutant NSCLC preclinical models when FAKi is added along with G12Ci + avutometinib.

Verastem anticipates the following milestones for avutometinib in combination with KRAS G12C inhibitors in 2024:

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

Avutometinib and Defactinib Combination in Frontline Metastatic Pancreatic Cancer

- Plan to present initial safety and efficacy results from RAMP 205 trial of avutometinib and defactinib in combination with current standard of care gemcitabine and nab-paclitaxel in frontline metastatic pancreatic cancer in H1 2024.

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

- Completed investigational new drug (IND)-enabling studies for oral KRAS G12D (ON/OFF) inhibitor GFH375 (VS-7375), the lead program in the collaboration with GenFleet Therapeutics ("GenFleet").
- GenFleet is expected to submit an IND application for GFH375 (VS-7375) in China in H1 2024 with plans to begin a Phase 1 trial in H2 2024. Discovery/lead optimization continues for second and third programs.

Upcoming Presentations

Verastem previously announced the acceptance of multiple abstracts for presentation at upcoming medical conferences:

- 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 will include 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 FAK inhibitor in recurrent LGSOC as well as a trials-in-progress poster about the Phase 3 RAMP 301 trial. See press release here.
- Five preclinical data abstracts were accepted for poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2024 on April 5-10 in San Diego. These presentations will highlight anti-tumor efficacy data of GFH375 (VS-7375), data on RAF/MEK clamp avutometinib and FAK inhibition in pancreatic ductal adenocarcinoma models supporting the ongoing RAMP 205 trial, and avutometinib and a FAK inhibitor combination in cutaneous melanoma models to overcome resistance to BRAF and MEK inhibitors, resistance to immunotherapy, and brain metastasis. See press release here.

Corporate Updates

- Strengthened the executive leadership team with appointments of Mike Crowther to Chief Commercial and Business Strategy Officer and the promotion of Dan Calkins to Chief Financial Officer in October 2023.

Fourth Quarter 2023 Financial Results

Verastem Oncology ended the fourth quarter of 2023 with cash, cash equivalents and investments of $137.1 million.

Total operating expenses for the three months ended December 31, 2023 (the "2023 Quarter") were $31.1 million, compared to $16.8 million for the three months ended December 31, 2022 (the "2022 Quarter").

Research & development expenses for the 2023 Quarter were $22.5 million, compared to $10.7 million for the 2022 Quarter. The increase of $11.8 million, or 110.3%, primarily resulted from increased contract research organization costs, increased drug substance and drug product costs, and increased personnel costs, including non-cash stock compensation.

Selling, general & administrative expenses for the 2023 Quarter were $8.6 million, compared to $6.1 million for the 2022 Quarter. The increase of $2.5 million, or 41.0%, was primarily related to increased personnel costs, including non-cash stock compensation, increased consulting and professional fees, and additional costs in anticipation of a potential launch of avutometinib and defactinib in LGSOC.

Net loss for the 2023 Quarter was $27.4 million, or $1.02 per share (basic and diluted), compared to a net loss of $16.8 million, or $0.99 per share (basic and diluted, each as adjusted for the Company's reverse stock split), for the 2022 Quarter.

For the 2023 Quarter, non-GAAP adjusted net loss was $29.6 million, or $1.10 per share (diluted), compared to non-GAAP adjusted net loss of $15.4 million, or $0.90 per share (diluted, as adjusted for the Company's reverse stock split), for the 2022 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Full-Year 2023 Financial Results

Total operating expenses for the year ended December 31, 2023 (the "2023 Period") were $92.1 million, compared to $75.5 million for the year ended December 31, 222 (the "2022 Period").

Research & development expenses for the 2023 Period were $61.4 million, compared to $50.6 million for the 2022 Period. The increase of $10.8 million, or 21.3%, was primarily related to increases in contract research organization costs, the $2.0 million upfront payment made to GenFleet pursuant to the collaboration and option agreement, and increased personnel costs, including non-cash stock compensation.

Selling, general & administrative expenses for the 2023 Period were $30.7 million, compared to $25.0 million for the 2022 Period. The increase of $5.7

million, or 22.8%, was primarily related to increased personnel costs, including non-cash stock compensation, additional costs in anticipation of a potential launch of avutometinib and defactinib in LGSOC, and increased consulting and professional fees.

Net loss for the 2023 Period was $87.4 million, or $3.96 per share (basic and diluted, each as adjusted for the Company's reverse stock split), compared to $73.8 million, or $4.57 per share (basic and diluted, each as adjusted for the Company's reverse stock split) for the 2022 Period.

For the 2023 Period, non-GAAP adjusted net loss was $85.2 million, or $3.86 per share (diluted, as adjusted for the Company's reverse stock split), compared to non-GAAP adjusted net loss of $67.4 million, or $4.18 per share (diluted, as adjusted for the Company's reverse stock split), for the 2022 Period. 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 and year ended December 31, 2023 and 2022 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 for the combination of Verastem Oncology's investigational RAF/MEK clamp avutometinib, with defactinib, a selective FAK inhibitor, for the treatment of all patients with recurrent 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 its RAF/MEK clamp avutometinib in RAS/MAPK driven tumors as part of its (**R**af **A**nd **M**ek **P**rogram). RAMP 301 (NCT06072781) is a 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. Supported by the "Therapeutic Accelerator Award" received from PanCAN, Verastem Oncology is conducting 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.

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. GenFleet plans to submit an IND in China for GFH375 (VS-7375) in the first half of 2024, and upon approval 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 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 outcome and benefits of the collaboration with GenFleet, the potential clinical value of various of its 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)

	December 31, 2023	December 31, 2022
Cash, cash equivalents, & investments	$ 137,129	$ 87,894
Accounts receivable, net	—	31
Prepaid expenses and other current assets	6,553	4,945
Property and equipment, net	37	92
Right-of-use asset, net	1,171	1,789
Restricted cash and other assets	4,828	299
Total assets	**$ 149,718**	**$ 95,050**
Current Liabilities	$ 26,380	$ 21,663

Long term debt	40,086	24,526
Lease liability, long-term	530	1,470
Preferred stock tranche liability	4,189	—
Convertible preferred stock	21,159	—
Stockholders' equity	57,374	47,391
Total liabilities, convertible preferred stock and stockholders' equity	**$ 149,718**	**$ 95,050**

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

	Three months ended December 31,		Year ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Sale of COPIKTRA license and related assets revenue	$ —	$ —	$ —	$ 2,596
Total revenue	—	—	—	2,596
Operating expenses:				
Research and development	22,502	10,740	61,356	50,558
Selling, general and administrative	8,637	6,106	30,728	24,975
Total operating expenses	31,139	16,846	92,084	75,533
Loss from operations	(31,139)	(16,846)	(92,084)	(72,937)
Other income (expense)	(49)	(7)	(109)	47
Interest income	1,869	769	6,214	1,215
Interest expense	(1,120)	(724)	(4,139)	(2,137)
Change in fair value of preferred stock tranche liability	3,071	—	2,751	—
Net loss	$ (27,368)	$ (16,808)	$ (87,367)	$ (73,812)
Net loss per share—basic and diluted	$ (1.02)	$ (0.99)[(1)]	$ (3.96)[(1)]	$ (4.57)[(1)]
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted	26,808	17,042[(1)]	22,054[(1)]	16,138[(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 December 31,		Year ended December 31,	
	2023	**2022**	**2023**	**2022**
Net loss reconciliation				
Net loss (GAAP basis)	$ (27,368)	$ (16,808)	$ (87,367)	$ (73,812)
Adjust:				
Stock-based compensation expense	1,598	1,287	5,860	6,047
Non-cash interest, net	(837)	(3)	(1,132)	228
Change in fair value of preferred stock tranche liability	(3,071)	—	(2,751)	—
Severance and other	113	109	199	109
Adjusted net loss (non-GAAP basis)	$ (29,565)	$ (15,415)	$ (85,191)	$ (67,428)
Reconciliation of net loss per share				
Net loss per share – diluted (GAAP Basis)	$ (1.02)	$ (0.99)(1)	$ (3.96)(1)	$ (4.57)(1)
Adjust per diluted share:				
Stock-based compensation expense	0.06	0.09(1)	0.26(1)	0.38(1)
Non-cash interest, net	(0.03)	—(1)	(0.05)(1)	0.01(1)
Change in fair value of preferred stock tranche liability	(0.11)	—	(0.12)(1)	—
Severance and other	—	—	0.01(1)	0.01(1)
Adjusted net loss per share – diluted (non-GAAP basis)	$ (1.10)	$ (0.90)(1)	$ (3.86)(1)	$ (4.18)(1)
Weighted average common shares outstanding used in computing net loss per share—diluted	26,808	17,042(1)	22,054(1)	16,138(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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