



## Verastem Oncology Reports Fourth Quarter and Full Year 2022 Financial Results and Highlights Recent Company Progress

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*Positive Interim Data Read-Out of RAMP 201 and Productive FDA Meeting Support Avutometinib + Defactinib Combination in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC)*

*Studies of Avutometinib Combinations in Other RAS Pathway-Driven Cancers Advancing*

*Company Cash, Cash Equivalents, and Investments of \$87.9 Million as of December 31, 2022; Pro-Forma \$117.9 Million Including the Sale of Series B Convertible Preferred Stock*

BOSTON--(BUSINESS WIRE)--Mar. 14, 2023-- 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, 2022, and highlighted recent progress.

"Building on our breakthrough therapy designation, we have made significant progress advancing our LGSOC program, including selecting the combination of avutometinib and defactinib as the go-forward treatment regimen in recurrent disease regardless of KRAS mutation with the goal of filing for accelerated approval upon data maturity in the RAMP 201 trial and initiation of a confirmatory study," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "We believe we are well-positioned to bring this potential new combination therapy to patients who have been waiting for the first U.S. Food and Drug Administration (FDA) approved medicine for this disease. Our debt facility and recent private placement offering add flexibility to our financial strength and are expected to support the continued development of avutometinib in combinations across RAS pathway-driven cancers of high unmet need."

### Fourth Quarter 2022 and Recent Highlights

#### Low Grade Serous Ovarian Cancer (LGSOC)

- The Company held a productive meeting with the FDA to discuss the encouraging results to date of the ongoing RAMP 201 LGSOC trial evaluating avutometinib ± defactinib among patients with recurrent LGSOC, confirmed the go forward treatment regimen selection of avutometinib and defactinib based on a planned interim analysis with prespecified criteria and discussed the regulatory path forward.
- Of the 29 patients evaluable for response by blinded independent central review (BICR) in the combination arm, the initial results showed a confirmed objective response rate (ORR) of 28% in all patients and 27% vs 29% in KRAS mutant (n=15) and KRAS wild-type (n=14) LGSOC, respectively. Three additional patients with KRAS mutant LGSOC showed an unconfirmed partial response. The overall disease control rate (stable disease plus partial response) was 93%. Most evaluable patients (62%) were still on study treatment on the combination arm at the time of the data cut with a minimum follow-up of five months. No new safety signals were reported with a continued favorable safety and tolerability profile.
- Completed enrollment in primary cohort of 72 patients in the combination arm of RAMP 201. Continued enrollment in the combination arm of RAMP 201 is ongoing to expand the clinical experience in anticipation of initiation of a confirmatory study.
- The Company intends to include mature data from RAMP 201, the Verastem sponsored clinical trial, and the FRAME study, led by The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust, to potentially support filing for accelerated approval.

#### Other Programs

- In the Company's RAMP 203 and RAMP 204 clinical trials, evaluating the combination of avutometinib with Amgen's LUMAKRAS® (sotorasib) (RAMP 203) and with Mirati's KRAZATI® (adagrasib) (RAMP 204) in KRAS G12C mutant NSCLC, RAMP 203 progressed to the final dose escalation cohort and enrollment was initiated and dose escalation is ongoing in RAMP 204.
- Initiated RAMP 205, a Phase 1b/2 clinical trial of avutometinib and defactinib to evaluate a more complete blockade of KRAS signaling with standard of care chemotherapy ((GEMZAR® (gemcitabine) and ABRAXANE®)). The trial is supported by the Company's receipt of the first "Therapeutic Accelerator Award" from the Pancreatic Cancer Network (PanCAN).

#### Corporate Updates

- The Company entered into a definitive agreement to sell up to approximately 2.1 million shares of its Series B convertible

preferred stock to affiliates of BVF Partners L.P. in a private placement to raise aggregate gross proceeds of up to approximately \$60 million in two tranches. On January 27, 2023, Verastem Oncology closed on the initial tranche of 1.2 million shares of its Series B convertible preferred stock with gross proceeds of \$30 million.

- The Company has achieved the Term B Milestone pursuant to its credit facility with Oxford and plans to draw down an additional \$15 million in March 2023. Under the credit facility, Verastem has the ability to access up to an additional \$110 million in a series of tranches, \$60 million of which are based on certain pre-determined milestones and \$50 million of which are at the lender's discretion.
- Intermittent dosing intellectual property for both avotometinib alone and in combination with defactinib was recently allowed, extending patent coverage up to 2038 and 2040, respectively.
- Appointed Anil Kapur, Executive Vice President, Corporate Strategy and Chief Commercial Officer at Geron Corporation and Robert Gagnon, the Chief Financial Officer and Operating Partner at Gurnet Point Capital to its Board of Directors.

#### **Fourth Quarter 2022 Financial Results**

Verastem Oncology ended the fourth quarter of 2022 with cash, cash equivalents and investments of \$87.9 million. On a pro forma basis, inclusive of the \$30 million gross proceeds raised through issuance of Series B convertible preferred stock, cash, cash equivalents and investments were \$117.9 million as of December 31, 2022. Additionally, the Company plans to draw down \$15 million on the Oxford Loan and Security Agreement in March 2023.

Total operating expenses for the three months ended December 31, 2022 (the "2022 Quarter") were \$16.8 million, compared to \$17.1 million for the three months ended December 31, 2021 (the "2021 Quarter").

Research & development expenses for the 2022 Quarter were \$10.7 million, compared to \$11.4 million for the 2021 Quarter. The decrease of \$0.7 million, or 6.1%, primarily resulted from a decrease in investigator fees and drug product and drug substance costs.

Selling, general & administrative expenses for the 2022 Quarter were \$6.1 million, compared to \$5.7 million for the 2021 Quarter. The increase of \$0.4 million, or 7.0%, was primarily related to additional costs in anticipation of potential commercialization of avotometinib and defactinib in LGSOC.

Net loss for the 2022 Quarter was \$16.8 million, or \$0.08 per share (basic and diluted), compared to net loss of \$16.5 million, or \$0.09 per share (basic and diluted) for the 2021 Quarter.

For the 2022 Quarter, non-GAAP adjusted net loss was \$15.4 million, or \$0.08 per share (diluted), compared to non-GAAP adjusted net loss of \$14.9 million, or \$0.08 per share (diluted) for the 2021 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

#### **Full-Year 2022 Financial Results**

Total revenue for the year ended December 31, 2022 ("2022 Period") was \$2.6 million, compared to \$2.1 million for the year ended December 31, 2021 ("2021 Period"). Revenue for the 2022 Period was primarily comprised of one regulatory milestone achieved by Secura Bio, Inc.'s ("Secura") sublicensee, CSPC Pharmaceutical Group Limited. Revenue for the 2021 Period was primarily comprised of two regulatory milestones achieved by Secura's sublicensee, Sanofi, and transition services revenue for certain support functions provided to Secura pursuant to the Secura transition services agreement, which was entered into in connection with the sale of COPIKTRA to Secura.

Total operating expenses for the 2022 Period were \$75.5 million, compared to \$63.5 million for the 2021 Period.

Research & development expenses for the 2022 Period were \$50.6 million, compared to \$39.3 million for the 2021 Period. The increase of \$11.3 million, or 28.8%, was primarily related to an increase in drug substance and drug product costs and contract research organization costs.

Selling, general & administrative expenses for the 2022 Period were \$25.0 million, compared to \$24.1 million for the 2021 Period. The increase of \$0.9 million, or 3.7%, was primarily related to additional costs in anticipation of potential commercialization of avotometinib and defactinib in LGSOC.

Net loss for the 2022 Period was \$73.8 million, or \$0.38 per share (basic and diluted), compared to \$71.2 million, or \$0.41 per share (basic and diluted) for the 2021 Period.

For the 2022 Period, non-GAAP adjusted net loss was \$67.4 million, or \$0.35 per share (diluted), compared to non-GAAP adjusted net loss of \$54.1 million, or \$0.31 per share (diluted), for the 2021 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: [pro-forma cash], 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, 2022 and 2021 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

## About Avutometinib (VS-6766)

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 pathway inhibition. Avutometinib is currently in late-stage development.

In contrast to other MEK 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 inhibitors. The U.S. Food and Drug Administration granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK clamp avutometinib, 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.

Verastem Oncology is currently conducting clinical trials with its RAF/MEK clamp avutometinib in RAS- driven tumors as part of its (**Raf And Mek Program**). RAMP 201 is a registration-directed trial of avutometinib in combination with defactinib in patients with recurrent LGSOC. Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS® (sotorasib) and KRAZATI® (adagrasib) in combination with avutometinib in KRAS G12C mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively. As part of the "Therapeutic Accelerator Award" Verastem Oncology received from PanCAN, Verastem Oncology is conducting RAMP 205, a Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer.

## 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](http://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 its financial condition, its potential borrowings, the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports, interactions with regulators 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 avutometinib 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 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 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, including as a result of conducting additional studies; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib 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 Secura will achieve the milestones that result in payments to us under our asset purchase agreement with Secura; that we will be unable to execute on our partnering strategies for avutometinib 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 Verastem Oncology's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission (SEC) on March 14, 2023 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 Verastem Oncology 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, December 31,

	2022	2021
Cash, cash equivalents, & investments	\$ 87,894	\$ 100,256
Accounts receivable, net	31	516
Prepaid expenses and other current assets	4,945	4,968
Property and equipment, net	92	210
Right-of-use asset, net	1,789	2,302
Restricted cash and other assets	299	410
<b>Total assets</b>	<b>\$ 95,050</b>	<b>\$ 108,662</b>
Current Liabilities	\$ 21,663	\$ 18,590
Long term convertible senior notes	—	249
Long term debt	24,526	—
Lease Liability, long-term	1,470	2,264
Stockholders' equity	47,391	87,559
<b>Total liabilities and stockholders' equity</b>	<b>\$ 95,050</b>	<b>\$ 108,662</b>

#### Verastem Oncology

#### Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)  
(unaudited)

	Three months ended December 31, Year ended December 31,			
	2022	2021	2022	2021
Revenue:				
Sale of COPIKTRA license and related assets revenue	\$ —	\$ 545	\$ 2,596	\$ 1,447
Transition services revenue	—	—	—	606
Total revenue	—	545	2,596	2,053
Operating expenses:				
Research and development	10,740	11,396	50,558	39,347

Selling, general and administrative	6,106	5,660	24,975	24,115
Total operating expenses	16,846	17,056	75,533	63,462
Loss from operations	(16,846)	(16,511)	(72,937)	(61,409)
Other income (expense)	(7)	—	47	—
Interest income	769	40	1,215	181
Interest expense	(724)	(10)	(2,137)	(9,972)
Net loss	\$ (16,808)	\$ (16,481)	\$ (73,812)	\$ (71,200)
Net loss per share—basic and diluted	\$ (0.08)	\$ (0.09)	\$ (0.38)	\$ (0.41)
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted	204,501	182,672	193,654	174,406

## 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,	
	2022	2021	2022	2021
<b>Net loss reconciliation</b>				
Net loss (GAAP basis)	\$ (16,808)	\$ (16,481)	\$ (73,812)	\$ (71,200)
<b>Adjust:</b>				
Stock-based compensation expense	1,287	1,574	6,047	7,711
Non-cash interest, net	(3)	44	228	9,331
Severance and other	109	—	109	40
<b>Adjusted net loss (non-GAAP basis)</b>	<b>\$ (15,415)</b>	<b>\$ (14,863)</b>	<b>\$ (67,428)</b>	<b>\$ (54,118)</b>
<b>Reconciliation of net loss per share</b>				
Net loss per share – diluted (GAAP basis)	\$ (0.08)	\$ (0.09)	\$ (0.38)	\$ (0.41)
<b>Adjust per diluted share</b>				
Stock-based compensation expense	—	0.01	0.03	0.04

Non-cash interest, net	—	—	—	0.06
Severance and other	—	—	—	—
<b>Adjusted net loss per share – diluted (non-GAAP basis)</b>	<b>\$ (0.08)</b>	<b>\$ (0.08)</b>	<b>\$ (0.35)</b>	<b>\$ (0.31)</b>
Weighted average common shares outstanding used in computing net loss per share—diluted	204,501	182,672	193,654	174,406

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