# Verastem Oncology Reports Third Quarter 2022 Financial Results and Highlights Recent Company Progress

November 3, 2022

***Combination Trials with Avutometinib (VS-6766) Ongoing as Part of Development Program Designed to Maximize Potential Across RAS Pathway-Driven Tumors***

***Company Confirms Q4 FDA Meeting Based on Encouraging Results to Date in Ongoing RAMP 201 Trial of Avutometinib (VS-6766) ± Defactinib in Low-Grade Serous Ovarian Cancer***

***RAMP Trials with Avutometinib (VS-6766) Combinations in KRAS G12C Mutant NSCLC and Frontline Metastatic Pancreatic Cancer on Track***

BOSTON--(BUSINESS WIRE)--Nov. 3, 2022-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today reported financial results for the three months ended September 30, 2022, and highlighted recent progress.

“In the third quarter, we provided an overall update regarding our RAMP program with RAF/MEK clamp avutometinib (VS-6766), including the encouraging interim results of the RAMP 201 trial that are the basis for advancing our discussions with the FDA regarding the go forward treatment regimen selection and regulatory path forward. Building on our breakthrough therapy designation, our efforts are focused on rapidly advancing this program to make a difference for patients in this highly recurrent, chemotherapy-resistant cancer where no treatments are specifically approved and limited other treatment options are available,” said Brian Stuglik, CEO of Verastem Oncology. “Based on the response results and safety profile seen to date in the RAMP 201 trial, we are looking forward to the results of our broader development program which is aimed at maximizing combinations with avutometinib (VS-6766) across RAS pathway-driven tumors, including KRAS G12C mutant non-small cell lung cancer, frontline metastatic pancreatic cancer and KRAS mutant colorectal cancer.”

**Third Quarter 2022 and Recent Highlights**

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

- Verastem recently conducted a second planned interim analysis of the ongoing RAMP 201 trial among patients with recurrent LGSOC. Based on the results, including independently confirmed responses and no new safety signals, the Company has confirmed a meeting with the U.S. Food and Drug Administration (FDA) by the end of the year to review the data set, to discuss the go forward treatment regimen selection and align on requirements to initiate a New Drug Application submission. The Company will provide an update after the upcoming meeting with the FDA.
- Since the first interim analysis announced in June, the trial has been continuing with all four cohorts (avutometinib (VS-6766) ± defactinib in KRAS mutant and KRAS wild type patient populations) with full enrollment based on the study protocol expected by the end of the year.

***KRAS Mutant Non-Small Cell Lung Cancer (NSCLC) Combination Studies***

- The RAMP 203 Phase 1/2 trial to evaluate the safety, tolerability and efficacy of avutometinib (VS-6766) in combination with Amgen’s KRAS G12C inhibitor LUMAKRAS $^{TM}$ (sotorasib) in patients with KRAS G12C mutant NSCLC, has advanced to Cohort 2 of 4 mg avutometinib (VS-6766) in combination with 960 mg of LUMAKRAS$^{TM}$. Initial safety results are expected by the end of the year.
- The RAMP 204 Phase 1/2 trial of avutometinib (VS-6766) and Mirati’s adagrasib, which will determine the maximum tolerated dose and recommended Phase 2 dose for the combination and evaluate the safety, tolerability and efficacy of the combination in patients who have progressed on a KRAS G12C inhibitor, is open and enrolling.
- The RAMP 203 and 204 studies will investigate the potential benefits of a more complete vertical blockade of the RAS pathway as acquired resistance to KRAS G12C inhibitors in patients occurs predominantly through additional mutations in the RAS pathway, many of which could be addressed with a downstream inhibitor such as avutometinib (VS-6766).
- Results of the ongoing investigator-initiated trial of avutometinib (VS-6766) and everolimus in KRAS-mutant NSCLC are anticipated in the first half of 2023.
- In a planned analysis of the Part A data from the RAMP 202 trial among patients with KRAS G12V and non G12V KRAS NSCLC treated with the combination of avutometinib (VS-6766) and defactinib, no subtype was identified for further clinical evaluation of avutometinib (VS-6766) with defactinib in this trial. Verastem plans to present the Part A results of RAMP 202 at an upcoming medical congress.

***Frontline Metastatic Pancreatic Cancer***

- The Company announced plans to open the RAMP 205 Phase 1b/2 clinical trial of avutometinib (VS-6766) with defactinib in addition to standard of care chemotherapy (gemcitabine/nab-paclitaxel) in frontline metastatic pancreatic cancer in the fourth quarter of this year. The trial, in partnership with the Pancreatic Cancer Action Network (PanCAN) will evaluate whether blockade of KRAS signaling, which is mutated in more than 90% of pancreatic cancer tumors, along with chemotherapy and reduction of stromal density, will improve outcomes for patients with pancreatic cancer.

**Corporate Updates**

- Avutometinib has been accepted as the International Nonproprietary Name (INN) and United States Adopted Name (USAN) for VS-6766.
- Intermittent dosing intellectual property for both avutometinib (VS-6766) alone (previously announced) and in combination with defactinib was recently allowed, extending patent coverage up to 2038 and 2040, respectively.
- Anil Kapur, the Executive Vice President, Corporate Strategy and Chief Commercial Officer at Geron Corporation, was appointed to the Company's Board of Directors, effective October 20, 2022.

**Third Quarter 2022 Financial Results**

Verastem Oncology ended the three months ended September 30, 2022 (2022 Quarter) with cash, cash equivalents and investments of $104.0 million. Total operating expenses for the 2022 Quarter were $17.7 million, compared to $14.8 million for the three months ended September 30, 2021 (2021 Quarter).

Research and development expenses for the 2022 Quarter were $11.3 million, compared to $9.3 million for the 2021 Quarter. The increase of $2.0 million, or 21.5%, primarily resulted from an increase in drug product and drug substance costs, consulting costs, clinical supply costs, pre-clinical costs, and personnel costs, including non-cash stock-based compensation.

Selling, general and administrative expenses for the 2022 Quarter were $6.4 million, compared to $5.5 million for the 2021 Quarter. The increase of $0.9 million, or 16.4%, primarily resulted from an increase in commercial costs, and consulting and professional costs.

Net loss for the 2022 Quarter was $18.1 million, or $0.09 per share (basic and diluted), compared to net loss of $22.8 million, or $0.13 per share (basic and diluted), for the 2021 Quarter.

For the 2022 Quarter, non-GAAP adjusted net loss was $16.6 million, or $0.08 per share (diluted), compared to non-GAAP adjusted net loss of $12.8 million, or $0.07 per share (diluted), for the 2021 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 and nine months ended September 30, 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 (**R**af **A**nd **M**ek **P**rogram). RAMP 201 is a registration-directed trial of avutometinib alone and in combination with defactinib in patients with recurrent LGSOC. Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS™ (sotorasib) and 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, the Company 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.

**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 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 labeling and other matters that could affect the 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; 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 Bio, Inc. will achieve the milestones that result in payments to us under our asset purchase agreement with Secura Bio, Inc.; 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission (SEC) on March 28, 2022 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.

**References**

[1] Verastem Oncology Press Release. Verastem Oncology Receives Breakthrough Therapy Designation for VS-6766 with Defactinib in Recurrent Low-Grade Serous Ovarian Cancer. May 24, 2021. Available at: https://investor.verastem.com/news-releases/news-release-details/verastem-oncology-receives-breakthrough-therapy-designation-vs. Accessed March 2022.

**Verastem Oncology**

**Condensed Consolidated Balance Sheets**

(in thousands)

(unaudited)

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Cash, cash equivalents, & investments | $ 103,976 | $ 100,256 |

| | | |
|---|---|---|
| Accounts receivable, net | 74 | 516 |
| Prepaid expenses and other current assets | 4,709 | 4,968 |
| Property and equipment, net | 121 | 210 |
| Right-of-use asset, net | 1,927 | 2,302 |
| Restricted cash and other assets | 288 | 410 |
| **Total assets** | **$ 111,095** | **$ 108,662** |

| | | |
|---|---|---|
| Current Liabilities | $ 21,873 | $ 18,590 |
| Convertible senior notes | 268 | 249 |
| Long term debt | 24,399 | — |
| Lease Liability, long-term | 1,682 | 2,264 |
| Stockholders' equity | 62,873 | 87,559 |
| **Total liabilities and stockholders' equity** | **$ 111,095** | **$ 108,662** |

**Verastem Oncology**

**Condensed Consolidated Statements of Operations**

(in thousands, except per share amounts)

(unaudited)

| | **Three months ended September 30,** | | **Nine months ended September 30,** | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Revenue: | | | | |
| Sale of COPIKTRA license and related assets revenue | $ — | $ — | $ 2,596 | $ 902 |
| Transition services revenue | — | 2 | — | 606 |
| Total revenue | — | 2 | 2,596 | 1,508 |
| Operating expenses: | | | | |

| | | | | |
|---|---|---|---|---|
| Research and development | 11,288 | 9,325 | 39,818 | 27,951 |
| Selling, general and administrative | 6,421 | 5,523 | 18,869 | 18,455 |
| Total operating expenses | 17,709 | 14,848 | 58,687 | 46,406 |
| Loss from operations | (17,709) | (14,846) | (56,091) | (44,898) |
| Other income | 20 | — | 54 | — |
| Interest income | 316 | 40 | 446 | 141 |
| Interest expense | (717) | (7,980) | (1,413) | (9,962) |
| Net loss | $ (18,090) | $ (22,786) | $ (57,004) | $ (54,719) |
| Net loss per share—basic and diluted | $ (0.09) | $ (0.13) | $ (0.30) | $ (0.31) |
| Weighted average common shares outstanding used in computing: | | | | |
| Net loss per share – basic and diluted | 197,151 | 179,861 | 189,999 | 174,524 |

**Verastem Oncology**

**Reconciliation of GAAP to Non-GAAP Financial Information**

(in thousands, except per share amounts)

(unaudited)

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| **Net loss reconciliation** | | | | |
| Net loss (GAAP basis) | $ (18,090) | $ (22,786) | $ (57,004) | $ (54,719) |
| **Adjust:** | | | | |
| Stock-based compensation expense | 1,356 | 1,987 | 4,760 | 6,137 |
| Non-cash interest, net | 120 | 7,959 | 231 | 9,287 |
| Severance and Other | — | 40 | — | 40 |
| **Adjusted net loss (non-GAAP basis)** | $ (16,614) | $ (12,800) | $ (52,013) | $ (39,255) |

| | | | | |
|---|---|---|---|---|
| **Reconciliation of net loss per Share** | | | | |
| Net loss per share – diluted (GAAP Basis) | (0.09) | (0.13) | (0.30) | (0.31) |
| **Adjust per diluted share:** | | | | |
| Stock-based compensation expense | 0.01 | 0.01 | 0.02 | 0.04 |
| Non-cash interest, net | — | 0.05 | — | 0.05 |
| Severance and Other | — | — | — | — |
| **Adjusted net loss per share – diluted (non-GAAP basis)** | $ (0.08) | $ (0.07) | $ (0.28) | $ (0.22) |
| Weighted average common shares outstanding used in computing net loss per share—diluted | 197,151 | 179,861 | 189,999 | 174,524 |

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