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

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Company Reported Interim Findings from RAMP 201 Trial of VS-6766 +/- Defactinib in Low-Grade Serous Ovarian Cancer; Continued Evaluation of Both Monotherapy and Combination Therapy with Timing of Go Forward Treatment Regimen Selection Driven by Data Maturity

Verastem Oncology Awarded Pancreatic Cancer Action Network's First Therapeutic Accelerator Award to Evaluate the Combination of VS-6766 and Defactinib in Addition to Standard of Care Chemotherapy in Front-Line Metastatic Pancreatic Cancer

U.S. Patent and Trademark Office Granted Patent for Novel VS-6766 Dosing Regimen for Cancers with KRAS/NRAS/HRAS Mutations; Extending Patent Protection Through 2038

BOSTON--(BUSINESS WIRE)--Aug. 8, 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 June 30, 2022, and highlighted recent progress.

"In the second quarter, we announced findings from the interim analysis of our registration-directed RAMP 201 trial in low-grade serous ovarian cancer and are encouraged by the anti-tumor activity that we have seen to date in patients with both KRAS mutant and KRAS wild-type tumors. We look forward to evaluating a more mature data set to select the go forward regimen." said Brian Stuglik, CEO of Verastem Oncology. "We also advanced our broader development program, including being honored by the Pancreatic Cancer Network as the first recipient of their Therapeutic Accelerator Award. This award will support a Phase 1b/2 clinical trial evaluating VS-6766 and defactinib in addition to standard of care chemotherapy in front-line metastatic pancreatic cancer. The goal of the trial is to increase response rate and survival through a more complete blockade of tumorigenic signaling."

Second Quarter 2022 and Recent Highlights

Low Grade Serous Ovarian Cancer (LGSOC)

- Verastem Oncology completed a planned interim analysis of the registration-directed RAMP 201 trial with the goal of selecting a go forward treatment regimen of either VS-6766 monotherapy or VS-6766 in combination with defactinib. The analysis indicated encouraging efficacy results with confirmed responses by independent review in patients treated with VS-6766 monotherapy and patients treated with VS-6766 in combination with defactinib. The findings also include confirmed responses by independent review in both KRAS mutant and KRAS wild-type LGSOC. To date, there have been no additional safety signals with a continued favorable safety profile in both the monotherapy and combination treatment arms with approximately 6% of patients discontinuing due to adverse events.
- With approximately 80% of patients in the RAMP 201 study remaining on study treatment with a median duration of follow-up of four months, data from the interim analysis were not mature enough to make a final decision on the go forward treatment regimen and the trial continues with all four cohorts. The Company plans to complete enrollment of all four cohorts of the trial in the second half of this year. Each cohort is expected to have approximately 36 patients for a total of 144 patients.

KRAS Mutant Non-Small Cell Lung Cancer (NSCLC)

- The registration-directed RAMP 202 study investigating VS-6766 alone and in combination with defactinib continues to enroll patients with V600E or non-V600E BRAF mutations. Planned enrollment is complete in the selection phase (Part A; n=32) in patients with KRAS G12V-mutant NSCLC. Enrollment has also been completed in the non-G12V mutant cohort in the selection phase (Part A). The Company expects to report topline results from Part A, initiate Part B and discuss the data with regulatory authorities during the second half of 2022.
- The Phase 1/2 RAMP 204 clinical trial evaluating VS-6766 in combination with Mirati's adagrasib in KRAS G12C-mutant NSCLC opened and is enrolling participants.
- The Phase 1/2 RAMP 203 clinical trial evaluating VS-6766 in combination with Amgen's LUMAKRAS ^{TM} (sotorasib) in KRAS G12C-mutant NSCLC continues to enroll and initial results are expected to be reported during the second half of 2022.

Corporate Updates

- The U.S Patent and Trademark Office has granted Patent No. 11,400,090 which covers the novel, intermittent twice-weekly

dosing regimen used in the VS-6766 development program. This extends the current patent protection for VS-6766 in RAS-driven cancers (KRAS/NRAS/HRAS mutations) to 2038.

- The Company received the first “Therapeutic Accelerator Award” from the Pancreatic Cancer Network (PanCAN). The award will support a Phase 1b/2 clinical trial of the Company’s lead investigational candidates, RAF/MEK Clamp, or VS-6766, with FAK inhibitor, defactinib to evaluate whether a more complete blockade of KRAS signaling *in addition to standard of care chemotherapy will* improve outcomes for patients with front-line metastatic pancreatic cancer. KRAS mutations occurs in more than 95% of pancreatic cancer tumors.
- Results from a Phase 1 investigator-initiated trial evaluating RAF/MEK clamp VS-6766 in combination with everolimus presented at the American Society of Clinical Oncology (ASCO) found encouraging responses across various RAS-driven tumor types as well as a tolerable intermittent dosing schedule. The data also included a median progression-free survival interval of 6.3 months in KRAS mutant NSCLC and median progression-free survival of 35.8 and 41.8 months in two enrolled patients with KRAS mutant LGSOC, respectively. The trial is continuing with an ongoing expansion cohort for patients with KRAS mutant NSCLC.

Second Quarter 2022 Financial Results

Verastem Oncology ended the second quarter 2022 with cash, cash equivalents and investments of $94.3 million. With proceeds available upon achievement of certain milestones from the Oxford Finance LLC credit facility and expected milestones and royalties from the sale of COPIKTRA, Verastem Oncology expects that it has a cash runway until at least 2025 to deliver on the current programs for VS-6766 and defactinib, including expenditures and development in LGSOC and KRAS mutant NSCLC.

Total revenue for the three months ending June 30, 2022 (2022 Quarter) was $0.0 million, compared to $0.5 million for the three months ended June 30, 2021 (2021 Quarter).

Total operating expenses for the 2022 Quarter were $21.4 million, compared to $16.4 million for the 2021 Quarter.

Research & development expenses for the 2022 Quarter were $14.9 million, compared to $9.7 million for the 2021 Quarter. The increase of $5.2 million, or 53.6%, primarily resulted from an increase in drug product and drug substance costs, contract research organization costs and investigator fees.

Selling, general & administrative expenses for the 2022 Quarter were $6.5 million, compared to $6.7 million for the 2021 Quarter. The decrease of $0.2 million, or 3.0%, primarily resulted from lower consulting and professional fees.

Net loss for the 2022 Quarter was $22.0 million, or $0.12 per share (basic and diluted), compared to net loss of $16.9 million, or $0.10 per share (basic and diluted), for the 2021 Quarter.

For the 2022 Quarter, non-GAAP adjusted net loss was $20.1 million, or $0.11 per share (diluted), compared to non-GAAP adjusted net loss of $14.0 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.

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) income and non-GAAP net (loss) income 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 six months ended June 30, 2022, and 2021 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About VS-6766

VS-6766 (formerly known as CH5126766 and RO5126766) 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. VS-6766 is currently in late-stage development.

In contrast to other MEK inhibitors, VS-6766 blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows VS-6766 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 inhibitor VS-6766, 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.[1]

Verastem Oncology is conducting Phase 2 registration-directed trials of VS-6766 alone and with defactinib in patients with recurrent LGSOC and in patients with recurrent KRAS G12V-mutant NSCLC as part of its RAMP (Raf And Mek Program) clinical trials, RAMP 201 and RAMP 202, respectively. Verastem Oncology has also established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS™ (sotorasib) and adagrasib in combination with VS-6766 in KRAS G12C-mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively.

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 cash runway, the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports, 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 VS-6766 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 VS-6766 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 VS-6766 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.

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Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	June 30, 2022	December 31, 2021

Cash, cash equivalents, & investments	$ 94,307	$ 100,256
Accounts receivable, net	131	516
Prepaid expenses and other current assets	3,437	4,968
Property and equipment, net	151	210
Right-of-use asset, net	2,058	2,302
Restricted cash and other assets	325	410
Total assets	**$ 100,409**	**$ 108,662**

Current Liabilities	$ 20,092	$ 18,590
Convertible senior notes	262	249
Long term debt	24,276	—
Lease Liability, long-term	1,887	2,264
Stockholders' equity	53,892	87,559
Total liabilities and stockholders' equity	**$ 100,409**	**$ 108,662**

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Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		**Six months ended June 30,**	
	2022	**2021**	**2022**	**2021**
Revenue:				
Sale of COPIKTRA license and related assets revenue	$ —	$ 52	$ 2,596	$ 902
Transition services revenue	—	448	—	604
Total revenue	—	500	2,596	1,506
Operating expenses:				

Research and development	14,888	9,730	28,530	18,626
Selling, general and administrative	6,514	6,714	12,448	12,932
Total operating expenses	21,402	16,444	40,978	31,558
Loss from operations	(21,402)	(15,944)	(38,382)	(30,052)
Other expense	6	—	34	—
Interest income	84	49	130	101
Interest expense	(640)	(1,007)	(696)	(1,982)
Net loss	$ (21,952)	$ (16,902)	$ (38,914)	$ (31,933)
Net loss per share—basic and diluted	$ (0.12)	$ (0.10)	$ (0.21)	$ (0.19)
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted	186,463	171,985	186,364	171,811

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Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
Net loss reconciliation				
Net loss (GAAP basis)	$ (21,952)	$ (16,902)	$ (38,914)	$ (31,933)
Adjust:				
Stock-based compensation expense	1,758	2,170	3,404	4,150
Non-cash interest, net	94	692	111	1,328
Adjusted net loss (non-GAAP basis)	$ (20,100)	$ (14,040)	$ (35,399)	$ (26,455)

Reconciliation of net loss per Share

Net loss per share – diluted (GAAP Basis)	(0.12)	(0.10)	(0.21)	(0.19)
Adjust per diluted share:				
Stock-based compensation expense	0.01	0.01	0.02	0.03
Non-cash interest, net	—	0.01	—	0.01
Adjusted net loss per share – diluted (non-GAAP basis)	$ (0.11)	$ (0.08)	$ (0.19)	$ (0.15)
Weighted average common shares outstanding used in computing net loss per share—diluted	186,463	171,985	186,364	171,811

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