



Verastem Oncology Reports Third Quarter 2021 Financial Results and Highlights Recent Company Progress

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Announced Clinical Collaboration with Amgen to Evaluate VS-6766 with LUMAKRAS™ in Non-Small Cell Lung Cancer in Upcoming Clinical Trial

Updated Data from Investigator-Sponsored Phase 1/2 FRAME Study of VS-6766 and Defactinib in Low-Grade Serous Ovarian Cancer Presented at ESMO 2021

Appointed Louis J. Denis, M.D., as Chief Medical Officer

BOSTON--(BUSINESS WIRE)--Nov. 4, 2021-- 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, 2021 and highlighted recent progress.

"The third quarter was marked by several significant milestones for Verastem as we continued to advance our development program to establish VS-6766 as a backbone therapy across RAS pathway-driven solid tumors, including our entry into a clinical collaboration with Amgen to evaluate VS-6766 in combination with LUMAKRAS™ (sotorasib) in patients with KRAS G12C-mutant NSCLC. This Phase 1/2 study will investigate the potential of a more complete vertical blockade along the RAS pathway," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "We were also pleased to highlight updated data from the investigator-initiated Phase 1/2 FRAME study that were presented at ESMO 2021 and continue to demonstrate encouraging response rates, along with 23.0 months PFS, in patients with low-grade serous ovarian cancer (LGSOC), including in patients who had previously received a MEK inhibitor."

Recent Corporate Highlights

Low-Grade Serous Ovarian Cancer (LGSOC)

- Updated data from the LGSOC cohort of the ongoing, investigator-sponsored Phase 1/2 FRAME study evaluating VS-6766 in combination with defactinib in patients with LGSOC were presented at the European Society of Medical Oncology (ESMO) Congress 2021. Results show encouraging response rates and progression-free survival (PFS). The initial results of the FRAME study were the basis for the U.S. Food and Drug Administration granting Breakthrough Therapy designation for the combination in LGSOC.
 - Median PFS across all patients was 23.0 months (n=24)
 - Overall response rate (ORR) across all patients was 46% (11 of 24 patients)
 - ORR across patients with KRAS mutant LGSOC was 64% (7 of 11 patients)
 - ORR across patients with KRAS wild type LGSOC was 44% (4 of 9 patients)
- Continued progress with the company-sponsored, registration-directed Phase 2 study (RAMP 201) investigating VS-6766 alone and in combination with defactinib for the treatment of recurrent LGSOC. The Company expects to report top-line results from the selection phase of RAMP 201 and commence expansion phase during the first half of 2022.

KRAS Mutant Non-small Cell Lung Cancer (NSCLC)

- Announced strategic partnership with Amgen to evaluate the safety, tolerability, and efficacy of VS-6766 in combination with LUMAKRAS™ (sotorasib), Amgen's KRAS G12C inhibitor, in patients with locally advanced or metastatic KRAS G12C-mutant NSCLC. This Phase 1/2 clinical trial is expected to initiate by the end of 2021.
- Continued progress in company-sponsored, registration-directed Phase 2 study (RAMP 202) investigating VS-6766 alone and in combination with defactinib for the treatment of patients with KRAS G12V mutant NSCLC. The Company expects to report top-line results from the selection phase of RAMP 202 and commence expansion phase during first half of 2022.

Corporate and Financial

- Appointed Michelle Robertson to join the Verastem Board of Directors. Ms. Robertson is the Chief Financial Officer at Editas Medicine and brings more than 25 years of Finance and Commercial Operations leadership to the Board.
- Appointed Louis J. Denis, M.D., as Chief Medical Officer. Dr. Denis brings more than 25 years of clinical development and oncology experience to Verastem having served at several biotech and pharmaceutical companies during his career, including Asana BioSciences, Boehringer Ingelheim and Pfizer.
- Converted all of the \$28.0 million aggregate principal of the Company's 2020 5.00% Convertible Senior Notes due 2048 in exchange for approximately 8.6 million shares of common stock. The conversion eliminates substantially all outstanding

debt and preserves approximately \$31.2 million in cash, including \$3.2 million in future interest payments that would have been payable through November 1, 2023.

Third Quarter 2021 Financial Results

Verastem Oncology ended the third quarter of 2021 with cash, cash equivalents and investments of \$103.4 million.

Total revenue for the three months ending September 30, 2021 (2021 Quarter) was \$0.0 million, compared to \$78.6 million for the three months ended September 30, 2020 (2020 Quarter). Revenue for the 2020 Quarter was comprised of (i) \$70.0 million recognized for the upfront payment made as part of the COPIKTRA sale to Secura Bio, Inc., (ii) \$5.8 million of net product revenue, and (iii) \$2.8 million of license and collaboration revenue primarily comprised of \$2.5 million for Sanofi achieving two development milestones under the license and collaboration agreement between Sanofi and Verastem.

Total research and development (R&D) and selling, general and administrative (SG&A) expenses for the 2021 Quarter were \$14.8 million, compared to \$31.6 million for the 2020 Quarter.

SG&A expenses for the 2021 Quarter were \$5.5 million, compared to \$20.6 million for the 2020 Quarter. The decrease of \$15.1 million, or 73%, primarily resulted from the Company's shift in strategic direction and the COPIKTRA sale to Secura Bio, Inc., which led to lower employee-related expenses and consulting and professional fees.

R&D expenses for the 2021 Quarter were \$9.3 million, compared to \$11.0 million for the 2020 Quarter. The decrease of \$1.7 million, or 15%, was primarily related to lower contract research organization costs, consulting fees, and clinical supply costs.

Net (loss) for the 2021 Quarter was \$(22.8) million, or \$(0.13) per share (basic and diluted), compared to net income of \$13.1 million, or \$0.08 per share (basic and diluted), for the 2020 Quarter.

For the 2021 Quarter, non-GAAP adjusted net (loss) was \$(12.8) million, or \$(0.07) per share (diluted), compared to non-GAAP adjusted net income of \$18.8 million, or \$0.11 per share (diluted), for the 2020 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Financial Guidance and Outlook

With the proceeds and expected milestones and royalties from the sale of COPIKTRA, Verastem Oncology expects that it has a cash runway until at least 2024 to deliver on the current programs for VS-6766 and defactinib, including expenditures and development in LGSOC and KRAS mutant NSCLC. Verastem Oncology expects its 2021 annual operating expenses to be approximately \$55-60 million.

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 nine months ended September 30, 2021 and 2020 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About the VS-6766/Defactinib Combination

The combination of VS-6766 and defactinib has been found to be clinically active in patients with KRAS mutant tumors. In an ongoing investigator-initiated Phase 1/2 FRAME study, the combination of VS-6766 and defactinib is being evaluated in patients with low-grade serous ovarian cancer (LGSOC), KRAS mutant NSCLC and colorectal cancer (CRC). The FRAME study was expanded to include new cohorts in pancreatic cancer, KRAS mutant endometrioid cancer and KRAS-G12V NSCLC. Verastem Oncology is also supporting an investigator-initiated Phase 2 trial evaluating VS-6766 with defactinib in patients with metastatic uveal melanoma. Verastem Oncology has initiated Phase 2 registration-directed trials of VS-6766 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).

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK inhibitor VS-6766, with defactinib, its focal adhesion kinase (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.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) (Verastem, Inc.) 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 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 the RAF/MEK/FAK combination, the potential benefits of Breakthrough Therapy designation and the timing of commencing and completing registration-directed trials for the RAF/MEK/FAK combination. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "encouraging" 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 defactinib in combination with VS-6766; 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 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 we will be unable to execute on our partnering strategies for defactinib in combination with VS-6766; that we will not pursue or submit regulatory filings for our product candidates; that we do not receive additional proceeds from the contingent payments negotiated in the sale of COPIKTRA; 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, 2020 as filed with the Securities and Exchange Commission (SEC) on March 18, 2021 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.

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Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	September 30, December 31,	
	2021	2020
Cash, cash equivalents, & investments	\$ 103,416	\$ 147,221
Accounts receivable, net	105	239
Prepaid expenses and other current assets	5,236	3,473
Property and equipment, net	240	416
Right-of-use asset, net	2,416	2,726
Restricted cash and other assets	464	274
Total assets	\$ 111,877	\$ 154,349

Current Liabilities	\$ 13,536	\$ 17,093
Convertible senior notes	243	19,051
Lease Liability, long-term	2,443	2,931
Stockholders' equity	95,655	115,274
Total liabilities and stockholders' equity	\$ 111,877	\$ 154,349

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Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	\$ —	\$ 5,829	\$ —	\$ 15,098
License and collaboration revenue	—	2,818	—	2,912
Sale of COPIKTRA license and related assets revenue	—	70,000	902	70,000
Transition services revenue	2	—	606	—
Total revenue	2	78,647	1,508	88,010
Operating expenses:				
Cost of sales - product	—	866	—	1,753
Cost of sales - intangible amortization	—	8	—	793
Cost of sales - Sale of COPIKTRA license and related assets	—	31,187	—	31,187
Research and development	9,325	10,955	27,951	31,223
Selling, general and administrative	5,523	20,614	18,455	55,660
Total operating expenses	14,848	63,630	46,406	120,616
(Loss) income from operations	(14,846)	15,017	(44,898)	(32,606)
Other expense	—	—	—	(1,313)
Interest income	40	19	141	497

Interest expense	(7,980)	(1,898)	(9,962)	(14,440)
Net (loss) income	\$ (22,786)	\$ 13,138	\$ (54,719)	\$ (47,862)
Net (loss) income per share—basic	\$ (0.13)	\$ 0.08	\$ (0.31)	\$ (0.32)
Net (loss) income per share—diluted	\$ (0.13)	\$ 0.08	\$ (0.31)	\$ (0.32)
Weighted average common shares outstanding used in computing:				
Net (loss) income per share – basic	179,861	169,510	174,524	147,766
Net (loss) income per share – diluted	179,861	169,760	174,524	147,766

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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,	
	2021	2020	2021	2020
Net (loss) income reconciliation				
Net (loss) income (GAAP basis)	\$ (22,786)	\$ 13,138	\$ (54,719)	\$ (47,862)
Adjust:				
Amortization of acquired intangible asset	—	8	—	793
Stock-based compensation expense	1,987	2,156	6,137	5,185
Non-cash interest, net	7,959	506	9,287	9,765
Severance and other	40	2,993	40	4,781
Change in fair value of derivative	—	—	—	1,313
Chugai license payment	—	—	—	3,000
Adjusted net (loss) income (non-GAAP basis)	\$ (12,800)	\$ 18,801	\$ (39,255)	\$ (23,025)

Reconciliation of net (loss) income per Share

Net (loss) income per share – diluted (GAAP Basis)	\$ (0.13)	\$ 0.08	\$ (0.31)	\$ (0.32)
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Adjust per diluted share

Amortization of acquired intangible asset	—	—	—	—
Stock-based compensation expense	0.01	0.01	0.04	0.03
Non-cash interest, net	0.05	—	0.05	0.07
Severance and other	—	0.02	—	0.03
Change in fair value of derivative	—	—	—	0.01
Chugai license payment	—	—	—	0.02
Adjusted net (loss) income per share – diluted (non-GAAP basis)	\$ (0.07)	\$ 0.11	\$ (0.22)	\$ (0.16)
Weighted average common shares outstanding used in computing net (loss) income per share—diluted	179,861	169,760	174,524	147,766

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