Verastem Oncology Reports Fourth Quarter and Full Year 2021 Financial Results and Highlights Recent Company Progress

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Company Secures up to $150 Million in Non-Dilutive Funding from Oxford Finance LLC; Expected Cash Runway Through 2025 to Support Continued Development and Potential Commercial Launches of VS-6766 and Defactinib

Enrollment Complete in Selection Phase (Part A) of RAMP 201 Evaluating VS-6766 +/- Defactinib for the Treatment of Low-Grade Serous Ovarian Cancer; Expect to Report Results from Part A in 2Q 2022

Enrollment Complete in Selection Phase (Part A) of RAMP 202 Evaluating VS-6766 +/- Defactinib for the Treatment of KRAS G12V Mutant Non-Small Cell Lung Cancer; Expect to Report Results from Part A in 2H 2022

Clinical Collaborations and Investigator-Sponsored Trial Programs Ongoing in Additional Areas of High Unmet Need

BOSTON--(BUSINESS WIRE)--Mar. 28, 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 and full year ended December 31, 2021, and highlighted recent progress.

"We anticipate a catalyst-driven year and are well-positioned to maximize the potential of VS-6766 as a backbone therapy across RAS pathway-driven solid tumors in order to bring new solutions to patients in areas of high unmet need. Our recent debt facility adds flexibility to our financial strength and is expected to support the continued development and potential commercial launches of VS-6766 and defactinib, including building on our breakthrough therapy designation in low-grade serous ovarian cancer," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "We plan to report results from the selection phase of RAMP 201, our lead program in patients with low-grade serous ovarian cancer, regardless of KRAS status, during the second quarter. And, as part of our non-small cell lung cancer program, we are targeting KRAS mutant patient subpopulations across four clinical trials and we are anticipating initial readouts from three NSCLC studies, including RAMP 202 with defactinib, the investigator-sponsored study with everolimus, and RAMP 203 with LUMAKRAS™ (sotorasib) this year."

Fourth Quarter 2021 and Recent Highlights

Verastem's lead drug candidate VS-6766 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.

Low Grade Serous Ovarian Cancer (LGSOC)

- Planned enrollment is complete in the selection phase (Part A; n=64) of the registration-directed Phase 2 RAMP 201 study investigating VS-6766 alone or in combination with defactinib for the treatment of recurrent LGSOC. Verastem remains on track to report topline results from Part A during the second quarter of 2022, following discussions with regulatory authorities.
- Enrollment has commenced in the expansion phase (Part B) of RAMP 201, with both treatment arms (VS-6766 alone and in combination with defactinib) currently advancing in all patients. Verastem expects to complete enrollment in Part B during the second half of 2022.

KRAS Mutant Non-Small Cell Lung Cancer (NSCLC)

- Planned enrollment is now complete in the selection phase (Part A; n=32) of the registration-directed RAMP 202 study investigating VS-6766 alone and in combination with defactinib in patients with KRAS G12V mutant NSCLC. The Company expects to report topline results from Part A and initiate Part B during the second half of 2022, following discussions with regulatory authorities.
- Based on preclinical rationale, Verastem has added BRAF mutant cohorts to the RAMP 202 study in order to efficiently evaluate VS-6766 with defactinib in BRAF-mutant NSCLC. In Part A of the study, the Company expects to enroll two cohorts comprised of 15 patients each to evaluate the combination in patients with V600E or non-V600E BRAF mutations, respectively. These cohorts are open and enrolling.
- The Company entered into two clinical agreements to study VS-6766 in combination with KRAS G12C inhibitors in patients with KRAS G12C-mutant NSCLC, including patients who have progressed on a KRAS G12C inhibitor. Initial results from the ongoing Phase 1/2 RAMP 203 study evaluating VS-6766 in combination with Amgen's LUMAKRAS ™ (sotorasib) are expected to be reported during the second half of 2022. Initiation of the Phase 1/2 RAMP 204 study evaluating VS-6766 in combination with Mirati's adagrasib is expected during the second quarter of 2022.

Corporate Updates

- Secured debt facility with Oxford Finance LLC for up to $150 Million. Under the terms of the credit facility with Oxford Finance LLC, Verastem drew an initial $25 million term loan at closing. The Company has the ability to access up to an additional $125 million in a series of tranches, $75 million of which are based on certain pre-determined milestones and $50 million at the lender's discretion.
- With the credit facility and expected milestones related to the sale of COPIKTRA® (duvelisb) to Secura Bio Inc. (Secura) in 2020, the Company expects to have a cash runway through 2025 to support the continued development and potential commercial launches of VS-6766 and defactinib.
- In the first quarter of 2022, Secura Bio Inc.'s (Secura) sublicensee, CSPC Pharmaceutical Group Limited, obtained drug registration approval for duvelisib granted by the National Medical Products Administration of the People's Republic of China for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least two prior systematic therapies. This entitles Verastem to a $2.5 million milestone payment from Secura, pursuant to the sale of COPIKTRA® (duvelisb) to Secura in 2020.
- 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. Timothy Barberich will be retiring from the Board as of March 31, 2022. Verastem appreciates his significant contributions since his appointment in March, 2014.
- Appointed Channing Der, PhD, Sarah Graham Kenan Distinguished Professor at the University of North Carolina at Chapel Hill to the Company's Scientific Advisory Board.

Fourth Quarter 2021 Financial Results

Total revenue for the three months ending December 31, 2021 (2021 Quarter) was $0.5 million, compared to $0.5 million for the three months ended December 31, 2020 (2020 Quarter).

Total research and development (R&D) and selling, general and administrative (SG&A) expenses for the 2021 Quarter were $17.1 million, compared to $17.3 million for the 2020 Quarter.

R&D expenses for the 2021 Quarter were $11.4 million, compared to $10.2 million for the 2020 Quarter. The increase of $1.2 million, or 11.8%, primarily resulted from increase in contract research organization costs and investigator fees.

SG&A expenses for the 2021 Quarter were $5.7 million, compared to $7.1 million for the 2020 Quarter. The decrease of $1.4 million, or 19.7%, primarily resulted from lower employee related expenses and consulting and professional fees.

Net loss for the 2021 Quarter was $16.5 million, or $0.09 per share (basic and diluted), compared to net loss of $19.9 million, or $0.12 per share (basic and diluted), for the 2020 Quarter.

For the 2021 Quarter, non-GAAP adjusted net loss was $14.9 million, or $0.08 per share (diluted), compared to non-GAAP adjusted net loss of $14.8 million, or $0.09 per share (diluted), for the 2020 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Full-Year 2021 Financial Results

Verastem Oncology ended the fourth quarter of 2021 with cash, cash equivalents and investments of $100.3 million. On a pro forma basis, inclusive of the funding received from the $25 million drawdown of new debt facility, cash, cash equivalents and investments were $125.3 million as of December 31, 2021.

Total revenue for the year ended December 31, 2021 (2021 Period) was $2.1 million, compared to $88.5 million for the year ended December 31, 2020 (2020 Period). Revenue for the 2021 Period was comprised of (i) $1.4 million of revenue recognized for milestones and royalties as part of the sale of COPIKTRA to Secura Bio, Inc. (Secura), and (ii) $0.6 million of 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. Revenue for the 2020 Period revenue was comprised of (i) $70.0 million recognized for the upfront payment made as part of the sale of COPIKTRA to Secura, (ii) $15.2 million of net product revenue, (iii) $2.9 million of license and collaboration revenue, and (iv) $0.4 million of transition services revenue for certain support functions provided to Secura.

Total R&D and SG&A expenses for the 2021 Period were $63.5 million, compared to $104.1 million for the 2020 Period.

R&D expense for the 2021 Period was $39.3 million, compared to $41.4 million for the 2020 Period. The decrease of $2.1 million, or 5.1%, was primarily related to the upfront non-refundable payment of $3.0 million to Chugai Pharmaceutical Co., Ltd for the VS-6766 license in the 2020 Period, and a decrease in other operating costs. This decrease was partially offset by an increase in investigator fees and an increase in personnel related costs.

SG&A expense for the 2021 Period was $24.1 million, compared to $62.8 million for the 2020 Period. The decrease of $38.7 million, or 61.6%, was primarily resulted from the Company's shift in strategic direction and the sale of COPIKTRA to Secura, which led to lower employee-related expenses and consulting and professional fees.

Net loss for the 2021 Period was $71.2 million, or $0.41 per share (basic and diluted), compared to $67.7 million, or $0.44 per share (basic and diluted), for the 2020 Period.

For the 2021 Period, non-GAAP adjusted net loss was $54.1 million, or $0.31 per share (diluted), compared to non-GAAP adjusted net loss of $37.8 million, or $0.25 per share (diluted), for the 2020 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) 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 months and year ended December 31, 2021 and 2020 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 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 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)

	December 31, 2021	December 31, 2020
Cash, cash equivalents, & investments	$ 100,256	$ 147,221
Accounts receivable, net	516	239
Prepaid expenses and other current assets	4,968	3,473
Property and equipment, net	210	416
Right-of-use asset, net	2,302	2,726
Restricted cash and other assets	410	274
Total assets	**$ 108,662**	**$ 154,349**
Current Liabilities	$ 18,590	$ 17,093
Convertible senior notes	249	19,051
Lease Liability, long-term	2,264	2,931
Stockholders' equity	87,559	115,274
Total liabilities and stockholders' equity	**$ 108,662**	**$ 154,349**

Verastem Oncology

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	$ —	$ 134	$ —	$ 15,232
License and collaboration revenue	—	—	—	2,912
Sale of COPIKTRA license and related assets revenue	545	—	1,447	70,000
Transition services revenue	—	372	606	372
Total revenue	545	506	2,053	88,516
Operating expenses:				
Cost of sales - product	—	12	—	1,765
Cost of sales - intangible amortization	—	—	—	793
Cost of sales – sale of COPIKTRA license and related assets	—	—	—	31,187
Research and development	11,396	10,153	39,347	41,376
Selling, general and administrative	5,660	7,095	24,115	62,755
Total operating expenses	17,056	17,260	63,462	137,876
Loss from operations	(16,511)	(16,754)	(61,409)	(49,360)
Other expense	—	—	—	(1,313)
Interest income	40	18	181	515
Interest expense	(10)	(1,354)	(9,972)	(15,794)
Loss on debt extinguishment	—	(1,580)	—	(1,580)
Net loss before income taxes	$ (16,481)	$ (19,670)	$ (71,200)	$ (67,532)
Income tax expense	—	194	—	194
Net loss	(16,481)	(19,864)	(71,200)	(67,726)
Net loss per share—basic and diluted	$ (0.09)	$ (0.12)	$ (0.41)	$ (0.44)
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted	182,672	169,902	174,406	153,330

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,	
	2021	**2020**	**2021**	**2020**
Net loss reconciliation				
Net loss (GAAP basis)	$ (16,481)	$ (19,864)	$ (71,200)	$ (67,726)
Adjust:				
Amortization of acquired intangible asset	—	—	—	793
Stock-based compensation expense	1,574	2,933	7,711	8,118
Non-cash interest, net	44	554	9,331	10,319
Severance and Other	—	(160)	40	4,621
Change in fair value of derivative	—	—	—	1,313
Chugai license payment	—	—	—	3,000
Loss on debt extinguishment	—	1,580	—	1,580
Notes third party exchange costs	—	171	—	171
Adjusted net loss (non-GAAP basis)	$ (14,863)	$ (14,786)	$ (54,118)	$ (37,811)
Reconciliation of Net loss Per Share				
Net loss per share – diluted (GAAP Basis)	$ (0.09)	$ (0.12)	$ (0.41)	$ (0.44)
Adjust per diluted share				
Amortization of acquired intangible asset	—	—	—	—
Stock-based compensation expense	0.01	0.02	0.04	0.05
Non-cash interest, net	—	—	0.06	0.07
Severance and Other	—	—	—	0.03
Change in fair value of derivative	—	—	—	0.01

Chugai license payment	—	—	—	0.02
Loss on debt extinguishment	—	0.01	—	0.01
Notes third party exchange costs	—	—	—	—
Adjusted net loss per share – diluted (non-GAAP Basis)	$ (0.08)	$ (0.09)	$ (0.31)	$ (0.25)
Weighted average common shares outstanding used in computing net loss per share—diluted	182,672	169,902	174,406	153,330

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Investors:

Ajay Munshi
Vice President, Corporate Development
+1 781-469-1579
amunshi@verastem.com

Nate LiaBraaten
+1 212-600-1902
nate@argotpartners.com

Media:

Lisa Buffington
Corporate Communications
+1 781-292-4205
lbuffington@verastem.com

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