Verastem Oncology Reports Fourth Quarter and Full-Year 2019 Financial Results

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BOSTON--(BUSINESS WIRE)-- Verastem, Inc. (Nasdaq:VSTM) (also known as Verastem Oncology), a biopharmaceutical company committed to developing and commercializing new medicines for patients battling cancer, today reported financial results for the three months and full-year ended December 31, 2019, and provided an overview of recent corporate highlights.

Brian Stuglik, Chief Executive Officer of Verastem Oncology, commented, “We are very excited to be executing on our new strategic direction. Our newly expanded development pipeline and priorities, combined with our recently strengthened balance sheet, leave us well positioned to deliver on our key corporate objectives in 2020 and beyond.”

New Strategic Direction

CH5126766 (VS-6766) in Combination with Defactinib

- ***Accelerating Development for KRAS Mutant Solid Tumors.*** In early 2020, Verastem Oncology licensed exclusive global development and commercialization rights to CH5126766 (VS-6766), a unique and promising inhibitor of the RAF/MEK signaling pathway. The combination of CH5126766 (VS-6766) and defactinib is currently being investigated in a Phase 1 clinical study and expansion cohorts in patients with KRAS mutant advanced solid tumors, including low grade serous ovarian cancer, non-small cell lung cancer and colorectal cancer. Verastem Oncology plans to initiate discussions with regulatory authorities during the first half of 2020, with the goal of commencing a registration-directed trial as soon as possible.

  Data from the Phase 1 combination study were submitted for presentation to the American Association for Cancer Research (AACR) 2020 Annual Meeting. The AACR recently announced that it was terminating the April 2020 meeting due to the COVID-19 outbreak and is planning to reschedule the meeting for later this year. Verastem Oncology is actively working with the appropriate organizations and institutions to determine next steps.

Duvelisib (COPIKTRA®)

- ***Prioritizing the Advancement of Duvelisib in Relapsed/Refractory PTCL.*** At the American Society of Hematology 2019 Annual Meeting, Verastem Oncology presented positive data from the dose optimization portion of the Phase 2 PRIMO study evaluating duvelisib in patients with relapsed or refractory PTCL, an aggressive disease with a lack of effective therapeutic options. This initial phase of the trial demonstrated promising clinical activity including complete and durable responses, as assessed by independent central review, with a manageable safety profile. The expansion phase of this registration-directed study continues to accrue patients and Verastem Oncology expects to complete enrollment in 2020 and report top-line results from the expansion cohorts in early 2021. Verastem Oncology intends to build on the existing Fast Track and Orphan Drug Designations and submit a regulatory package to the U.S. Food and Drug Administration to expand the approved indications for COPIKTRA to include relapsed or refractory PTCL.
- ***Focusing COPIKTRA Commercial Activities.*** Verastem Oncology will be reducing the resources directed to the promotion and sale of COPIKTRA in its current indications, including reducing the size of its salesforce and non-core clinical research. The Company plans to shift its COPIKTRA promotional resources toward large, community-based practices and academic institutions, which represent the majority of the appropriate third-line patients with chronic lymphocytic leukemia/small lymphocytic lymphoma and follicular lymphoma. The Company expects to reduce its overall headcount number to approximately 90 employees.

Corporate and Financial

- ***Strengthened the Balance Sheet Through a Private Placement with Premier Life Science Investors.*** On March 3, 2020, Verastem Oncology completed a private placement offering of approximately 46.5 million shares of its common stock to certain institutional investors, including RA Capital Management, Vivo Capital, Venrock Healthcare Capital Partners, Farallon Capital Management, Acuta Capital, EcoR1 Capital LLC, Avidity Partners and Logos Capital at a price of $2.15 per share, a 12.6% premium to the February 27, 2020 closing price. The gross proceeds to Verastem Oncology were $100 million. After deducting the underwriting discounts and commissions and other estimated offering expenses, net proceeds to the Company were approximately $92.0 million.

Fourth Quarter 2019 Financial Results

Net product revenue for the three months ended December 31, 2019 (2019 Quarter) was $3.6 million, compared to $1.2 million for the three months ended December 31, 2018 (2018 Quarter), following the FDA's approval of COPIKTRA on September 24, 2018. COPIKTRA demand units for the 2019 Quarter increased 20% compared to the third quarter of 2019. There was no license and collaboration revenue for the 2019 or 2018 Quarter.

Total operating expenses for the 2019 Quarter were $36.9 million, compared to $35.5 million for the 2018 Quarter. Excluding non-recurring charges of $2.2 million related to the Convertible Notes Exchange, the total operating expenses for the 2019 Quarter were $34.7 million.

Research and development (R&D) expense for the 2019 Quarter was $12.5 million, compared to $8.8 million for the 2018 Quarter. The increase of $3.7 million, or 42.0%, was primarily related to higher contract research organization costs to support the development of the Phase 2 TEMPO study for Intermittent Dosing, pre-clinical collaborations, and personnel costs related to the October 2019 rightsizing of the organization. This is partially offset by a decrease in investigator fees and CMC costs related to the FDA Approval of COPIKTRA in 2018.

Selling, general and administrative expense for the 2019 Quarter was $23.7 million, compared to $26.2 million for the 2018 Quarter. The decrease of $2.5 million, or 9.5%, was primarily due to lower personnel and external consulting costs.

Net loss for the 2019 Quarter was $38.8 million, or $0.51 per share (diluted), compared to $11.3 million, or $0.37 per share (diluted), for the 2018 Quarter. The 2019 Quarter includes $1.3M of non-cash interest expense related to conversions of Convertible Senior Notes into shares of common stock.

For the 2019 Quarter, non-GAAP adjusted net loss was $30.3 million, or $0.40 per share (diluted), compared to non-GAAP adjusted net loss of $33.1 million, or $0.36 per share (diluted), for the 2018 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Full-Year 2019 Financial Results

Total revenue for the year ended December 31, 2019 (2019 Period) was $17.5 million. Net product revenue for the 2019 Period was $12.3 million, compared to $1.7 million for the year ended December 31, 2018 (2018 Period), following the FDA's approval of COPIKTRA on September 24, 2018. License and collaboration revenue for the 2019 Period was $5.1 million, compared to $25.0 million for the 2018 Period.

Total operating expenses for the 2019 Period were $149.8 million compared to $121.5 million for the 2018 Period.

R&D expense for the 2019 Period was $45.8 million, compared to $43.6 million for the 2018 Period. The increase of $2.2 million, or 5.0%, was primarily related to higher contract research organization and personnel costs to support the development of the Phase 2 TEMPO study for Intermittent Dosing and the Phase 2 PRIMO study for the treatment of PTCL.

Selling, general and administrative expense for the 2019 Period was $101.2 million, compared to $77.3 million for the 2018 Period. The increase of $23.9 million, or 30.9%, was primarily due to the hiring and staffing of the sales and commercial teams to support the launch of COPIKTRA.

Net loss for the 2019 Period was $149.2 million, or $2.00 per share (diluted), compared to $72.4 million, or $1.37 per share (diluted), for the 2018 Period.

For the 2019 Period, non-GAAP adjusted net loss was $126.0 million, or $1.69 per share (diluted), compared to non-GAAP adjusted net loss of $88.4 million, or $1.27 per share (diluted), for the 2018 Period. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Verastem Oncology ended 2019 with cash, cash equivalents and short-term investments of $111.3 million.

Financial Guidance for Fiscal 2020

As a result of its new strategic direction, Verastem Oncology expects to reduce its operating expenses by approximately 40% for 2020 compared to 2019. Based on its current operating plans, Verastem Oncology expects its R&D and SG&A expenses for the full year 2020 to be in the range of $70 million to $85 million. In light of all these changes, the company is guiding that 2020 COPIKTRA revenues may be in the range of $12 million to $16 million. Verastem Oncology expects that its existing cash and cash equivalents, along with the revenue it expects to generate from COPIKTRA, will be sufficient to fund its planned operations into the fourth quarter of 2021.

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 twelve months ended December 31, 2019 and 2018 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a commercial 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 phosphoinositide 3-kinase (PI3K), focal adhesion kinase (FAK) and

RAF/MEK inhibition.

Our first FDA approved product is available for the treatment of patients with certain types of indolent non-Hodgkin's lymphoma (iNHL).

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 opportunity to rapidly advance the development of clinical programs through Verastem Oncology's expanded development pipeline and strengthened balance sheet, the timing of top-line results for clinical trials, anticipated reductions in operating expenses from Verastem Oncology's strategic realignment, the timing of commencing a registration-directed trial for CH5126766 (VS-6766) and financial guidance estimates. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," 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.

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 CH5126766 (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 CH5126766 (VS-6766) license agreement; that we may not have sufficient cash to fund our contemplated operations; that we may be unable to make additional draws under our debt facility or 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 CH5126766 (VS-6766); 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, 2019, as filed with the Securities and Exchange Commission (SEC) on March 11, 2020 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.

Verastem, Inc.

Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	December 31, 2019	**December 31, 2018**
Cash, cash equivalents, & investments	$ 75,506	$ 249,653
Accounts receivable, net	2,524	306
Inventory	3,096	327
Prepaid expenses and other current assets	3,835	2,973

Property and equipment, net	947	1,369
Intangible assets, net	20,008	21,577
Right-of-use asset, net	3,077	—
Restricted cash and other assets	36,053	1,031
Total assets	**$ 145,046**	**$ 277,236**

Current Liabilities	$ 29,890	$ 37,077
Long-term debt	35,067	19,506
Convertible senior notes	68,556	95,231
Lease Liability, long-term	3,489	—
Other liabilities	870	1,123
Stockholders' equity	7,174	124,299
Total liabilities and stockholders' equity	**$ 145,046**	**$ 277,236**

Verastem, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended December 31,		**Year ended December 31,**	
	2019	**2018**	**2019**	**2018**
Revenue:				
Product revenue, net	$ 3,617	$ 1,210	$ 12,339	$ 1,718
License and collaboration revenue	—	—	5,117	25,000
Total revenue	3,617	1,210	17,456	26,718
Operating expenses:				
Cost of sales - product	332	116	1,238	165
Cost of sales - intangible amortization	393	392	1,569	423

Research and development	12,455	8,762	45,778	43,648
Selling, general and administrative	23,728	26,199	101,212	77,265
Total operating expenses	36,908	35,469	149,797	121,501
Loss from operations	(33,291)	(34,259)	(132,341)	(94,783)
Other (expense)/income	(641)	25,556	(641)	25,556
Interest income	611	1,306	4,381	2,603
Interest expense	(5,453)	(3,952)	(20,608)	(5,810)
Net Loss	$ (38,774)	$ (11,349)	$ (149,209)	$ (72,434)
Net loss per share—basic	$ (0.51)	$ (0.15)	$ (2.00)	$ (1.12)
Net loss per share—diluted	$ (0.51)	$ (0.37)	$ (2.00)	$ (1.37)
Weighted average common shares outstanding used in computing net loss per share—basic	76,331	73,766	74,578	64,962
Weighted average common shares outstanding used in computing net loss per share—diluted	76,331	91,061	74,578	69,321

Verastem, Inc.

Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)

(unaudited)

	Three months ended December 31,		**Year ended December 31,**	
	2019	**2018**	**2019**	**2018**
Net Loss Reconciliation				
Net Loss (GAAP basis)	$ (38,774)	$ (11,349)	$ (149,209)	$ (72,434)
Adjust:				
Amortization of acquired intangible asset	393	392	1,569	423
Stock-based compensation expense	1,311	1,763	8,539	6,671
Non-cash interest, net	2,705	1,479	7,131	1,814
Severance and Other	1,232	218	3,200	710

Notes third party exchange costs	2,168	—	2,168	—
Change in fair value of interest make whole provision and conversion option for Notes	641	(25,556)	641	(25,556)
Adjusted Net Loss (non-GAAP basis)	$ (30,324)	$ (33,053)	$ (125,961)	$ (88,372)
Reconciliation of Net Loss Per Share				
Net Loss per share – diluted (GAAP Basis)	(0.51)	(0.37)	(2.00)	(1.37)
Adjust per diluted share				
Amortization of acquired intangible asset	0.01	0.00	0.02	0.01
Stock-based compensation expense	0.02	0.02	0.11	0.09
Non-cash interest, net	0.04	0.02	0.10	0.03
Severance and Other	0.01	0.00	0.04	0.01
Notes third party exchange costs	0.02	—	0.03	—
Change in fair value of interest make whole provision and conversion option for Notes	0.01	(0.03)	0.01	(0.04)
Adjusted Net Loss per share – diluted (non-GAAP Basis)	$ (0.40)	$ (0.36)	$ (1.69)	$ (1.27)
Weighted average common shares outstanding used in computing net loss per share—diluted	76,331	91,061	74,578	69,321

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