Verastem Reports Second Quarter 2015 Financial and Corporate Results

August 10, 2015

— COMMAND Interim Analysis Anticipated in Third Quarter 2015 —

BOSTON--(BUSINESS WIRE)--Aug. 10, 2015-- Verastem, Inc. (NASDAQ:VSTM), focused on discovering and developing drugs to treat cancer by the targeted killing of cancer stem cells, today reported financial results for the second quarter ended June 30, 2015, and also provided an overview of certain corporate accomplishments and plans.

“Execution of the ongoing COMMAND trial continues to progress well and we remain on track to report the outcome of the interim analysis during the third quarter of 2015,” said Robert Forrester, President and Chief Executive Officer of Verastem. “The independent Data and Safety Monitoring Board (DSMB) will examine pre-specified efficacy and safety data sets to decide whether to recommend continuation in all patients as planned, or to enrich the study population based upon merlin status, or to stop the study early for futility. This will be an important milestone for Verastem.”

Q2 2015 and Recent Highlights

VS-6063 (Focal Adhesion Kinase Inhibition)

- COMMAND (**C**ontrol **O**f **M**esothelioma with **MA**inte**N**ance **D**efactinib) Study
  - Registration-directed, randomized, double-blind, placebo-controlled study of VS-6063 as a switch maintenance treatment in patients with malignant pleural mesothelioma benefiting from frontline therapy with pemetrexed (Alimta®) and platinum
  - Co-primary endpoints are Progression Free Survival (PFS) and Overall Survival (OS). The study is designed to provide 90% power to assess the superiority of PFS, with a 1 sided type I error rate of 0.025, assuming a hazard ratio of 0.67
  - 308 patients enrolled at 72 centers in 15 countries as of August 6, 2015
  - Interim analysis to define the primary patient population anticipated in Q3 2015

Presentations and Publications

- Reported encouraging scientific data in support of Verastem’s cancer stem cell inhibitors (VS-6063, VS-4718, and VS-5584) in multiple tumor types, including mesothelioma, small cell lung cancer, breast cancer, and hematologic malignancies, at the 2015 American Association of Cancer Research (AACR) Annual Meeting. Copies of the presentations can be accessed at: http://bit.ly/12otlcV

Corporate

- Appointed Lou Vaickus, MD, FACP as Interim Chief Medical Officer
- Hosted an analyst and investor event at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting. Guest speakers Professor Dean Fennell, Ph.D., FRCP, and Max Wicha, M.D., gave presentations on mesothelioma and the rationale and importance of targeting cancer stem cells through FAK inhibition

Upcoming Clinical Milestones

Verastem’s anticipated upcoming data milestones include:

VS-6063

- COMMAND interim analysis: Q3 2015
- Phase 2 results in KRAS-mutated NSCLC at the World Conference of Lung Cancer in Denver, CO on September 6-9th
- Updated results from the VS-6063/paclitaxel combination in patients with ovarian cancer: H2 2015
- Biomarker “Window of Opportunity” mesothelioma study with preliminary results from the extended treatment cohort: H1 2016

VS-4718

- Preliminary Phase 1 results in patients with advanced solid tumors: H2 2015

VS-5584

- Preliminary Phase 1 results in patients with advanced solid tumors: H2 2015

Second Quarter 2015 Financial Results

As of June 30, 2015, Verastem had cash, cash equivalents and investments of $132.1 million compared to $92.7 million as of December 31, 2014. Verastem used $12.0 million for operating activities in the second quarter ended June 30, 2015 (the “2015 Quarter”).

Net loss for the 2015 Quarter was $15.4 million, or $0.42 per share, as compared to net loss of $13.0 million, or $0.51 per share, for the same period in 2014 (the “2014 Quarter”). Net loss includes stock-based compensation expense of $2.6 million and $3.2 million for the 2015 Quarter and 2014 Quarter, respectively.

Research and development expense for the 2015 Quarter was $11.0 million compared to $8.3 million for the 2014 Quarter. The $2.7 million increase from the 2014 Quarter to the 2015 Quarter was primarily related to an increase of $2.1 million in contract research organization expense for outsourced biology, development and clinical services, which includes Verastem’s clinical trial costs, and an approximate $732,000 increase in personnel costs. These increases were partially offset by a decrease in stock-based compensation expense of approximately $162,000.

General and administrative expense for the 2015 Quarter was $4.4 million compared to $4.8 million for the 2014 Quarter. The $400,000 decrease was primarily due to a decrease in stock-based compensation expense.

There were 36,853,805 common shares outstanding as of June 30, 2015.

Financial Guidance

Based on current operating plans, the Company expects to have sufficient cash, cash equivalents and investments to fund its research and development programs and operations into the first half of 2017.

About VS-6063

VS-6063 (defactinib) is an orally available compound designed to target cancer stem cells through the potent inhibition of focal adhesion kinase (FAK). Cancer stem cells are an underlying cause of tumor resistance to chemotherapy, recurrence and ultimate disease progression. Research has demonstrated that FAK activity is critical for the growth and survival of cancer stem cells. VS-6063 is currently being studied in the registration-directed COMMAND trial in mesothelioma (www.COMMANDmeso.com), a “Window of Opportunity” study in patients with mesothelioma prior to surgery, a Phase 1/1b study in combination with paclitaxel in patients with ovarian cancer, a trial in patients with KRAS-mutated non-small cell lung cancer and a trial evaluating the combination of VS-6063 and VS-5584 in patients with relapsed mesothelioma. VS-6063 has been granted orphan drug designation for use in mesothelioma in the U.S. and EU.

About VS-4718

VS-4718 is an orally available compound designed to target cancer stem cells through the potent inhibition of focal adhesion kinase (FAK). VS-4718 is currently being studied in a Phase 1 dose escalation study in patients with advanced cancers.

About VS-5584

VS-5584 is an orally available compound that has demonstrated potent and highly selective activity against class 1 PI3K enzymes and dual inhibitory actions against mTORC1 and mTORC2. In preclinical studies, VS-5584 has been shown to reduce the percentage of cancer stem cells and induce tumor regression in chemotherapy-resistant models. Verastem is currently conducting a dose escalation trial of VS-5584 in patients with advanced solid tumors as a single agent and a combination trial of VS-5584 and VS-6063 in patients with relapsed mesothelioma. VS-5584 has been granted orphan drug designation for use in mesothelioma in the U.S. and EU.

About Verastem, Inc.

Verastem, Inc. (NASDAQ:VSTM) is discovering and developing drugs to treat cancer by the targeted killing of cancer stem cells. Cancer stem cells are an underlying cause of tumor recurrence and metastasis. Verastem is developing small molecule inhibitors of signaling pathways that are critical to cancer stem cell survival and proliferation: FAK and PI3K/mTOR. For more information, please visit www.verastem.com.

Forward-looking statements:

This press release includes forward-looking statements about the Company’s strategy, future plans and prospects, including statements regarding the development and activity of the Company’s product candidates, VS-6063, VS-4718 and VS-5584, and the Company’s FAK, PI3K/mTOR and diagnostics programs generally, the timeline for clinical development and regulatory approval of our product candidates, the expected timing for the reporting of data from on-going trials and for the COMMAND interim analysis, the structure of our planned or pending clinical trials, our rights to develop or commercialize our product candidates and our ability to finance contemplated development activities and fund operations for a specified period.. The words “anticipate,” “appear,” “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. Applicable risks and uncertainties include the risks that the preclinical testing of the Company’s product candidates and preliminary or interim data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that data may not be available when we expect it to be, that enrollment of clinical trials may take longer than expected, that our product candidates will cause unexpected safety events, that the Company will be unable to successfully initiate or complete the clinical development of its product candidates, that the development of the Company’s product candidates will take longer or cost more than planned, and that the Company’s product candidates will not receive regulatory approval or become commercially successful products. 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, 2014 and in any subsequent SEC filings. The forward-looking statements contained in this press release reflect the Company’s current views with respect to future events, and the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Verastem, Inc.

Unaudited Selected Consolidated Balance Sheet Information

(in thousands)

	June 30, 2015	December 31, 2014
Cash, cash equivalents and investments	$ 132,093	$ 92,675
Prepaid expenses and other current assets	651	2,641
Property and equipment, net	2,456	2,825
Other assets	496	508
Total assets	**$ 135,696**	**$ 98,649**
Accounts payable and accrued expenses	$ 9,837	$ 8,735
Other liabilities	598	1,148
Stockholders' equity	125,261	88,766
Total liabilities and stockholders' equity	**$ 135,696**	**$ 98,649**

Verastem, Inc.

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 11,045	$ 8,305	$ 21,573	$ 16,716
General and administrative	4,417	4,782	9,131	9,505
Total operating expenses	15,462	13,087	30,704	26,221
Loss from operations	(15,462)	(13,087)	(30,704)	(26,221)
Interest income	85	65	147	137
Net loss	($15,377)	($13,022)	($30,557)	($26,084)
Net loss per share–basic and diluted	($0.42)	($0.51)	($0.87)	($1.02)
Weighted-average number of common shares used in net loss per share -basic and diluted	36,522	25,669	34,931	25,574

View source version on businesswire.com: http://www.businesswire.com/news/home/20150810005389/en/

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