Verastem Initiates Phase 1 Clinical Trial of VS-4718 in Patients with Advanced Cancer

June 26, 2013

--VS-4718 is the Second Cancer Stem Cell Inhibitor to Enter Clinical Development--

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 26, 2013-- Verastem, Inc., (NASDAQ: VSTM) focused on discovering and developing drugs to treat cancer by the targeted killing of cancer stem cells, announced the initiation of a Phase 1 trial of VS-4718, a novel, small molecule inhibitor of focal adhesion kinase (FAK), in patients with advanced cancer.

Research by the company and Robert Weinberg, Ph.D., Verastem co-founder and chair of the Scientific Advisory Board, has demonstrated in preclinical models of multiple tumor types that the FAK pathway is critical for the growth and survival of cancer stem cells, which are an underlying cause of tumor metastasis and recurrence.

“It is exciting to bring a novel small molecule inhibitor targeting the FAK pathway, a key regulator of cancer stem cells, into the clinic,” said Principal Investigator Alain Mita, M.D., Co-Director, Experimental Therapeutics Program, Cedars-Sinai Medical Center, Los Angeles, CA. “There is significant scientific evidence to suggest that FAK could be an important therapeutic target in metastatic solid tumors. We have incorporated a biomarker strategy into the design of this trial to help us further define the role of cancer stem cells and FAK in disease progression for patients with advanced tumors.”

“We believe that cancer stem cells are ultimately responsible for disease progression in many cancers,” said Dr. Joanna Horobin, Verastem Chief Medical Officer. “By inhibiting FAK, we have the potential to directly address this underlying cell population in tumors. This study should give us the necessary safety profile and dosing information to determine the future course of clinical development for VS-4718.”

The Phase 1 trial is an open-label, multicenter, dose-escalation study of VS-4718 in patients. These patients are assessed for safety, pharmacokinetics, pharmacodynamics, and initial evidence of activity as determined by cancer stem cell biomarkers. The study will enroll up to 40 patients at three U.S. locations.

“VS-4718 is the second compound in our portfolio to enter clinical development,” said Robert Forrester, Verastem President and Chief Operating Officer. “We have an ongoing combination trial of lead FAK inhibitor, VS-6063, and paclitaxel in patients with ovarian cancer. In addition, we will soon initiate a potentially pivotal, multinational, randomized, double-blind and placebo controlled study of VS-6063 in patients with mesothelioma.”

“Our unique understanding of cancer stem cell biology, and diligent execution by our research and development team, has allowed us to build a leading portfolio of cancer stem cell targeting agents,” said Christoph Westphal, M.D., Ph.D., Verastem Chairman and Chief Executive Officer. “We have the opportunity to make a meaningful difference in the lives of cancer patients through our focus on targeting cancer stem cells in multiple tumor types.”

For more information on the trial, please visit: http://www.clinicaltrials.gov/ct2/show/NCT01849744.

Upcoming events:

Verastem Annual Research and Development Day

Date: July 11, 2013
Time: 12:30pm to 3:30pm
Place: Harvard Club, 35 West 44th Street, New York, NY
RSVP: bsullivan@verastem.com
Conference Call Dial-in: 866-515-2907
Conference Call Passcode: 60920106
Webcast: http://phx.corporate-ir.net/phoenix.zhtml?c=250749&p=irol-EventDetails&EventId=4979610

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, PI3K/mTOR and Wnt. 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 of the Company’s compounds, including VS-6063, VS-4718 and VS-5584, and the Company’s FAK, PI3K/mTOR and diagnostic programs generally, the timeline for clinical development and regulatory approval of the Company’s compounds and the structure of the Company’s planned clinical trials. 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 compounds may not be predictive of the success of later clinical trials, that the Company will be unable to successfully complete the clinical development of its compounds, including VS-6063, VS-4718 and VS-5584, that the development of the Company’s compounds will take longer or cost more than planned, and that the Company’s compounds 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, 2012 and in any subsequent SEC filings. The forward-looking statements contained in this presentation 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.

Source: Verastem, Inc.

Verastem, Inc.
Brian Sullivan, 617-252-9314
bsullivan@verastem.com