Verastem Announces Long Term Follow-up Data from the DYNAMO Study Selected for Oral Presentation at the 14th International Conference on Malignant Lymphoma

May 3, 2017

BOSTON--(BUSINESS WIRE)--May 3, 2017-- Verastem, Inc. (NASDAQ:VSTM), focused on discovering and developing drugs to improve the survival and quality of life of cancer patients, today announced that an abstract describing long term follow-up data from the DYNAMO® study has been selected for oral presentation at the 14th International Conference on Malignant Lymphoma (ICML) being held June 14-17, 2017 in Lugano, Switzerland. DYNAMO is a Phase 2 clinical trial evaluating the safety and efficacy of duvelisib in patients with indolent non-Hodgkin lymphoma (iNHL) that are double refractory to both rituximab and chemotherapy.

“The potential of duvelisib is supported by previously reported clinical data demonstrating anti-cancer activity and a manageable safety profile as an oral monotherapy in a wide range of lymphoid malignancies, including relapsed/refractory iNHL, chronic lymphocytic leukemia (CLL) and T-cell lymphomas,” said Hagop Youssoufian, MSc, MD, Head of Hematology and Oncology Development at Verastem. “At Verastem, we are committed to investigating duvelisib’s potential as it may represent a valuable treatment for patients with relapsed/refractory disease who currently have limited treatment options. We look forward to presenting these long term follow-up data from the DYNAMO study in iNHL at ICML this year.”

Details for the oral presentation at ICML 2017 are:

Title: DYNAMO: A Phase 2 Study Demonstrating the Clinical Activity of Duvelisib in Patients with Double-Refractory Indolent Non-Hodgkin Lymphoma

Presenter: Pier Luigi Zinzani, MD, PhD, University of Bologna Institute of Hematology

Session name: Session 4; Targeting the BCR Pathways

Location: Room A. Cinema Corso and Aula Magna (Lugano University)

Date and time: Thursday, June 15, 2017 at 15:40 CET

A copy of the oral presentation slides will be available here following the conclusion of Dr. Zinzani’s presentation.

About the Tumor Microenvironment

The tumor microenvironment encompasses multiple tumor and non-tumor cell populations and an extracellular matrix that support cancer cell survival. This includes immunosuppressive regulatory T-cells, myeloid-derived suppressor cells, tumor-associated macrophages, cancer-associated fibroblasts and extracellular matrix proteins that can hamper the entry and therapeutic benefit of cytotoxic T-cells and anti-cancer drugs. In addition to targeting the proliferative and survival signaling of cancer cells, Verastem’s product candidates, including duvelisib and defactinib, also target the tumor microenvironment to potentially improve a patient’s response to therapy.

About Duvelisib

Duvelisib is an investigational, dual inhibitor of phosphoinositide 3-kinase (PI3K)-delta and PI3K-gamma, two enzymes that are known to help support the growth and survival of malignant B-cells and T-cells. PI3K signaling may lead to the proliferation of malignant B-cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment.[1,2,3] Duvelisib is currently being evaluated in late- and mid-stage clinical trials, including DUO™, a randomized, Phase 3 monotherapy study in patients with relapsed or refractory CLL[4], and DYNAMO™, a single-arm, Phase 2 monotherapy study in patients with refractory iNHL that achieved its primary endpoint of ORR upon top-line analysis of efficacy data.[5] Duvelisib is also being evaluated for the treatment of hematologic malignancies through investigator-sponsored studies, including T-cell lymphoma.[6] Information about duvelisib clinical trials can be found on www.clinicaltrials.gov.

About Verastem, Inc.

Verastem, Inc. (NASDAQ: VSTM) is a biopharmaceutical company focused on discovering and developing drugs to improve outcomes for patients with cancer. Verastem is currently developing duvelisib, a dual inhibitor of PI3K-delta and PI3K-gamma, which has successfully met its primary endpoint in a Phase 2 study in iNHL and is currently being evaluated in a Phase 3 clinical trial in patients with CLL. In addition, Verastem is developing the FAK inhibitor defactinib, which is currently being evaluated in three separate clinical collaborations in combination with immunotherapeutic agents for the treatment of several different cancer types, including pancreatic cancer, ovarian cancer, non-small cell lung cancer, and mesothelioma. Verastem’s product candidates seek to treat cancer by modulating the local tumor microenvironment, enhancing anti-tumor immunity and reducing cancer stem cells. For more information, please visit www.verastem.com.

Verastem, Inc. forward-looking statements notice:

This press release includes forward-looking statements about Verastem's strategy, future plans and prospects, including statements regarding the development and activity of Verastem's investigational product candidates, including duvelisib and defactinib, and Verastem's PI3K and FAK programs generally, the structure of our planned and pending clinical trials and the timeline and indications for clinical development, and our rights to develop or commercialize our product candidates. 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. Applicable risks and uncertainties include the risks that the preclinical testing of Verastem'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 expected; that enrollment of clinical trials may take longer than expected; that our product candidates will cause unexpected safety events or result in an unmanageable safety profile as compared to their level of efficacy; that duvelisib will be ineffective at treating patients with lymphoid malignancies; that Verastem will be unable to successfully initiate or complete the clinical development of its product candidates; that the development of Verastem's product candidates will take longer or cost more than planned; that Verastem may not have sufficient cash to fund its contemplated operations; that Verastem or Infinity Pharmaceuticals, Inc. will fail to fully perform under the duvelisib license agreement; that Verastem will not pursue or submit regulatory filings for its product candidates; and that Verastem's 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 Verastem's Annual Report on Form 10-K for the year ended December 31, 2016 and in any subsequent filings with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Verastem's views as of the date of this release, and Verastem does not undertake and specifically disclaims any obligation to update any forward-looking statements.

References

[1] Winkler D.G., Faia K.L., DiNitto J.P. et al. PI3K-delta and PI3K-gamma inhibition by IPI-145 abrogates immune responses and suppresses activity in autoimmune and inflammatory disease models. Chem Biol 2013; 20:1-11.

[2] Reif K et al.Cutting Edge: Differential Roles for Phosphoinositide 3 kinases, p110-gamma and p110-delta, in lymphocyte chemotaxis and homing. J Immunol 2004:173:2236-2240.

[3] Schmid M et al. Receptor Tyrosine Kinases and TLR/IL1Rs Unexpectedly activate myeloid cell PI3K, a single convergent point promoting tumor inflammation and progression. Cancer Cell 2011;19:715-727.

[4] www.clinicaltrials.gov, NCT02004522

[5] www.clinicaltrials.gov, NCT01882803

[6] www.clinicaltrials.gov, NCT02783625, NCT02783625, NCT02158091

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