Verastem Announces Presentations at ASH Annual Meeting

November 3, 2016

BOSTON--(BUSINESS WIRE)--Nov. 3, 2016-- Verastem, Inc. (NASDAQ:VSTM), focused on discovering and developing drugs to treat cancer, today announced that new data for duvelisib, an investigational, oral, dual inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma, will be presented at the American Society of Hematology (ASH) 2016 Annual Meeting, being held December 3-6, 2016 in San Diego.

Data from DYNAMO®, a Phase 2 monotherapy study evaluating the efficacy and safety of duvelisib in relapsed/refractory iNHL, will be presented in an oral session. Updated data from CONTEMPO, a Phase 1b/2 study evaluating duvelisib in combination with rituximab or obinutuzmab in treatment-naïve follicular lymphoma patients, and preclinical research on the role of Focal Adhesion Kinase (FAK) inhibition in AML, will be presented in a poster session.

Details for the presentations at ASH are below:

Oral Presentation

Title: DYNAMO: A phase 2 study demonstrating the clinical activity of duvelisib in patients with relapsed refractory indolent non-Hodgkin lymphoma
Lead Author: Ian Flinn, M.D., Ph.D., Director, Hematologic Malignancies Program, Sarah Cannon Research Institute
Abstract Number: 1218
Location: San Diego Convention Center, Ballroom 20BC
Date and Time: Monday, December 5, 2016, 7:30 – 7:45 pm PT

The full abstract can be viewed here.

Poster Presentations

Title: Preliminary results in first-line treatment of follicular lymphoma with the oral dual PI3K-delta,gamma inhibitor, duvelisib, in combination with rituximab or obinutuzumab
Lead Author: Carla Casulo, M.D., Assistant Professor, Wilmot Cancer Institute, University of Rochester
Abstract Number: 2979
Location: San Diego Convention Center, Hall GH
Date and Time: Sunday, December 4, 2016, 6:00 - 8:00 pm PT

The full abstract can be viewed here.

Title: Inhibition of FAK Exerts Anti-Leukemic Activity and Potentiates ABT-199-Induced Apoptosis in AML
Lead Author: Bing Carter, Ph.D.., Associate Professor, Department of Leukemia - Research, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center
Abstract Number: 1574
Location: San Diego Convention Center, Hall GH
Date and Time: Saturday, December 3, 2016, 5:30 – 7:30 pm PT

The full abstract can be viewed here.

About the Tumor Microenvironment

The tumor microenvironment encompasses various cellular populations and extracellular matrices within the tumor or cancer niche that support cancer cell survival. This includes immunosuppressive cell populations such as regulatory T cells, myeloid-derived suppressor cells, M2 tumor-associated macrophages, as well as tumor-associated fibroblasts and extracellular matrix proteins which can hamper the entry and therapeutic benefit of cytotoxic immune cells and anti-cancer drugs. In addition to targeting the proliferative and survival signaling of cancer cells, Verastem's compounds duvelisib, defactinib, VS-4718 and VS-5584 also target the tumor microenvironment as a mechanism of action 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/refractory chronic lymphocytic leukemia (CLL)[4], and DYNAMO®, a single-arm, Phase 2 monotherapy study in patients with refractory indolent non-Hodgkin lymphoma (iNHL) that achieved its primary endpoint of overall response rate upon topline 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 phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma, which has successfully met its primary endpoint in a Phase 2 study and is currently being evaluated in a Phase 3 clinical trial in patients with chronic lymphocytic leukemia (CLL). Other clinical product candidates include focal adhesion kinase (FAK) inhibitors VS-6063 and VS-4718, and dual PI3K/mTOR inhibitor VS-5584. VS-6063 is currently being evaluated in three separate clinical collaborations in combination with immunotherapeutic agents for the treatment of several different cancer types, including pancreatic, ovarian and 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 product candidate duvelisib, and Verastem's PI3K/mTOR program generally, the structure of our planned and pending clinical trials and the timeline and indications for clinical development, including reporting top-line data, and regulatory submissions and, our rights to develop or commercialize our product candidates. 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 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, including for the Phase 3 DUO study; 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 will fail to fully perform under the license agreement; that the transition of the duvelisib program from Infinity will not be completed; that Verastem will not pursue or submit regulatory filings for its product candidates, including for duvelisib in patients with CLL or iNHL; 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, 2015 and in any subsequent SEC filings. The forward-looking statements contained in this press release reflect Verastem's current views with respect to future events, 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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