



Verastem Oncology to Present Scientific Data Supporting Immuno-Oncology Applications of Duvelisib & Defactinib at the 3rd Annual Advances in Immuno-Oncology Congress

May 21, 2018

BOSTON--(BUSINESS WIRE)--May 21, 2018-- Verastem, Inc. (NASDAQ: VSTM) (Verastem Oncology or the Company), focused on developing and commercializing drugs to improve the survival and quality of life of cancer patients, today announced that Jonathan Pachter, PhD, the Company's Chief Scientific Officer, will give an oral presentation and moderate a roundtable discussion at the 3rd Annual Advances in Immuno-Oncology Congress being held May 24-25, 2018 in London, UK.

"The data that will be presented at the Immuno-Oncology Congress demonstrate the unique potential of duvelisib, as a dual inhibitor of PI3K-delta and PI3K-gamma, to enhance the efficacy of immune checkpoint and co-stimulatory antibodies in preclinical models of both hematological malignancies and solid tumors," said Dr. Pachter. "These results support continued research and lend particular importance as we move toward the commercialization of duvelisib, Verastem's lead candidate an oral, dual inhibitor of PI3K-delta and PI3K-gamma. The duvelisib New Drug Application (NDA) is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of patients with relapsed or refractory CLL/SLL, and accelerated approval for the treatment of patients with relapsed or refractory follicular lymphoma. I will also give an update on the scientific rationale and clinical progress of our FAK inhibitor defactinib in combination with PD-1 and PD-L1 inhibitors in solid tumors."

Details for the presentation and round table discussion at the Congress are as follows:

Oral Presentation Title: Immunological Effects of Clinical Stage FAK & PI3K-Delta/Gamma Inhibitors

Session: Translational Immuno-Oncology

Date and time: Thursday, May 24, 2018 at 5:40 – 6:10 PM BST

Round Table Discussion Title: Novel Checkpoint Pathways & Strategies for Combined Modality Treatment

Date and time: Friday, May 25, 2018 at 7:30 – 8:00 AM BST

A copy of the oral presentation will be available [here](#) following the presentation.

About Duvelisib

Duvelisib is a first-in-class investigational oral, dual inhibitor of phosphoinositide 3-kinase (PI3K)-delta and PI3K-gamma, two enzymes 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- and T-cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment.^{1,2,3} Duvelisib was evaluated in late- and mid-stage extension trials, including DUO™, a randomized, Phase 3 monotherapy study in patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL),⁴ and DYNAMO™, a single-arm, Phase 2 monotherapy study in patients with refractory indolent non-Hodgkin lymphoma (iNHL).⁵ Both DUO and DYNAMO achieved their primary endpoints. Verastem Oncology's New Drug Application (NDA) requesting the full approval of duvelisib for the treatment of patients with relapsed or refractory CLL/SLL, and accelerated approval for the treatment of patients with relapsed or refractory follicular lymphoma (FL) was accepted for filing by the U.S. Food and Drug Administration (FDA), granted Priority Review and assigned a target action date of October 5, 2018. Duvelisib is also being developed by Verastem Oncology for the treatment of peripheral T-cell lymphoma (PTCL), and is being investigated in combination with other agents through investigator-sponsored studies.⁶ Information about duvelisib clinical trials can be found on www.clinicaltrials.gov.

About Defactinib

Defactinib is an investigational inhibitor of focal adhesion kinase (FAK), a non-receptor tyrosine kinase that mediates oncogenic signaling in response to cellular adhesion and growth factors.⁷ Based on the multi-faceted roles of FAK, defactinib is used to treat cancer through modulation of the tumor microenvironment and enhancement of anti-tumor immunity.^{8,9} Defactinib 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 (NSCLC), and mesothelioma. These studies are combination clinical trials with pembrolizumab and avelumab from Merck & Co. and Pfizer/Merck KGaA, respectively.^{10,11,12} Information about these and additional clinical trials evaluating the safety and efficacy of defactinib can be found on www.clinicaltrials.gov.

About Verastem Oncology

Verastem, Inc. (Nasdaq:VSTM), operating as Verastem Oncology, is a biopharmaceutical company focused on developing and commercializing drugs to improve the survival and quality of life of cancer patients. Verastem Oncology 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 indolent Non-Hodgkin Lymphoma (iNHL) and a Phase 3 clinical trial in patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Verastem Oncology's New Drug Application (NDA) requesting the full approval of duvelisib for the treatment of patients with relapsed or refractory CLL/SLL, and accelerated approval for the treatment of patients with relapsed or refractory follicular lymphoma (FL) was accepted for filing by the U.S. Food and Drug Administration (FDA), granted Priority Review and assigned a target action date of October 5, 2018. In addition, Verastem Oncology 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 (NSCLC), and mesothelioma. Verastem Oncology's product candidates seek to treat cancer by modulating the local tumor microenvironment and enhancing anti-tumor immunity. For more information, please visit www.verastem.com.

References

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- ⁴ www.clinicaltrials.gov, NCT02004522
- ⁵ www.clinicaltrials.gov, NCT01882803
- ⁶ www.clinicaltrials.gov, NCT02783625, NCT02158091
- ⁷ Schaller M.D. and Parsons J.T. Focal adhesion kinase: an integrin-linked protein tyrosine kinase. *Trends Cell Biol.* 1993 3: 258-62.
- ⁸ Jiang H et al. Targeting focal adhesion kinase renders pancreatic cancers responsive to checkpoint immunotherapy. *Nat Med* 2016: Aug 22(8) 851-60.
- ⁹ Sulzmaier F.J. et al. FAK in cancer: mechanistic findings and clinical applications. *Nature Rev Cancer.* 2014 14: 598-610.
- ¹⁰ www.clinicaltrials.gov, NCT02546531
- ¹¹ www.clinicaltrials.gov, NCT02943317
- ¹² www.clinicaltrials.gov, NCT02758587

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