Verastem Announces Executive Leadership Appointments and Changes

January 19, 2017

Hagop Youssoufian, MSc, MD Named Head of Hematology and Oncology Development; Greg I. Berk, MD to Transition to Senior Advisor and Member of Clinical and Scientific Advisory Board

Lori Kunkel, MD and Edmund J. Pezalla, MD, MPH Appointed to Clinical and Scientific Advisory Board

Michael Ferraresso to Join the Company as Vice President, Commercial Operations

BOSTON--(BUSINESS WIRE)--Jan. 19, 2017-- Verastem, Inc. (NASDAQ: VSTM), focused on discovering and developing drugs to treat cancer, today announced that Hagop Youssoufian, MSc, MD, has been appointed Head of Hematology and Oncology Development. In this role, Dr. Youssoufian will oversee the clinical and regulatory development of the Company's pipeline, including duvelisib, an investigational product candidate currently in development for hematologic malignancies, and provide overall strategic and tactical leadership to Verastem's hematology-oncology clinical programs. Dr. Youssoufian brings over 25 years of product development and commercialization experience to Verastem. In addition, Lori Kunkel, MD, and Edmund J. Pezalla, MD, MPH, have been appointed to the Clinical and Scientific Advisory Board (CSAB), and Michael Ferraresso will join the Company as Vice President, Commercial Operations. Greg I. Berk, MD, will transition to the role of Senior Advisor from Chief Medical Officer and will join the CSAB.

"We welcome Hagop to the Verastem team to lead the late-stage development of duvelisib in lymphoid malignancies," said Robert Forrester, President and Chief Executive Officer of Verastem. "Both Hagop and Lori are highly regarded leaders in oncology drug development who bring to Verastem deep experience in developing successful clinical and regulatory strategies that result in globally approved novel oncology therapies. In addition, we are now in early commercial planning and are selectively building out the team to potentially launch duvelisib following the readout of the Phase 3 DUO study in CLL. To help make this a reality, we welcome Mike from Infinity Pharmaceuticals where he was involved in the commercial strategy for duvelisib. Ed is a leading innovator in payer strategy and has extensive relationships with a variety of policy and industry groups. These individuals have an impressive track record of unlocking the value of new products that we believe will prove invaluable as we pursue future market opportunities. We believe these appointments are key additions to the Verastem leadership team and represent our commitment to advancing our lead assets, duvelisib and defactinib, through several key clinical and regulatory milestones in the coming quarters. We thank Greg for his tenure as Chief Medical Officer and look forward to his continued contributions as Senior Advisor and as a member of the CSAB."

Prior to joining Verastem, Dr. Youssoufian served most recently as Chief Medical Officer at BIND Therapeutics. Prior to BIND, he was Executive Vice President at Progenics Pharmaceuticals and President, Research & Development and Chief Medical Officer at Ziopharm Oncology. Before joining Ziopharm, Dr. Youssoufian served as Chief Medical Officer and Senior Vice President, Global Clinical Sciences at Imclone Systems. Prior to Imclone, he served in leadership positions at Sanofi Aventis and Bristol-Myers Squibb. During his career in industry, Dr. Youssoufian was involved in the development and approval of several oncology treatments, including Sprycel®, Taxotere® and Erbitux®. Dr. Youssoufian graduated from Boston College (BS, Magna Cum Laude) and the University of Massachusetts Medical School (MSc, MD). After training in Internal Medicine at Cleveland Clinic and Johns Hopkins, he completed fellowships in Clinical Genetics at Johns Hopkins and in Hematology-Oncology at Massachusetts General Hospital, and was a Visiting Scientist at Whitehead Institute, MIT. He then served on the faculties of Harvard Medical School as Assistant Professor of Medicine and at Baylor College of Medicine as Associate Professor and Division Chief of Medical Genetics.

Dr. Kunkel has more than two decades of experience in oncology and immunology drug development and commercialization. Dr. Kunkel presently serves on the Board of Directors of Loxo Oncology, where she was previously the acting Chief Medical Officer. Prior to Loxo, she served as Chief Medical Officer at Pharmacyclics (acquired by AbbVie) and Proteolix, Inc. (acquired by Onyx Pharmaceuticals), where she contributed to the global approvals of cancer therapeutics IMBRUVICA® and Kyprolis®, respectively. Prior to that, she served as Vice President of Clinical Development at Xencor, Inc. Before these executive leadership positions, Dr. Kunkel was a clinical scientist at Genentech where she worked on the development of RITUXAN®. Additionally, as a clinical drug development specialist, she has advised multiple clients including Chiron (acquired by Novartis), Genentech/Roche, Salmedics (acquired by Celgene), Stemcentrx, Inc. and Amphivena Therapeutics, and she serves on the Board of Directors of Curis, Inc., Tocagen and Maverick Therapeutics. Prior to joining the biotechnology industry, Dr. Kunkel spent ten years in academic medicine and served as a faculty member at the Bone Marrow Transplant Unit in the Division of Hematology/Oncology at University of California, Los Angeles. Dr. Kunkel obtained a medical degree from University of Southern California and a bachelor's degree in biology from University of California, San Diego. She is board certified in internal medicine and held board certifications in hematology and oncology.

Dr. Pezalla is active as a payer expert on a number of policy working groups including the New Drug Development Paradigm Project at MIT. He is the former Vice President for Pharmaceutical Policy and Strategy in the Office of the Chief Medical Officer at Aetna. In this position Dr. Pezalla developed and coordinated strategy for pharmaceutical evaluation and coverage across both the medical and pharmacy benefit, created Aetna's framework for innovative contracts, and developed Aetna's public policy positions on drug and device coverage. Dr. Pezalla is a member of the Board of Directors of the Pharmacy Quality Alliance and the Connecticut Biosciences Innovation Fund. He is also a member of the Business Advisory Board of Naia Pharmaceuticals and the Scientific Advisory Board of Temple Therapeutics. He was recently named a Scholar-in-Residence at the Duke-Margolis Health Policy Center in Washington, DC where he is working on policy approaches to stimulating the development of new antimicrobials, evaluation of value frameworks, and other policy projects. Dr. Pezalla received his BS in Biophysics from Georgetown University College of Arts and Sciences, and his MD Cum Laude from Georgetown University School of Medicine. He holds a Masters in Public Health from the University of California at Berkeley and was a health services research fellow and doctoral student in health policy at the University of Michigan.

Prior to joining Verastem, Mr. Ferraresso served as Vice President, Commercial at Infinity Pharmaceuticals where he was instrumental in designing the commercial strategy for duvelisib and chaired the joint commercial committee for the partnership. From 1998-2013, he served in sales and commercial operations roles of increasing responsibility at several biotechnology and pharmaceutical companies, including AVEO Pharmaceuticals,

AMAG Pharmaceuticals, Critical Therapeutics, Praecis Pharmaceuticals, Ascent Pediatrics and Muro Pharmaceuticals. Mr. Ferraresso has extensive experience in commercial strategy including partnerships, development, pricing and field deployment models and has launched Oprapred™, Plenaxis™, Zyflo™ and Feraheme™. Mr. Ferraresso holds a BA degree in Economics from Assumption College.

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 Defactinib

Defactinib (VS-6063) is an investigational inhibitor of Focal Adhesion Kinase (FAK), a non-receptor tyrosine kinase encoded by the PTK-2 gene 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, enhancement of anti-tumor immunity, and reduction of cancer stem cells.[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, ovarian, non-small cell lung cancer, 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, 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 defactinib (VS-6063) and VS-4718, and dual PI3K/mTOR inhibitor VS-5584. 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, 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 Verastem's PI3K/mTOR and FAK programs 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 as filed on March 3, 2016, the Company's quarterly report on Form 10-Q filed on November 7, 2016, and in any subsequent SEC filings. The forward-looking statements contained in this press release reflect Verastem's current views as of the date of this release 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

[7]Schaller MD and Parsons JT. 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 FJ 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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