Verastem Licenses Duvelisib from Infinity Pharmaceuticals

November 2, 2016

Transaction Adds Complementary Late-Stage Product Candidate from a Clinically Validated Drug Class to Verastem's Pipeline

Duvelisib Has Demonstrated Clinical Activity in Lymphoid Malignancies

License of Duvelisib Aligns with Verastem's Focus on Targeting the Tumor Microenvironment

Verastem Management to Host Conference Call and Webcast at 8:30 a.m. ET Today

BOSTON & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 2, 2016-- Verastem, Inc. (NASDAQ:VSTM) and Infinity Pharmaceuticals, Inc. (NASDAQ:INFI), today announced that the companies entered into a license agreement under which Verastem licensed exclusive worldwide rights to develop and commercialize Infinity's oncology product candidate duvelisib. Duvelisib is an oral inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma being investigated for the treatment of hematologic cancers, including chronic lymphocytic leukemia (CLL), indolent non-Hodgkin lymphoma (iNHL) and T cell lymphomas. Verastem will pay to Infinity up to $28 million in milestones, with positive data from DUO®, a Phase 3, randomized monotherapy study of duvelisib in patients with relapsed/refractory CLL, triggering the first milestone payment, and royalties on net sales.

"Duvelisib is a clinically validated, late-stage product candidate with a proven mechanism of action. This transaction has an attractive risk/reward profile given the modest financial investment prior to obtaining topline data from the DUO study, currently anticipated in the first half of 2017, as well as the potential applications for a variety of other lymphoid malignancies," said Robert Forrester, President and Chief Executive Officer of Verastem. "Duvelisib complements Verastem's oncology pipeline by augmenting our strategic focus of developing small molecule agents that target malignant cells both directly and through modulation of the tumor microenvironment. This transaction represents a positive step toward our goal of bringing new treatment options to patients with cancer. We are working closely with Infinity to ensure a smooth transition of the duvelisib program."

"The potential of duvelisib is supported by clinical data demonstrating anti-cancer activity and a manageable safety profile in a wide range of lymphoid malignancies, including relapsed/refractory iNHL, CLL and T cell lymphomas," said Gregory I. Berk, MD, Chief Medical Officer of Verastem. "While there have been significant advances recently in the treatment of lymphoid malignancies, not all patients experience benefits or can tolerate these treatments. There remains a need for new oral medicines, and the targeted inhibition of PI3K-delta and PI3K-gamma brings a unique approach designed to address both the malignant B cell and its supportive microenvironment. We look forward to reporting data from the DUO study, which could enable a submission for regulatory approval."

"Infinity has always been committed to finding innovative ways to develop novel medicines which hold significant promise for people living with cancer. Verastem provides duvelisib the best opportunity to advance toward regulatory filings and potential commercialization given their oncology-focused capabilities and deep knowledge of the tumor microenvironment," stated Adelene Perkins, President and Chief Executive Officer of Infinity. "Additionally, the license of duvelisib fulfills an important strategic goal for Infinity by preserving cash while enabling our shareholders to participate in the value of the duvelisib program through potential milestone payments and royalties to Infinity."

Terms of Transaction

Under the terms of the license agreement, Verastem is obligated to pay to Infinity up to $28 million in milestones. Infinity is entitled to receive two milestone payments, $6 million upon positive data from the DUO study and $22 million upon the first regulatory approval inside or outside of the U.S. Verastem will also pay Infinity tiered mid-to-high single-digit royalties on net sales and will be responsible for the single-digit-royalty on net sales of duvelisib owed by Infinity to MundiPharma International Corporation Limited and Purdue Pharmaceutical Products L.P.

Verastem's Expanded Oncology Pipeline

In addition to duvelisib, Verastem also holds worldwide rights to the tumor microenvironment-targeting focal adhesion kinase (FAK) inhibitors defactinib (VS-6063) and VS-4718. Verastem's lead FAK inhibitor, 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 or avelumab from Merck & Co. and Pfizer/Merck KGaA, respectively. Verastem also owns rights to the FAK inhibitor VS-4718 and the dual PI3K and mTORC1/2 inhibitor VS-5584 which are both currently being evaluated in Phase 1 clinical studies.

Financial Guidance

Based on current operating plans including duvelisib, Verastem expects to have sufficient cash, cash equivalents and short-term investments to fund its research and development programs and operations into 2018.

Conference Call Information

Verastem will host a conference call on November 2, 2016, at 8:30 a.m. ET to discuss the license agreement announced today. The call can be accessed by dialing 877-341-5660 (U.S. and Canada) or 315-625-3226 (international), and entering passcode 12230467. To access the live webcast, please use either the following link: http://edge.media-server.com/m/p/vsavfj6j or visit the investors section of the Verastem website at www.verastem.com. A replay of the call will be available on the Company's website for a period of 180 days from today.

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 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 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.

About Infinity Pharmaceuticals, Inc.

Infinity is an innovative biopharmaceutical company dedicated to advancing novel medicines for people with cancer. Infinity is advancing IPI-549, an oral immuno-oncology development candidate that selectively inhibits PI3K-gamma. A Phase 1 study in patients with advanced solid tumors is ongoing.[13] For more information on Infinity, please refer to Infinity's website at www.infi.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 candidates, duvelisib, defactinib (VS-6063), VS-4718 and VS-5584, and Verastem's FAK, PI3K/mTOR 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, our rights to develop or commercialize our product candidates and our ability to finance contemplated development activities and fund operations for a specified period. 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 the cost of the transaction to Verastem will not provide the intended positive financial results; 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.

Infinity Pharmaceuticals, Inc. forward-looking statements notice:

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding Infinity's expectations about: the receipt of milestone and royalty payments under the agreement with

Verastem; the therapeutic and commercial potential of duvelisib and PI3K inhibition; Infinitity's ability to transition the duvelisib program to Verastem; the preservation of Infinity's cash; and Infinity's ability to execute on its strategic plans. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Infinity's current expectations. For example, there can be no guarantee that the transition of the duvelisib program to Verastem will be completed or that Infinity will receive any of the benefits of the agreement with Verastem including the receipt of milestone and royalty payments. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: Infinity's results of clinical trials and preclinical studies; a failure of Infinity and/or Verastem to fully perform under the license agreement; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Infinity's ability to obtain and maintain requisite regulatory approvals and to enroll patients in its clinical trial of IPI-549; unplanned cash requirements and expenditures; development of agents by Infinity's competitors for diseases in which Infinity is currently developing or intends to develop its product candidates; and Infinity's ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" included in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 9, 2016, and other filings filed by Infinity with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Infinity expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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

13 www.clinicaltrials.gov, NCT02637531

View source version on businesswire.com: http://www.businesswire.com/news/home/20161102005608/en/

Source: Verastem, Inc. and Infinity Pharmaceuticals, Inc.

Verastem, Inc.
Brian Sullivan, 781-292-4214
Director, Corporate Development
bsullivan@verastem.com
or
Infinity Pharmaceuticals, Inc.
Jaren Irene Madden, 617-453-1336
Senior Director, Investor Relations and Corporate Communications
Jaren.Madden@infi.com