CSPC Pharmaceutical Group Limited and Verastem Oncology Sign Exclusive License Agreement for the Development and Commercialization of COPIKTRA™ (duvelisib) in China

September 25, 2018

Verastem Oncology to Receive an Upfront Payment of $15 Million USD; Then Eligible to Receive Up To $30 Million USD in Development Milestone Payments as well as Sales Milestone and Double-Digit Percentage Royalty Payments

CSPC Pharmaceutical Group Obtains Rights to Develop the Oral Inhibitor of Phosphoinositide 3-Kinase (PI3K), and the First Approved Dual Inhibitor of PI3K-delta and PI3K-gamma (PI3K-δ,γ), COPIKTRA (duvelisib) for All Oncology Indications in China

BOSTON & HONG KONG--(BUSINESS WIRE)--Sep. 25, 2018-- Verastem, Inc. (Nasdaq:VSTM) (Verastem Oncology or the Company), focused on developing and commercializing medicines to improve the survival and quality of life of cancer patients, and CSPC Pharmaceutical Group Limited (HKEx: 1093) (CSPC), a leading pharmaceutical company in China, today announced their entry into an exclusive licensing agreement for CSPC to develop and commercialize Verastem Oncology's COPIKTRA™ (duvelisib), an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, for the treatment of all oncology indications in China. COPIKTRA received approval from the U.S. Food and Drug Administration for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies.

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COPIKTRA also received accelerated approval for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The indication in FL is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Under the terms of the agreement, Verastem Oncology shall receive an upfront payment of $15 Million USD. Verastem Oncology is also entitled to receive additional development milestone payments of $30 Million USD, plus potential sales milestone payments and double-digit percentage royalties based on future net sales of COPIKTRA in China. CSPC will receive exclusive rights to develop and commercialize COPIKTRA and hold the marketing authorization and product license for COPIKTRA in China. CSPC will have the right to collaborate with Verastem Oncology on certain global development and clinical trial activities and will share pro-rata in the cost.

"This agreement with Verastem Oncology brings to our pipeline an overseas approved innovative oncology drug with the potential to help Chinese patients battling cancer, including some high unmet need hematologic malignancies," said Cai Dongchen, Chairman of CSPC. "Our long-standing development and commercial experience in the Chinese pharmaceutical market, together with Verastem Oncology's expertise with COPIKTRA, will ensure the timely and efficient development of this exciting therapy. At CSPC, we are dedicated to developing and commercializing innovative medicines and we are honored to form this strategic alliance with Verastem Oncology to advance COPIKTRA."

"We are delighted to be working with CSPC, a respected leader in developing, manufacturing and commercializing pharmaceuticals in China," said Robert Forrester, President and Chief Executive Officer of Verastem Oncology. "CSPC successfully markets multiple oncology products, including DUOMEISU (doxorubicin hydrochloride liposome injection), JINYOULI (PEG-rhGCSF injection) and KEAILI (paclitaxel for injection (albumin-bound)). CSPC is a constituent stock of the Hang Seng Index and is recognized as one of the most valuable brands in China. We believe this partnership underscores the global potential of COPIKTRA and complements the growing list of strategic partners focused on bringing COPIKTRA to patients worldwide. As we execute the launch of COPIKTRA in the U.S., we will work collaboratively in parallel with CSPC to rapidly advance COPIKTRA through the hospitals in China and ultimately to cancer patients in need."

About COPIKTRA™ (duvelisib)

COPIKTRA is an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, two enzymes known to help support the growth and survival of malignant B-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] COPIKTRA is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. COPIKTRA is also being developed by Verastem Oncology for the treatment of peripheral T-cell lymphoma (PTCL), for which it has received Fast Track status, and is being investigated in combination with other agents through investigator-sponsored studies.[4] For more information on COPIKTRA, please visit www.COPIKTRA.com. Information about duvelisib clinical trials can be found on www.clinicaltrials.gov.

About CSPC Pharmaceutical Group Limited

CSPC Pharmaceutical Group Limited is a leading pharmaceutical group in China. The Company has been listed on the Main Board of the Hong Kong Stock Exchange since 1994 and is currently a constituent stock of Hang Sang Index. CSPC is a leading developer and manufacturer of innovative and generic drugs in China. Blockbuster innovative products in CSPC Pharmaceutical's pipeline include NBP (butylphthalide), OULAINING (oxiracetam), XUANNING (maleate levamlodipine), DUOMEISU, JINYOULI and KEAILI. CSPC is also a major manufacturer of bulk drugs, including vitamin C, antibiotics and caffeine. The production facilities of CSPC are mainly located in Shijiazhuang City, Hebei Province, China. For more information, please visit its website at http://www.cspc.com.hk.

About Verastem Oncology

Verastem, Inc. (Nasdaq:VSTM) (Verastem Oncology or the Company), is a biopharmaceutical company focused on developing and commercializing medicines to improve the survival and quality of life of cancer patients. Verastem Oncology currently markets COPIKTRA™ (duvelisib), an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first approved dual inhibitor of PI3K-delta and PI3K-gamma, which is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) after at least two prior therapies and relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The indication in FL is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. In addition, Verastem Oncology is developing the focal adhesion kinase (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.

Verastem Oncology forward-looking statements notice:

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements regarding the development and activity of Verastem Oncology's lead product COPIKTRA, and Verastem Oncology's PI3K and FAK programs generally, its intent to commercialize COPIKTRA, the potential commercial success of COPIKTRA, the anticipated adoption of COPIKTRA by patients and physicians, the structure of its planned and pending clinical trials and the timeline and indications for clinical development, regulatory submissions and commercialization activities. 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, among other things, uncertainties regarding the launch timing and commercial success of COPIKTRA in the United States; uncertainties regarding physician and patient adoption of COPIKTRA, including those related to the safety and efficacy of COPIKTRA; the uncertainties inherent in research and development of COPIKTRA, such as negative or unexpected results of clinical trials; whether and when any applications for COPIKTRA may be filed with regulatory authorities in any other jurisdictions; whether and when regulatory authorities in any other jurisdictions may approve any such other applications that may be filed for COPIKTRA, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted and, if approved, whether COPIKTRA will be commercially successful in such jurisdictions; Verastem Oncology's ability to obtain, maintain and enforce patent and other intellectual property protection for COPIKTRA and its other product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of COPIKTRA; that regulatory authorities in the U.S. or other jurisdictions, if approved, could withdraw approval; whether preclinical testing of Verastem Oncology's product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for Verastem Oncology's product candidates is uncertain; the risk that third party payors (including government agencies) will not reimburse for COPIKTRA; that there may be competitive developments affecting its product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that COPIKTRA or Verastem Oncology's other product candidates will cause unexpected safety events, experience manufacturing or supply interruptions or failures, or result in unmanageable safety profiles as compared to their levels of efficacy; that COPIKTRA will be ineffective at treating patients with lymphoid malignancies; that Verastem Oncology will be unable to successfully initiate or complete the clinical development and eventual commercialization of its product candidates; that the development and commercialization of Verastem Oncology's product candidates will take longer or cost more than planned; that Verastem Oncology may not have sufficient cash to fund its contemplated operations; that Verastem Oncology or Infinity Pharmaceuticals, Inc. will fail to fully perform under the duvelisib license agreement; that Verastem Oncology may be unable to make additional draws under its debt facility or obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that Verastem Oncology will not pursue or submit regulatory filings for its product candidates, including for duvelisib in patients with CLL/SLL or FL in other jurisdictions; and that Verastem Oncology'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 the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 as filed with the Securities and Exchange Commission (SEC) on August 8, 2018, its Annual Report on Form 10-K for the year ended December 31, 2017 as filed with the SEC on March 13, 2018 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology's views as of the date hereof, and the Company does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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, NCT03372057.

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Source: Verastem, Inc.

Verastem Oncology:
Brian Sullivan, +1 781-469-1636
Senior Director, Corporate Development
bsullivan@verastem.com

or
Media:
FleishmanHillard
Adam Silverstein, +1 917-697-9313
media@verastem.com
or
Investors:
Argot Partners
Joseph Rayne, +1 617-340-6075
joseph@argotpartners.com