Verastem Oncology Appoints Louis J. Denis, M.D., as Chief Medical Officer

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BOSTON--(BUSINESS WIRE)--Sep. 22, 2021-- Verastem Oncology (Nasdaq:VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today announced the appointment of Louis J. Denis, M.D., as Chief Medical Officer. Dr. Denis brings more than 25 years of clinical development and oncology expertise to Verastem.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210922005333/en/

Verastem Oncology Appoints Louis J. Denis, M.D., as Chief Medical Officer (Photo: Business Wire)

"Louis' proven track record in drug development, including targeting the RAS pathway for treatment of cancer, and his background as a medical oncologist will be invaluable as we advance our registration-directed trials of VS-6766 and defactinib through the clinic," said Brian Stuglik, CEO of Verastem Oncology.

"I am delighted to join Verastem at such an exciting time. The encouraging results from the Phase 1/2 FRAME study presented at ESMO, along with the recent FDA breakthrough therapy designation in recurrent low-grade serous ovarian cancer and the clinical partnership with Amgen in KRAS G12C-mutant non-small cell lung cancer sets the Company up for its next stages of growth," said Dr. Denis. "I look forward to working alongside Verastem's experienced leadership team and scientific advisory board to advance its development programs and deliver new treatment options to cancer patients."

Prior to joining Verastem, Dr. Denis was the Chief Medical Officer of Asana BioSciences, where he provided strategic direction as well as medical and safety oversight to Asana's portfolio of oncology and immunology assets. Previously, Dr. Denis held various leadership roles in Oncology clinical development and medical affairs at Boehringer Ingelheim and Pfizer. Dr. Denis received his M.D. from Vrije Universiteit Brussel Medical School, Belgium, and did his post-doctoral fellowships in Internal Medicine/Medical Oncology at Middelheim Hospital, Antwerp; the Rotterdam Cancer Institute, The Netherlands; and the Institute for Drug Development, Cancer Therapy and Research Center, San Antonio, Texas.

About the VS-6766/Defactinib Combination

The combination of VS-6766 and defactinib has been found to be clinically active in patients with KRAS mutant tumors. In an ongoing investigator-initiated Phase 1/2 FRAME study, the combination of VS-6766 and defactinib is being evaluated in patients with low-grade serous ovarian cancer (LGSOC), KRAS mutant NSCLC and colorectal cancer (CRC). The FRAME study was expanded to include new cohorts in pancreatic cancer, KRAS mutant endometrioid cancer and KRAS-G12V NSCLC. Verastem Oncology is also supporting an investigator-initiated Phase 2 trial evaluating VS-6766 with defactinib in patients with metastatic uveal melanoma. Verastem Oncology has initiated Phase 2 registration-directed trials of VS-6766 with defactinib in patients with recurrent LGSOC and in patients with recurrent KRAS-G12V mutant NSCLC as part of its RAMP (**R**af **A**nd **M**ek **P**rogram).

The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK inhibitor VS-6766, with defactinib, its focal adhesion kinase (FAK) inhibitor, for the treatment of all patients with recurrent LGSOC regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.

About Verastem Oncology

Verastem Oncology (Nasdaq:VSTM) (Verastem, Inc.) is a development-stage biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. Our pipeline is focused on novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and FAK inhibition. For more information, please visit www.verastem.com.

Forward-Looking Statements Notice

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements related to the potential clinical value of the RAF/MEK/FAK combination, the potential benefits of Breakthrough Therapy designation and the timing of commencing and completing registration-directed trials for the RAF/MEK/FAK combination. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "encouraging" 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 and uncertainties, among other things, regarding: the success in the development and potential commercialization of our product candidates, including defactinib in combination with VS-6766; the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis or result in unmanageable safety profiles as compared to their levels of efficacy; our ability to obtain, maintain and enforce patent and other intellectual property protection for our 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 our product candidates; whether preclinical testing of our 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 our product candidates is uncertain; that third-party payors (including government agencies) may not reimburse; that there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that our product candidates will experience manufacturing or supply interruptions or failures; that we will be unable to successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the VS-6766 license agreement; that we may not have sufficient cash to fund our contemplated operations; that we may be unable to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that we will be unable to execute on our partnering strategies for defactinib in combination with VS-6766; that we will not pursue or submit regulatory filings for our product candidates; that we do not receive additional proceeds from the contingent payments negotiated in the sale of COPIKTRA; and that our 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 Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (SEC) on March 18, 2021 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.

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