Verastem Oncology Appoints Frank Neumann, M.D., Ph.D., as Chief Medical Officer

January 6, 2021 at 9:13 AM EST

Appointment Reflects Progress of Verastem's RAS Targeted Therapy Development Program

Verastem Recently Initiated Registration-Directed Trials with VS-6766 and Defactinib in Recurrent Low-Grade Serous Ovarian Cancer and KRAS Mutant Non-Small Cell Lung Cancer

BOSTON--(BUSINESS WIRE)--Jan. 6, 2021-- Verastem, Inc. (Nasdaq:VSTM) (also known as Verastem Oncology), a biopharmaceutical company committed to advancing new medicines for patients battling cancer, today announced the appointment of industry veteran Frank Neumann, M.D., Ph.D., as Chief Medical Officer to oversee the Company's clinical and regulatory strategy and Medical Affairs team.

"Frank brings deep expertise across the full spectrum of clinical and regulatory activities in all stages of Oncology drug development," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "His strong industry experience and commitment to urgently addressing the high unmet needs of patients will be critical to delivering novel treatments and establishing the backbone of RAS targeted therapy as we move forward with our registration-directed trials of VS-6766 and defactinib."

"I am thrilled to be joining Verastem at this time given the encouraging results to date of VS-6766 and defactinib for patients with difficult-to-treat KRAS mutant tumors and the possibility to address limitations seen with other therapeutic approaches," said Dr. Neumann. "The broad potential of these development programs and the opportunity to further establish Verastem's scientific and medical leadership is truly energizing."

Dr. Neumann joins Verastem from bluebird bio where he served as VP, Head of Oncology Clinical Research, Clinical Research Development. In this role, he was responsible for planning and execution of oncology research asset strategies from pre-clinical to Investigational New Drug Application (IND) submissions, across both solid tumor and hematological indications. He has also held various leadership roles at Takeda Pharmaceuticals, including global clinical lead for ICLUSIG® (ponatinib) and medical team lead for NINLARO® (ixazomib). He served as clinical development head for all of Takeda's cell therapy approaches globally from POC to Phase 1 and was also responsible for various U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) interactions for Takeda's programs.

Earlier in his career, Dr. Neumann was a member of the oncology medical teams at AstraZeneca and Sanofi-Aventis and was a research scholar at the University of Texas MD Anderson Cancer Center. Dr. Neumann received his medical degree from the Heinrich-Heine University in Duesseldorf, Germany and his Ph.D. from the Rheinische-Friedrich-Wilhelm University in Bonn, Germany. He is Board-Certified in Hematology/Oncology, Internal Medicine, and Palliative Care Medicine and is currently an assistant professor at the Heinrich Heine University in Düsseldorf, Germany.

About VS-6766

VS-6766 is an oral small molecule inhibitor of the RAF/MEK signaling pathway. In contrast to other MEK inhibitors in development, VS-6766 blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows VS-6766 to block MEK signaling without the compensatory activation of MEK that appears to limit the efficacy of other inhibitors.

About Defactinib

Defactinib (VS-6063) is an oral small molecule inhibitor of the FAK and PYK2 signaling pathways that is currently being evaluated as a potential combination therapy for various solid tumors. Verastem has received Orphan Drug Designation for defactinib in ovarian cancer in the U.S., EU and Australia. Preclinical research by Verastem Oncology scientists and collaborators at world-renowned research institutions have described the effect of FAK inhibition to enhance immune response by decreasing immuno-suppressive cells, increasing cytotoxic T cells, and reducing stromal density, which allows tumor-killing immune cells to enter the tumor.[1,2]

About the VS-6766/Defactinib Combination

RAS mutant tumors are present in about 30% of all human cancers, have historically presented a difficult treatment challenge and are often associated with significantly worse prognosis.[3] Challenges associated with identifying new treatment options for these types of cancers include resistance to single agents,[3] identifying tolerable combination regimens with MEK inhibitors and new RAS inhibitors in development addressing only a minority of all RAS mutated cancers.

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 recurrent low-grade serous ovarian cancer (LGSOC), KRAS mutant NSCLC and colorectal cancer. Updated data from this study presented at the 2nd Annual RAS-Targeted Drug Development Summit in September 2020 demonstrated a 56% overall response rate and long duration of therapy among patients with KRAS-G12 mutant LGSOC.[4] Based on an observation of higher response rates seen in NSCLC patients with KRAS-G12V mutations in the study, Verastem is also exploring the role of VS-6766 and defactinib in KRAS-G12V mutant NSCLC. The FRAME study was expanded in August 2020 to include new cohorts in pancreatic cancer, KRAS mutant endometrial cancer and KRAS-G12V mutant NSCLC.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) 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 focal adhesion kinase (FAK) inhibition. For more information, please visit www.verastem.com.

Forward-Looking Statements Notice

This press release includes forward-looking statements about Verastem's strategy, future plans and prospects, including statements related to the potential clinical value of the RAF/MEK/FAK combination. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "promising" 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 make additional draws under our debt facility or 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; 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 our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission (SEC) on November 9, 2020 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem's views as of the date hereof, and we do not assume and specifically disclaim 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] Chénard-Poirier, M. et al. Results from the biomarker-driven basket trial of RO5126766 (CH5127566), a potent RAF/MEK inhibitor, in RAS- or RAF-mutated malignancies including multiple myeloma. Journal of Clinical Oncology 2017: 35. 10.1200/JCO.2017.35.15_suppl.2506.

[2] ClinicalTrials.gov. Phase I Trial of VS-6063 and RO5126766. (FRAME). Available at: https://clinicaltrials.gov/ct2/show/NCT03875820. Accessed November 24, 2020.

[3] Baines, A. T., Xu, D., & Der, C. J. (2011). Inhibition of Ras for cancer treatment: the search continues. Future medicinal chemistry, 3(14), 1787–1808. https://doi.org/10.4155/fmc.11.121

[4] Verastem Press Release. Verastem Oncology Announces Presentation of Updated Phase 1/2 FRAME Study Data at the 2nd Annual RAS-Targeted Drug Development Summit. September 16, 2020. Available at: https://investor.verastem.com/news-releases/news-release-details/verastem-oncology-announces-presentation-updated-phase-12-frame. Accessed November 24, 2020.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210106005499/en/

Investors:
Ajay Munshi
Vice President, Corporate Development
1 781-469-1579
amunshi@verastem.com

Media:
Lisa Buffington
Corporate Communications
+1 781-292-4205
lbuffington@verastem.com

Source: Verastem, Inc.