Verastem Oncology Enters Discovery and Development Collaboration with GenFleet Therapeutics to Advance New Programs Targeting RAS Pathway-Driven Cancers

August 28, 2023 at 7:00 AM EDT

Synergistic Collaboration Based on Strengths of Verastem Oncology's Pipeline and Development Expertise and GenFleet Therapeutics' Discovery Capabilities

Exclusive Option for Verastem Oncology to License Up to Three Programs with Development and Commercialization Rights Outside China

BOSTON--(BUSINESS WIRE)--Aug. 28, 2023-- Verastem Oncology (Nasdaq: VSTM) (the "Company"), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today announced that the Company has entered into a discovery and development collaboration with GenFleet Therapeutics ("GenFleet") to advance three oncology discovery programs targeting RAS pathway-driven cancers.

The collaboration, which builds on the strengths of both Companies in oncology small molecule drug development, enables Verastem Oncology to partner its clinical development and regulatory expertise with GenFleet's accomplished discovery capabilities. This includes Verastem Oncology's experience and established network of collaborators, including scientific and clinical experts in RAS biology and RAS pathway-dependent cancers and GenFleet's accomplishments with its KRAS G12C inhibitor program. The risk-sharing structure of the collaboration is designed to allow Verastem Oncology the flexibility of a milestone-based option to license up to three compounds. The licenses would give Verastem Oncology development and commercialization rights outside of China while GenFleet would retain development and commercialization rights inside of China.

"With the aim of bringing needed therapies to patients where there is high unmet medical need, we are looking forward to working with GenFleet on this important discovery and development collaboration," said Dan Paterson, President and Chief Executive Officer of Verastem Oncology. "This synergistic collaboration augments our research and development pipeline in alignment with our strategy and expertise in RAS pathway-driven cancers. It also may enable new combinations with our lead assets avutometinib and defactinib."

"We are pleased to reach an agreement with Verastem Oncology to develop multiple products based on GenFleet's proprietary discovery platform and our extensive experience in developing RAS inhibitors. Both Companies have already achieved significant clinical breakthroughs in RAS pathway-driven cancers and we look forward to a synergistic collaboration between GenFleet's proven R&D capabilities and Verastem Oncology's clinical and regulatory expertise. This discovery partnership will also enhance GenFleet's global footprint in delivering potentially life-saving therapies to cancer patients," said Qiang Lu, Ph.D., Chairman of GenFleet.

The terms of the agreement include combined upfront, research support and option payments to GenFleet of $11.5 million for the first program, with potential total deal size across all three programs up to $625.5 million excluding royalties if Verastem Oncology exercises its in-license options. The collaboration provides Verastem Oncology with exclusive rights to obtain a license to each of the compounds after successful completion of pre-determined milestones in Phase 1 trials.

About Avutometinib (VS-6766)

Avutometinib is a RAF/MEK clamp that induces inactive complexes of MEK with ARAF, BRAF and CRAF potentially creating a more complete and durable anti-tumor response through maximal RAS pathway inhibition. Avutometinib is currently in late-stage development.

In contrast to other MEK inhibitors, avutometinib blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows avutometinib to block MEK signaling without the compensatory activation of MEK that appears to limit the efficacy of other inhibitors. The U.S. Food and Drug Administration granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK clamp avutometinib, with defactinib, its FAK inhibitor, for the treatment of all patients with recurrent low-grade serous ovarian cancer (LGSOC) regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.

Verastem Oncology is currently conducting clinical trials with its RAF/MEK clamp avutometinib in RAS pathway-driven tumors as part of its (**R**af **A**nd **M**ek **P**rogram). RAMP 201 is a registration-directed trial of avutometinib alone and in combination with defactinib in patients with recurrent LGSOC. Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS™ (sotorasib) and KRAZATI™ (adagrasib) in combination with avutometinib in KRAS G12C mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively. Supported by the "Therapeutic Accelerator Award" Verastem Oncology received from PanCAN, the Company is conducting RAMP 205, a Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer.

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 Oncology's strategy, future plans and prospects, including statements related to the expected outcome and benefits of the collaboration with Genfleet, the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports, interactions with regulators and potential for additional development programs

involving Verastem Oncology's lead compound. 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 avutometinib in combination with other compounds, including defactinib, LUMAKRAS™ and others; 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 trial design, labeling and other matters that could affect the timing, 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 we may not attract and retain high quality personnel; 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, including as a result of conducting additional studies; that our target market for our product candidates might be smaller than we are presently estimating; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that we or our other collaboration partners may fail to perform under our collaboration agreements; that any of our third-party contract research organizations, contract manufacturing organizations, clinical sites, or contractors, among others, who we rely on fail to fully perform; 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 Secura Bio, Inc. will achieve the milestones that result in payments to us under our asset purchase agreement with Secura Bio, Inc.; that we will be unable to execute on our partnering strategies for avutometinib in combination with other compounds; 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission (SEC) on March 14, 2023 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 Verastem Oncology 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230828461200/en/

Investors:

Dan Calkins
+1 781-469-1694
Investor Relations
dcalkins@verastem.com

Ryan Porter
+1 212-600-1902
ryan.porter@argotpartners.com

Media:
Lisa Buffington
Corporate Communications
+1 781-292-4502
lbuffington@verastem.com

Source: Verastem Oncology