Verastem Oncology Announces First Patient Dosed with GFH375/VS-7375, a KRAS G12D (ON/OFF) Inhibitor, in a Phase 1/2 Trial in China as Part of Collaboration with GenFleet Therapeutics

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GenFleet's IND in China was cleared in June 2024; this is the first discovery program from the collaboration Verastem announced in 2023 to advance into human clinical trials

Verastem plans to initiate development studies outside of China after evaluating initial dose escalation data from the Phase 1 study in China

BOSTON--(BUSINESS WIRE)--Jul. 12, 2024-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today announced that the first patient has been dosed in a Phase 1/2 trial in China, conducted by GenFleet Therapeutics, evaluating GFH375/VS-7375, a KRAS G12D (ON/OFF) inhibitor.

GFH375/VS-7375, was selected as Verastem's lead discovery program from its collaboration with GenFleet established in 2023. GFH375/VS-7375 is an oral, potent and selective KRAS G12D dual inhibitor of ON (GTP) and OFF (GDP) states. Preclinical data presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2024 demonstrated oral bioavailability across preclinical species, strong anti-tumor activity as a single agent and potency against intracranial tumor models suggesting the potential to treat brain metastases.

"In a short amount of time, we identified GFH375/VS-7375, a novel KRAS G12D (ON/OFF) inhibitor, as our lead discovery program last year and now the first patient has been dosed in the Phase 1/2 study by GenFleet in China," said Dan Paterson, president and chief executive officer of Verastem Oncology. "We look forward to leveraging the initial clinical dose escalation data to accelerate our development path in the U.S., as there are currently no FDA-approved KRAS G12D-targeted treatments despite the high prevalence of this KRAS mutation in various cancers, including pancreatic, colorectal, lung and uterine."

The Phase 1 study is being conducted in approximately 20 hospitals currently in China and will evaluate the safety and efficacy of GFH375/VS-7375 in patients with advanced KRAS G12D mutant solid tumors. The Phase 1 study will determine the recommended Phase 2 dose (RP2D) and then further evaluate in Phase 2 the efficacy and safety of GFH375/VS-7375 in patients with advanced solid tumors, such as pancreatic ductal adenocarcinoma, colorectal cancer and non-small cell lung cancer.

About GFH375/VS-7375

GFH375/VS-7375 is a potential best-in-class, potent and selective oral KRAS G12D (ON/OFF) inhibitor, identified as the lead discovery program from the Verastem Oncology discovery and development collaboration with GenFleet Therapeutics. GenFleet's IND for GFH375/VS-7375 was approved in China in June 2024 and the Phase 1/2 trial in KRAS G12D-mutant solid tumors was subsequently initiated and the first patient has been dosed in July 2024. The collaboration includes three discovery programs, the first being the KRAS G12D inhibitor, and provides Verastem Oncology with exclusive options to license three compounds selected for collaboration after successful completion of pre-determined milestones in Phase 1 trials. The licenses would give Verastem Oncology development and commercialization rights outside of the GenFleet territories of mainland China, Hong Kong, Macau, and Taiwan.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a late-stage development 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 RAS/MAPK-driven cancers, specifically 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 and follow us on LinkedIn.

Forward Looking Statements

This press release includes forward-looking statements about, among other things, Verastem Oncology's programs and product candidates, strategy, future plans and prospects, including statements related to the expected outcome and benefits of its collaboration with GenFleet Therapeutics (Shanghai), Inc. ("GenFleet"), the timing of commencing and completing trials, including topline data reports, interactions with regulators, the potential for the commercialization of product candidates, plans to initiate development studies outside of China and other 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. Forward-looking statements are not guarantees of future performance and are 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 uncertainties inherent in research and development, such as negative or unexpected results of clinical trials, the occurrence or timing of applications for our product candidates that may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications that may be filed for our product candidates, and, if approved, whether our product candidates will be commercially successful in such jurisdictions; 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; the market opportunities of our drug candidates are based on internal and third-party estimates which may prove to be incorrect; 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, which may delay our development programs, including delays in submission or review by the FDA of our NDA submission in recurrent KRAS mutant LGSOC if enrollment in our confirmatory trial is not well underway at the time of submission; that our product candidates will cause adverse safety events and/or unexpected concerns may arise from additional data or analysis, or result in unmanageable safety profiles as compared to their levels of efficacy; that we maybe unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so; that the mature RAMP 201 data and associated discussions with the FDA may not support the scope of our rolling NDA submission for the avutometinib and defactinib combination in LGSOC, including with respect to KRAS wild type LGSOC; that our product candidates may experience manufacturing or supply interruptions or failures; 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 face substantial competition, which may result in others developing or commercializing products before or more successfully than we do which could result in reduced market share or market potential for our product candidates; 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 or our decisions regarding execution of such commercialization; that we may not have sufficient cash to fund our contemplated operations , including certain of our product development programs; that we may not attract and retain high quality personnel; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that our total addressable and target markets for our product candidates might be smaller than we are presently estimating; that Secura Bio, Inc. will fail to fully perform under the asset purchase agreement with Secura Bio, Inc., including in relation to milestone payments; that we will not see a return on investment on the payments we have and may continue to make pursuant to the collaboration and option agreement with GenFleet or that GenFleet will fail to fully perform under the agreement; that we may not be able to establish new or expand on existing collaborations or partnerships, including with respect to in-licensing of our product candidates, on favorable terms, or at all; 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 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.

As a result of these and other factors, we may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. 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, 2023, as filed with the Securities and Exchange Commission (SEC) on March 14, 2024, and in any subsequent filings with the SEC, which are available at www.sec.gov and www.verastem.com.

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