Verastem Oncology Granted Fast Track Designation for VS-7375 for the Treatment of KRAS G12D-mutated Locally Advanced or Metastatic Pancreatic Cancer

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Enrollment is ongoing in U.S. Phase 1/2a trial for VS-7375, an oral KRAS G12D (ON/OFF) inhibitor, in KRAS G12D advanced solid tumors

KRAS G12D mutation is the most prevalent KRAS mutation in human cancers and 37% of pancreatic cancers harbor a KRAS G12D mutation

BOSTON--(BUSINESS WIRE)--Jul. 24, 2025-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with RAS/MAPK pathway-driven cancers, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) to VS-7375, an oral KRAS G12D (ON/OFF) inhibitor, for the first-line treatment of patients with KRAS G12D-mutated locally advanced or metastatic adenocarcinoma of the pancreas (PDAC) and for the treatment of patients with KRAS G12D-mutated locally advanced or metastatic PDAC who have received at least one prior line of standard systemic therapy. Fast Track is a process designed to facilitate the development and expedite the review of new drugs intended to treat or prevent serious conditions and address unmet medical needs.

"The Fast Track Designation for VS-7375 underscores the importance of our potential best-in-class KRAS G12D (ON/OFF) inhibitor. As we continue enrollment in our U.S. Phase 1/2a clinical trial, our goal is to accelerate the program's development given the lack of FDA-approved, KRAS G12D-targeted treatments for people living with KRAS G12D cancers," said Dan Paterson, president and chief executive officer of Verastem Oncology. "Given the encouraging initial safety and efficacy results in China reported by our partner, GenFleet Therapeutics, at ASCO this year, we are excited to be advancing VS-7375 in the U.S. to evaluate it in advanced pancreatic cancer and non-small cell lung cancer and in combination with cetuximab in advanced solid tumors, including colorectal cancer."

VS-7375-101 is a Phase 1/2a study being conducted in the U.S., with plans to expand globally, and will evaluate the safety and efficacy of VS-7375 in patients with advanced KRAS G12D mutant solid tumors, including PDAC. The monotherapy dose escalation phase of the study started at a 400mg QD dose based on an efficacious dose identified in the Phase 1/2 study conducted in China by the Company's partner, GenFleet Therapeutics. GenFleet announced encouraging initial safety and efficacy results from its Phase 1 dose-escalation phase of its study of VS-7375 (known as GFH375 in China) at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. Verastem plans to dose-escalate across dose levels where encouraging initial safety and efficacy were observed in patients with advanced KRAS G12D mutant solid tumor cancers in GenFleet's study. Upon successful completion of the dose-escalation phase, the Company will select a recommended Phase 2 dose and assess the efficacy and safety of monotherapy VS-7375 in expansion cohorts of patients with advanced pancreatic cancer and non-small cell lung cancer. In parallel with the monotherapy dose escalation, Verastem will evaluate VS-7375 in combination with cetuximab in advanced solid tumors. Subject to the results of the Phase 1 dose escalation combination of VS-7375 and cetuximab, Verastem plans to initiate a combination expansion cohort in colorectal cancer.

About KRAS G12D

KRAS G12D represents 26% of all KRAS mutations, making it the most prevalent KRAS mutation in human cancers. The KRAS G12D mutation occurs most commonly in pancreatic (37%), colorectal (12.5%), endometrial (8%), and non-small cell lung (5%) cancers. Currently, no therapies are approved by the U.S. Food and Drug Administration (FDA) specifically targeting KRAS G12D mutations in cancer.

About VS-7375, an Oral KRAS G12D (ON/OFF) Inhibitor

VS-7375 is a potential best-in-class, potent, and selective oral KRAS G12D dual ON/OFF inhibitor. VS-7375 is the lead program from the Verastem Oncology discovery and development collaboration with GenFleet Therapeutics. Verastem announced in April 2025 that the U.S. Investigational New Drug (IND) application for VS-7375 was cleared and initiated a Phase 1/2a clinical trial in June 2025. GenFleet's IND for VS-7375 (known as GFH375 in China) was approved in China in June 2024, and the first patient was dosed in a Phase 1/2 study in July 2024.

About the GenFleet Therapeutics Collaboration

The collaboration with GenFleet Therapeutics aims to advance three oncology discovery programs related to RAS/MAPK pathway-driven cancers. The collaboration provides Verastem with an exclusive option to obtain a license for each of the three compounds in the collaboration after the successful completion of pre-determined milestones in a Phase 1 trial. Verastem selected VS-7375 (also known as GFH375), an oral KRAS G12D (ON/OFF) inhibitor, as its lead program in December 2023 and the license for VS-7375 that was exercised in January 2025 is the first one from this collaboration. These licenses give Verastem development and commercialization rights outside the GenFleet markets of mainland China, Hong Kong, Macau, and Taiwan.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a biopharmaceutical company committed to developing and commercializing new medicines to improve the lives of patients diagnosed with RAS/MAPK pathway-driven cancers. Verastem markets AVMAPKI™ FAKZYNJA™ CO-PACK in the U.S. 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, FAK inhibition, and KRAS G12D inhibition. For more information, please visit www.verastem.com and follow us on LinkedIn.

Forward-Looking Statements Notice

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “plan,” “could,” “may,” “believe,” “estimate,” “forecast,” “goal,” “project,” and other words of similar meaning. Such forward-looking statements address various matters about, among other things, Verastem Oncology’s programs and product candidates, strategy, future plans and prospects, including statements related to the potential for and timing of commercialization of product candidates, the expected outcome and benefits of the Company’s collaboration with GenFleet Therapeutics (Shanghai), Inc., the timing of commencing and completing trials and compiling data, the expected timing of the presentation of data by the Company and the potential clinical value of various of the Company’s clinical trials. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: the uncertainties inherent in research and development, such as the possibility of negative or unexpected results of clinical trials; that we may 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 may fail to fully perform under the agreement; that the development and commercialization of our product candidates may take longer or cost more than planned, including as a result of conducting additional studies or our decisions regarding execution of such commercialization; that data may not be available when expected; the risk that our preliminary and interim data may not be representative of more mature data; uncertainties related to the recent change in the U.S. presidential administration, including regulatory and policy changes that may adversely affect our business; that our product candidates may not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients; and the risks identified under the heading "Risk Factors" as detailed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission (SEC) on March 20, 2025, as well as the other information we file with the SEC, are possibly realized. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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