



Verastem Oncology Announces Updated Data from Partner GenFleet Therapeutics' Phase 1 Study in China of GFH375 (VS-7375), an Oral KRAS G12D (ON/OFF) Inhibitor

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In the study in China, GFH375 demonstrated an ORR of 52% in patients with pancreatic ductal adenocarcinoma and an ORR of 42% with non-small cell lung cancer

Company activating sites in the U.S. for VS-7375 to begin enrollment in the Phase 1/2a trial

Company will host an R&D investor webcast on Monday, June 2, at 11:00 am CDT to review updated RAMP 205 data as well as updated data on GFH375 presented at the ASCO 2025 Annual Meeting

BOSTON--(BUSINESS WIRE)--Jun. 2, 2025-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with RAS/MAPK pathway-driven cancers, today announced positive updated data from the dose escalation phase of the Phase 1/2 trial of GFH375 (known as VS-7375 in the U.S.). As of May 16, 2025, 23 efficacy-evaluable patients with pancreatic ductal adenocarcinoma (PDAC) and 12 efficacy-evaluable patients with non-small cell lung cancer (NSCLC) achieved an overall response rate (ORR) of 52% and 42%, respectively. The updated data were presented by Verastem's partner, GenFleet Therapeutics, in a rapid oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting on June 2, 2025, in Chicago, IL.

"We are encouraged by the initial efficacy and safety results from the Phase 1 portion of the study of GFH375 in China by our partner, GenFleet Therapeutics. The results presented at ASCO further support our advancement of our clinical program for VS-7375 in the U.S., as we believe there remains a significant opportunity to further improve on the efficacy seen to date with other KRAS G12D-selective agents. VS-7375's dual inhibition of both the ON/OFF states has the potential to drive deep and durable cancer responses and allow for better combinability with other agents," said Dan Paterson, president and chief executive officer of Verastem Oncology.

ASCO 2025 Presentation Highlights

GenFleet reported that 62 patients were enrolled in the Phase 1 portion of the study in China, receiving oral doses ranging from 100 to 900 mg daily. In the study, 98% of patients had metastatic disease, and 75% had received ≥ 2 prior lines of therapy. As of the data cutoff of May 16, 2025, 23 efficacy-evaluable patients with PDAC and 12 efficacy-evaluable patients with NSCLC, who received daily dosages of 400 or 600 mg and had at least one post-treatment tumor assessment, achieved an ORR of 52% and a disease control rate (DCR) of 100%, and an ORR of 42% and a DCR of 83%, respectively.

As of the cutoff date of March 31, 2025, GenFleet reported that there were no dose-limiting toxicities (DLTs) observed across all dose levels (100-900 mg QD), and the treatment-related adverse events (TRAEs) were mostly Grade 1/2. The most common TRAEs occurring in at least 20% of patients were diarrhea, nausea, vomiting, and anemia. TRAEs \geq Grade 3 consisted mainly of decreased neutrophil count (8%) and diarrhea (5%). No TRAE-related deaths were reported.

Webcast Information

Verastem will hold an investor webcast on Monday, June 2, at 11:00 am CDT, to review the RAMP 205 updated data and the VS-7375 program including updated data from the study in China. The event will feature members of Verastem's management team and key opinion leaders. A live audio webcast of the call, along with accompanying slides, will be accessible [here](#). A replay of the webcast will be archived on the website for approximately 90 days following the presentation.

U.S. Phase 1/2a Study of VS-7375

The Phase 1/2a study will be conducted in the U.S., with the potential to expand globally, and will evaluate the safety and efficacy of VS-7375 in patients with advanced KRAS G12D mutant solid tumors. The starting dose for the Phase 1 study of 400 mg is based on the dose identified in the initial data from the GenFleet study to accelerate the trial's progress. Verastem plans to dose escalate across levels where responses were observed in GenFleet's study and will assess in the Phase 2a portion the efficacy and safety of VS-7375, both as monotherapy and in combination, in patients with advanced solid tumors, such as pancreatic, colorectal, and non-small cell lung cancers.

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 plans to initiate a Phase 1/2a clinical trial in mid-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

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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