Verastem Oncology Announces Late-Breaking Abstract from Partner GenFleet Therapeutics' Study in China of GFH375 (VS-7375) in Advanced Non-Small Cell Lung Cancer at IASLC 2025 World Conference on Lung Cancer

August 13, 2025 at 4:29 PM EDT

GFH375 demonstrated an overall response rate (ORR) of 68.8% in non-small cell lung cancer (NSCLC) at the recommended Phase 2 dose of 600 mg QD

GFH375 demonstrated an ORR of 57.7% in efficacy evaluable patients with NSCLC across all dose levels

Mini oral presentation on Sunday, September 7, 2025 from 12:00 to 1:15 pm (CEST)

BOSTON--(BUSINESS WIRE)--Aug. 13, 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 safety and efficacy data and late-breaking presentation details of partner GenFleet Therapeutics' Phase 1/2 study in China of GFH375, an oral KRAS G12D (ON/OFF) inhibitor, known as VS-7375 outside of China, in advanced non-small cell lung cancer patients with a KRAS G12D mutation. The data will be presented in a mini oral presentation at the IASLC 2025 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer from September 6-9, in Barcelona, Spain.

"These data at WCLC build on the encouraging data presented at ASCO earlier this year, where GenFleet initially reported an ORR of 42% in 12 patients with advanced non-small cell lung cancer harboring a KRAS G12D mutation," said Dan Paterson, president and chief executive officer of Verastem Oncology. "The significant increase in patients with advanced lung cancer demonstrating a response, 68.8% ORR at the recommended Phase 2 dose, and 57.7% ORR across all dose levels, is impressive and continues to support the development and potential of VS-7375 in advanced lung cancer and across other advanced KRAS G12D solid tumors."

The late-breaking abstract was issued today by the WCLC. GenFleet reported cumulative safety data across the entire study population and preliminary efficacy data specific to patients with advanced NSCLC from the Phase 1/2 study in China. As of the data cutoff of July 15, 2025, the median follow-up time was 4.5 (range: 1.8-12.2) months. Tumor response was observed across the dose range tested. The study population includes 142 patients, including 28 with advanced NSCLC, 85 with advanced pancreatic ductal adenocarcinoma (PDAC) and 29 with other solid tumors. Amongst the patients with NSCLC, all had metastatic disease at baseline, 64.3% had received at least two prior lines of systemic therapies, and 96.4% had received an anti-PD1/PD-L1 therapy.

At the recommended Phase 2 dose of 600 mg once daily (QD), the ORR was 68.8% (11/16) (both confirmed and unconfirmed) and the disease control rate (DCR) was 93.8% (15/16). Among the 26 evaluable patients with NSCLC treated across all dose levels, the ORR was 57.7% (15/26) (both confirmed and unconfirmed) and the DCR was 88.5% (23/26).

Across all cancer types and dose levels evaluated, the most common treatment-related adverse events (TRAEs) occurring in at least 20% of patients were diarrhea, vomiting, nausea, anemia, decreased appetite, neutrophil count decreased, white blood cell count decreased, aspartate aminotransferase increased, asthenia, hypoalbuminemia, and alanine aminotransferase increased, predominately Grade 1 or 2 in severity. TRAEs and severe adverse events (SAEs), greater than Grade 3, occurred in 27.5% (39/142) and 7.7% (11/142) of patients, respectively. Of the 142 patients in the safety population, 11 patients had dose reduction, and six discontinued due to TRAEs. No TRAE-related deaths were reported.

WCLC Details

- **Title:** Efficacy and Safety of GFH375 in Advanced Non-Small Cell Lung Cancer Patients with KRAS G12D Mutation
- **Session:** MA02- New Treatment Strategies in Other Than EGFR-Positive Tumors
- **Session Date/Time:** Sunday, September 7, 2025 from 12:00 pm – 1:15 pm CEST

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; risks associated with the current administration's reductions to the FDA's workforce and any subsequent reductions that may lead to disruptions and delays in the FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development programs; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250813624714/en/

For Investor and Media Inquiries:
Julissa Viana
Vice President, Corporate Communications and Investor Relations
investors@verastem.com or
media@verastem.com

Source: Verastem Oncology