

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



GenFleet Therapeutics (Shanghai) Inc.

勁方醫藥科技(上海)股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2595)

VOLUNTARY ANNOUNCEMENT EFFICACY DATA OF GFH375, AN ORAL KRAS G12D (ON/OFF) INHIBITOR, FOR PANCREATIC DUCTAL ADENOCARCINOMA PATIENTS PRESENTED AS A LATE-BREAKING ABSTRACT IN AN ORAL PRESENTATION AT ESMO CONGRESS 2025

This announcement is made by GenFleet Therapeutics (Shanghai) Inc. (the “**Company**” or “**GenFleet**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business updates of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that phase I/II data of GFH375 treating PDAC patients with KRAS G12D mutation were featured in a LBA for oral presentation at the ESMO Congress 2025 in Berlin on October 19, 2025, in local time. Prof. Aiping Zhou from the Cancer Hospital of the Chinese Academy of Medical Sciences delivered the presentation titled “Efficacy and Safety of GFH375 Monotherapy in Previously Treated Advanced KRAS G12D Mutant Pancreatic Ductal Adenocarcinoma (PDAC)” (Abstract No.: LBA84). The latest data demonstrated promising efficacy and manageable safety profile of GFH375 at 600 mg QD (RP2D) in PDAC patients.

Among 59 heavily pretreated patients with advanced disease (nearly 70% in the third- or later-line setting) who had their first dose at least 4 months prior to data cut-off date and finished at least one post-treatment tumor assessment: the objective response rate was 40.7%; the disease control rate was 96.7%; the median PFS was 5.52 months and the 4-month OS rate was 92.2%.

The G12D variant represents the dominant KRAS mutation subtype (accounting for approximately 30% of all KRAS mutations), and it’s projected by Frost Sullivan to affect nearly 1.38 million new cancer cases globally in 2025. The high incidence of the KRAS G12D mutation in pancreatic cancer (~40%), as documented in the scientific literature, translates to a substantial population with crucial unmet needs.

NMPA granted the IND clearance for GFH375 for a phase I/II monotherapy study in June 2024, followed by the FDA’s Fast Track Designation this year for GFH375/VS-7375 treating locally advanced or metastatic PDAC with KRAS G12D mutation across all lines of therapy. Preliminary data from GFH375 monotherapy trial in solid tumor patients were already featured in 2025 as LBA and in presentation sessions at major academic conferences including ASCO and WCLC.

The oral presentation primarily includes the following contents:

- As of September 27, 2025, a total of 66 patients were enrolled with advanced KRAS G12D mutant PDAC and all received first dose of GFH375 for at least 4 months prior to the cut-off date: most enrolled patients (95.5%) were diagnosed with stage IV disease at baseline, with metastases most frequently occurring in the liver (78.8%), lung (28.8%) and peritoneum (28.8%); 68.2% of patients had received at least two prior lines of therapy, primarily chemotherapies, and 1/3 of patients had been treated with immunotherapy.
- A total of 59 patients had at least one post-treatment tumor assessment: ORR was 40.7%; the DCR was 96.7%; and the majority of patients (91.5%) had reduction in target lesions. With a median follow-up time of 5.65 months, the median PFS was 5.52 months with the 4-month PFS rate being 78.2%. As of the data cutoff date, the median OS was not reached with the 4-month OS rate being 92.2%.
- As of the data cutoff date (August 27, 2025), GFH375 presented a manageable safety profile in this cohort: most frequent TRAEs were diarrhea, decreased neutrophil count, and vomiting; most TRAEs were grade 1 or 2 and manageable with supportive treatment; grade ≥ 3 TRAEs occurred in 31.8% of patients, including only one case of grade 4 (the patient experienced treatment-related neutropenia and recovered with treatment of G-CSF). No grade 5 TRAE was reported.

Yu Wang, M.D., Ph.D. Chief Medical Officer of GenFleet, stated: “Since the IND approval in June 2024, GFH375 monotherapy trial has achieved rapid advancement and encouraging efficacy. For KRAS G12D-mutant patients, a population with substantial medical needs, we are pursuing further breakthroughs through the planning of pivotal studies in late-line setting and combination regimens in frontline setting.”

References

Lee, J.K. et al, npj Precis. Onc. 6, 91 (2022).

Norton C, et al. JAMA Netw Open. 2025 Jan 2;8(1): e2453588.

Emma G. Sturgill et al. J Clin Oncol. 41(4_suppl), 738-738(2023).

About GFH375/VS-7375

GFH375 is an orally active, potent, highly selective small-molecule KRAS G12D (ON/OFF) inhibitor designed to target the GTP/GDP exchange, thereby disrupting the activation of downstream pathways and effectively inhibiting tumor cell proliferation. Preclinical studies demonstrated dose-dependent inhibition in models bearing KRAS G12D mutation; GFH375 also demonstrated low off-target risk in kinase selectivity and safety target assays.

GenFleet entered into a discovery and development collaboration with Verastem to advance three novel 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 I trial. Verastem selected GFH375/VS-7375, an oral KRAS G12D (ON/OFF) inhibitor, as its lead program from the collaboration, in December 2023 and the license for GFH375 that was exercised in January 2025 is the first one from this collaboration. The licenses would give Verastem development and commercialization rights outside of China while GenFleet would retain rights inside of China.

Forward-looking Statements

Specific information in this press release may contain or constitute forward-looking words that are not historical facts. They can be identified by using forward-looking terminology, such as “predict”, “believe”, “plan”, “expect”, “will”, “may”, “should” and other words of similar meanings. Based on the management’s current beliefs, plans, estimates and expectations of the company’s operation and market trends subject to changes beyond control, the forward-looking terminology reflects GenFleet Therapeutics’ beliefs, plans, estimates and expectations of future development. Actual outcome in the future may differ significantly from forward-looking words owing to market, policy, and R&D uncertainties, among others. Subject to the above-mentioned uncertainties, GenFleet Therapeutics makes no expressed or implied guarantee as to the accuracy, completeness or feasibility of this presentation, and you are cautioned not to solely rely on such forward-looking words. Neither the company nor any of its directors, officers, employees, shareholders, agents, related parties, consultants or representatives will be liable to you or any other person for consequences resulting from using this presentation. Investors are advised to exercise due diligence with reference to the company’s official disclosures for decision-making.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“ASCO”	American Society of Clinical Oncology
“DCR”	disease control rate, the proportion of patients who have achieved either a complete response, partial response, or stable disease after treatment
“ERK”	extracellular signal-regulated kinase, a key protein in the mitogen-activated protein kinase signaling pathway
“FDA”	U.S. Food and Drug Administration
“G-CSF”	Granulocyte Colony-Stimulating Factor
“GDP”	guanosine triphosphate serves as an energy carrier and is involved in protein synthesis and signal transduction upon its hydrolysis and binding (e.g., activating downstream pathway by binding to RAS proteins)

“GTP”	guanosine diphosphate is the precursor or resulted from hydrolysis of GTP and is involved in cell metabolism and signal transduction (e.g., inactivating downstream pathway via binding to RAS proteins)
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials
“KRAS”	Kirsten RAS, a member of the RAS family proteins
“LBA”	late-breaking abstract
“MAPK”	mitogen-activated protein kinase, a family of proteins involved in transmitting signals from cell surface receptors to the nucleus
“NMPA”	the National Medical Products Administration of China (國家藥品監督管理局) or, where the context so requires, its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局), or CFDA
“ORR”	objective response rate, the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, a length of time that a patient with a specific disease is still alive, used as a measurement of a drug’s effectiveness
“PDAC”	pancreatic ductal adenocarcinoma, a type of exocrine pancreatic cancer that develops from cells lining small tubes in the pancreas called ducts and accounts for over 90% of all pancreatic cancer cases
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
“QD”	once-daily administration
“RAS”	rat sarcoma, a family of proteins that are critical regulators of cellular signaling pathways; it primarily includes HRAS, KRAS, and NRAS

“RP2D”	recommended Phase II dose, the dosage of a drug that is suggested for use in Phase II clinical trials
“TRAE”	treatment-related adverse events
“Verastem”	Verastem, Inc., a company headquartered in Massachusetts and listed on NASDAQ (stock code: VSTM)
“WCLC”	World Conference on Lung Cancer

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will be able to develop, or ultimately market, GFH375, successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
GenFleet Therapeutics (Shanghai) Inc.
Dr. Qiang LU
Chairman and Executive Director

Hong Kong, October 20, 2025

As at the date of this announcement, the Board of the Company comprises: (i) Dr. Qiang LU, Dr. Jiong LAN and Ms. ZHANG Wei as executive directors; (ii) Mr. ZHU Jingyang and Ms. TAO Sha as non-executive directors; and (iii) Ms. Christine Shaohua LU-WONG, Dr. ZHOU Demin and Mr. LI Bo as independent non-executive directors.