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## **GenFleet Therapeutics (Shanghai) Inc.**

**劲方医药科技(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**

## **GFH375 Granted with First Breakthrough Therapy Designation in China for a KRAS G12D Inhibitor Treating Non-small Cell Lung Cancer**

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 oral KRAS G12D (ON/OFF) inhibitor GFH375 has been granted with the Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of the National Medical Products Administration, for treatment of KRAS G12D-mutant non-small cell lung cancer (NSCLC) patients who have received at least one prior systemic therapy.

This designation is supported by the phase I/II data from the GFH375X1101 study, demonstrating GFH375’s best-in-class monotherapy efficacy and manageable safety/tolerability for NSCLC treatment in the global KRAS G12D inhibitor landscape. The preliminary data from GFH375 monotherapy treating KRAS G12D-mutant patients with solid tumors and NSCLC were featured in late-breaking abstract (LBA) and oral presentation at the 2025 American Society of Clinical Oncology Annual Meeting and the 2025 World Conference on Lung Cancer. More updated study data are expected to be published at global academic events later this year.

“GenFleet has established its integrated R&D capabilities in the program of fulzerasib, a marketed KRAS G12C inhibitor. Globally, no targeted therapies for KRAS G12D mutation have yet been approved, representing a significant unmet medical need across major tumor types carrying the G12D mutation. Within the global landscape of KRAS G12D inhibitor clinical development, GFH375 is progressing at the fastest pace for NSCLC treatment, showing encouraging efficacy and a manageable safety profile. Given its favorable monotherapy druggability and efficacy, GFH375 holds promising clinical potential as a single agent and in combination regimens.” stated Prof. Shun Lu of Shanghai Chest Hospital.

“We are deeply impressed by the urgent need for targeted therapies among patients harboring KRAS G12D mutation. We are encouraged by GFH375’s robust efficacy in the study and hope the BTD granted by CDE helps to accelerate the development and the ultimate launch of GFH375 to benefit patients. Meanwhile, the extensive clinical program of GFH375/VS-7375 in China led by GenFleet and outside of China by our partner Verastem Oncology, underscores its broad therapeutic potential across multiple major tumor types. We look forward to presenting updated data for GFH375 in various indications at global academic events later this year.” stated Yu Wang, M.D., Ph.D., Chief Medical Officer of GenFleet.

GFH375 obtained clinical trial approval for a phase I/II study in China in June 2024. Currently, GFH375 monotherapy for metastatic pancreatic cancer has advanced into the world’s first phase III trial of an oral KRAS G12D inhibitor; besides, GFH375/VS-7375 has been granted with the U.S. FDA’s Fast Track Designation for the treatment of metastatic KRAS G12D-mutated pancreatic ductal adenocarcinoma (PDAC) across all lines of therapy. Multiple monotherapy and combination trials of GFH375/VS-7375 for different tumor types are advancing smoothly in China and overseas, including the GenFleet-initiated trial of GFH375 combined with chemotherapy (AG) as first-line treatment for PDAC.

### **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”, “forecast”, “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.

## GLOSSARY OF TECHNICAL TERMS

“AG”	albumin-bound paclitaxel and gemcitabine
“BTD”	Breakthrough Therapy Designation
“CDE”	Center for Drug Evaluation of the National Medical Products Administration
“FDA”	U.S. Food and Drug Administration
“KRAS”	Kirsten RAS, a member of the RAS family of 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
“NSCLC”	non-small-cell lung carcinoma, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
“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 cancers
“RAS”	ras sarcoma, a family of proteins that are critical regulators of cellular signaling pathways; it primarily includes HRAS, KRAS, and NRAS

**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, February 27, 2026

*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.*