GFH375

1 GFH375

2 GFH375

3

4

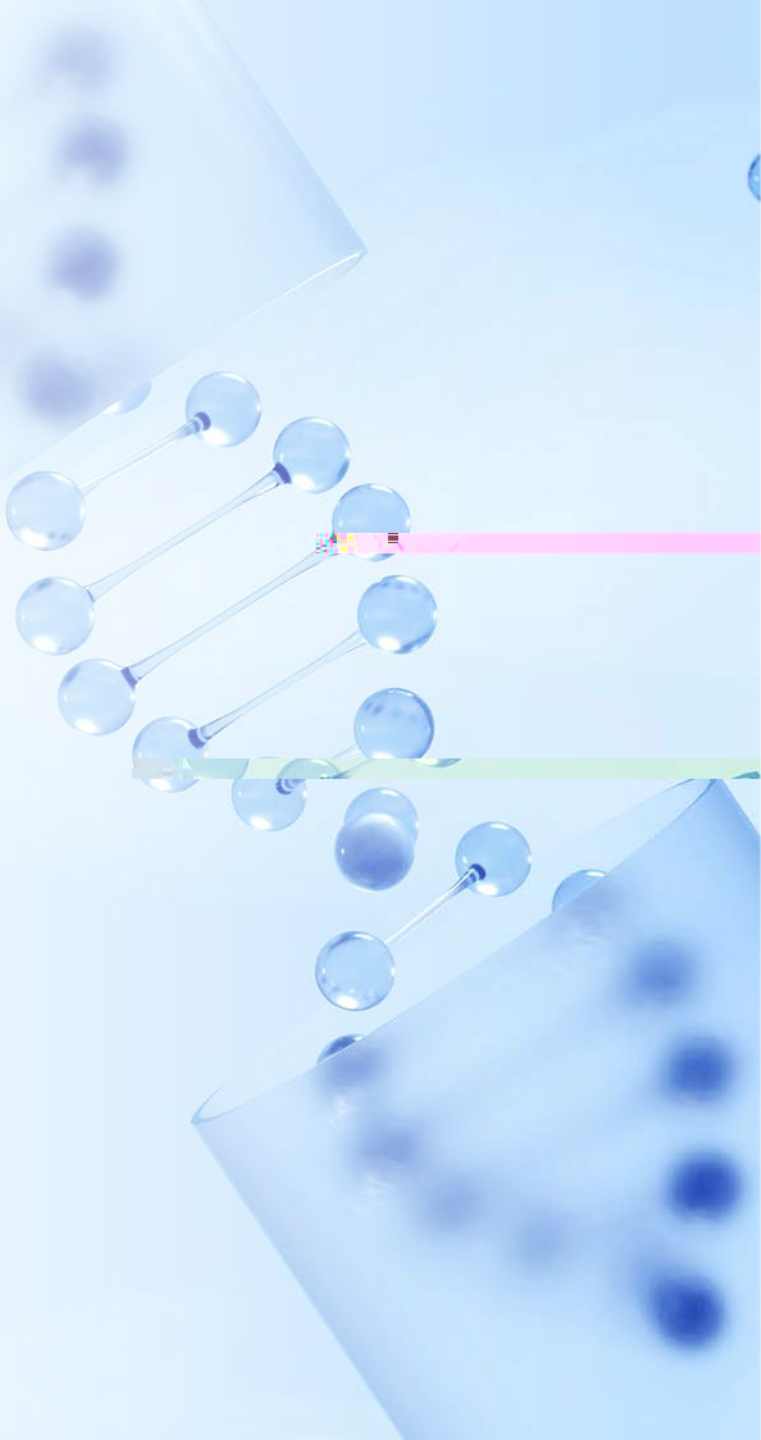
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PART 01

GFH375治疗各瘤种研究背景



GFH375 KRAS G12D

劲方医药 GENFLEET

[redacted]

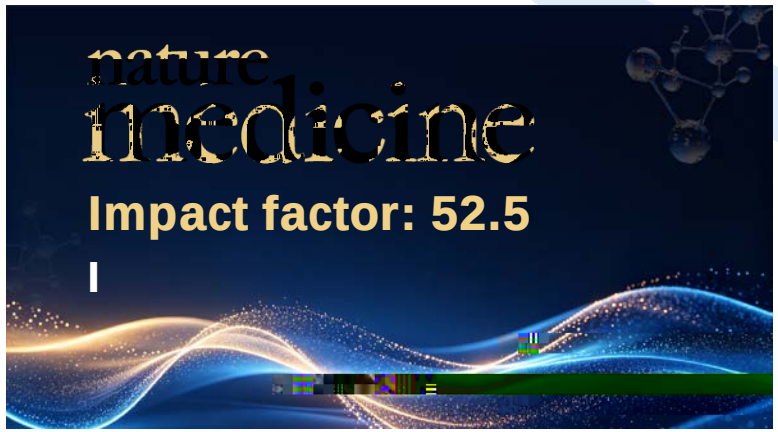
2024

2024.7 FPI

I

Start Point of
Clinical Development

D+11Months



2025

2025.6 ASCO Oral

66

2025.9 WCLC Oral

142

2025.10 ESMO Oral & combo

II PDAC LBA

2025.11 PDAC III

KRAS G12Di III

D+16M

2026

2026.2 NSCLC BTD

KRAS G12Di BTD

2026.4 PDAC BTD

KRAS G12D PDAC

2026.6 ASCO Oral

RAS

2026.7 NSCLC III

GFH375 III

D+24M

2026.8 1L combo

1L NSCLC RAS RAS+

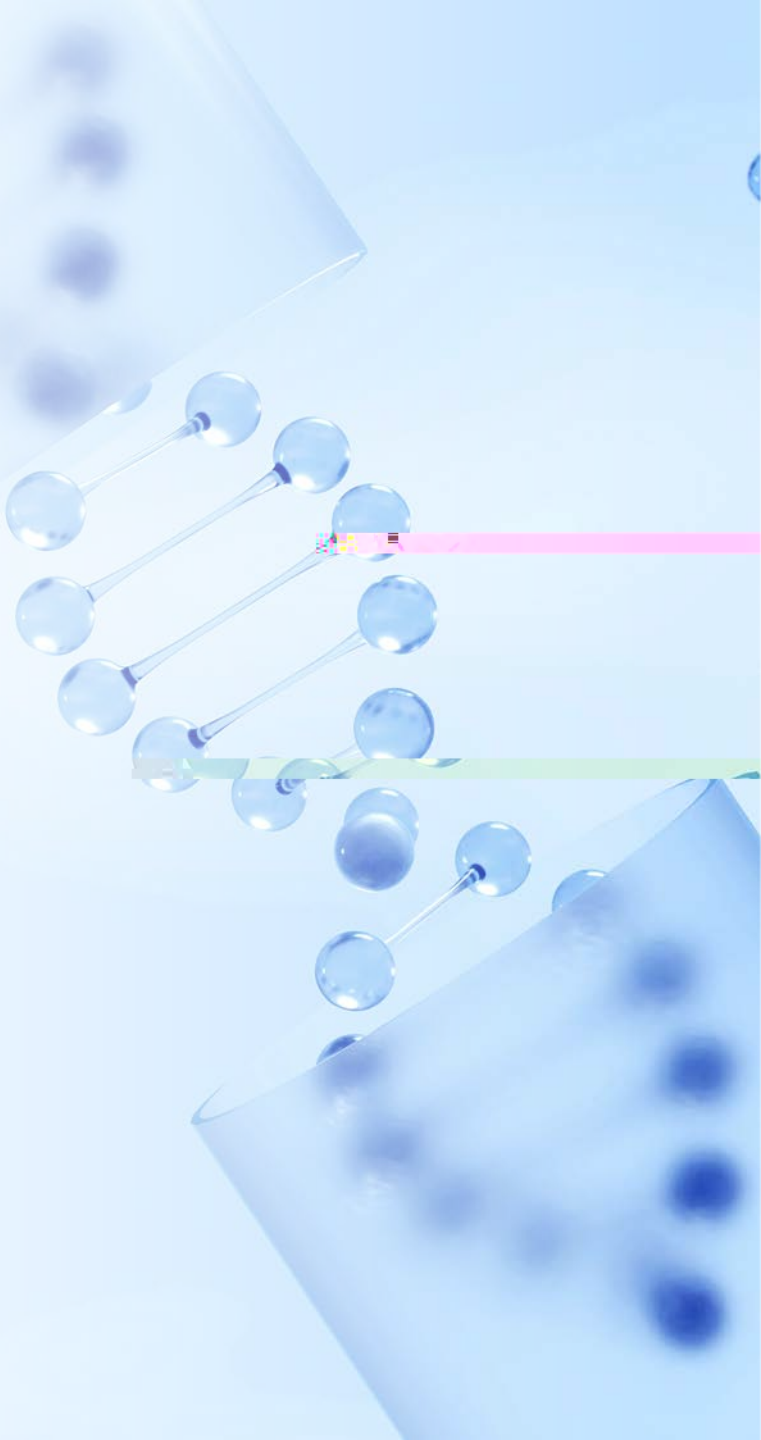
2026.9 WCLC Oral & BTD

II NSCLC WCLC

cetux KRAS G12D CRC BTD

PART 02

GFH375联合西妥昔单抗



GFH375 in combination with Cetuximab Demographics and Baseline Characteristics

CRC

- All patients had metastatic disease at baseline.
- 94% (51/54) of patients were treated in 3L+ setting; 50% (27/54) previously received 3 or more lines of anti-cancer therapy.

PDAC

- 96% (23/24) of patients had metastatic disease at baseline.
- All patients were treatment-naïve.

	CRC (N=54)	PDAC (N=24)
Median age, years (range)	**58 (33, 82)**	**68 (47, 78)**
Male, n(%)	**25 (46)**	**14 (58)**
ECOG PS, n(%)		
0	11 (20)	3 (12)
1	43 (80)	21 (88)
Metastasis at baseline, n(%)	**54 (100)**	**23 (96)**
Lung	31 (57)	3 (14)
Liver	27 (50)	14 (58)
Peritoneum	25 (46)	7 (29)
Bone	5 (9)	2 (8)
Number of prior anti-cancer therapies in metastatic setting, n(%)		
Median (range)	**2.5 (1, 6+)**	**0**
0	0	24 (100)
1	3 (6)	0
2	24 (44)	0
≥ 3	27 (50)	0

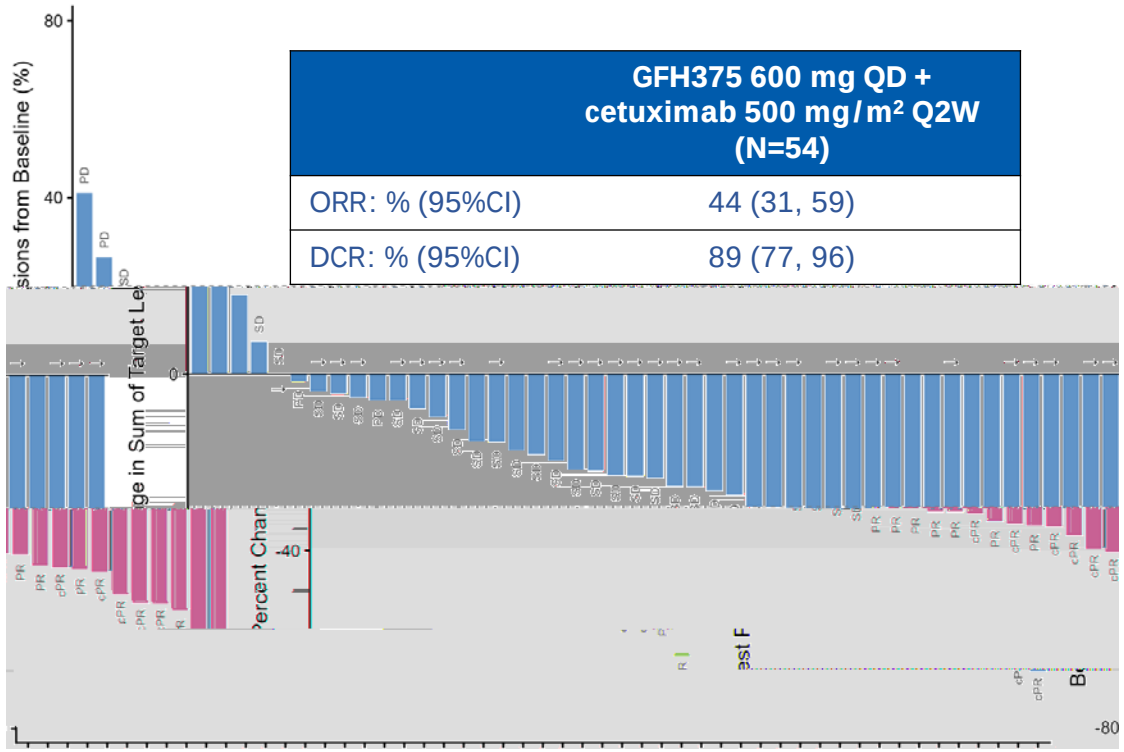
Enrollment cut-off date: 24-Jun-2026.

CRC, colorectal cancer; PDAC, pancreatic ductal adenocarcinoma; ECOG PS, Eastern Cooperative Oncology Group Performance Status.

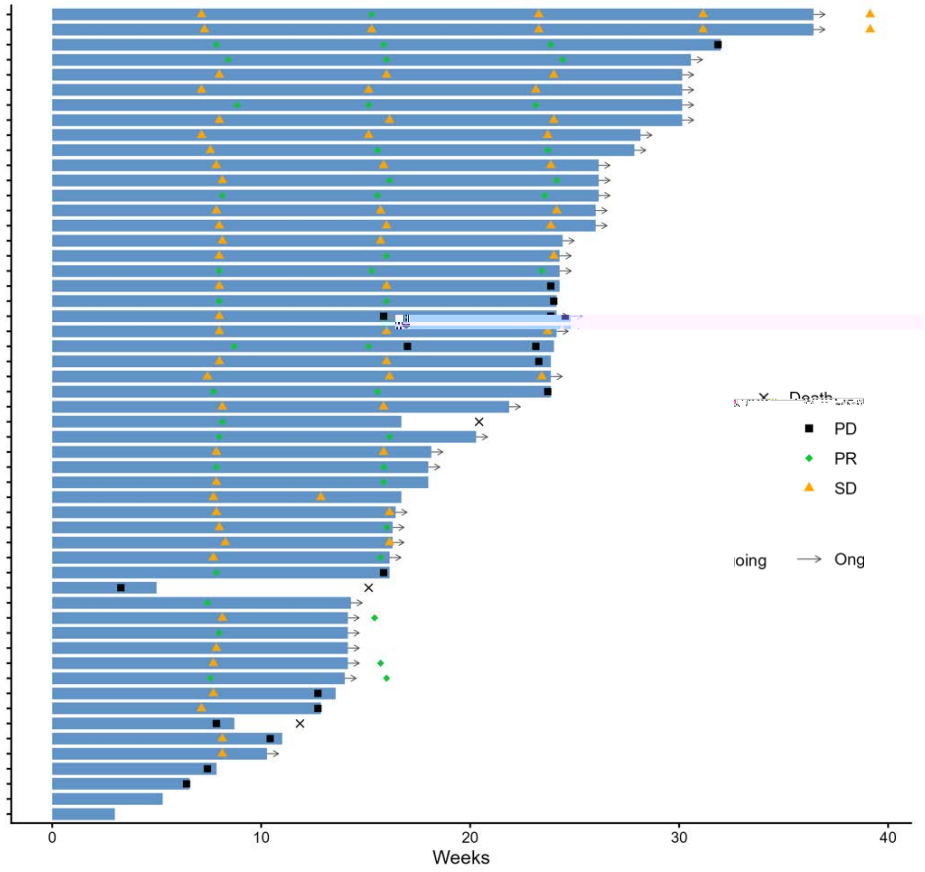
Efficacy in Pretreated KRAS G12D-mutant mCRC

- Median follow-up: 5.7 months (range: 2.8, 9.2).
- ORR: 44% (24/54), 11 uPR (8 patients remaining on treatment, 3 EOT).

	GFH375 600 mg QD + cetuximab 500 mg/m² Q2W (N=54)
ORR: % (95%CI)	44 (31, 59)
DCR: % (95%CI)	89 (77, 96)



- 65% (35/54) of patients remain on treatment.

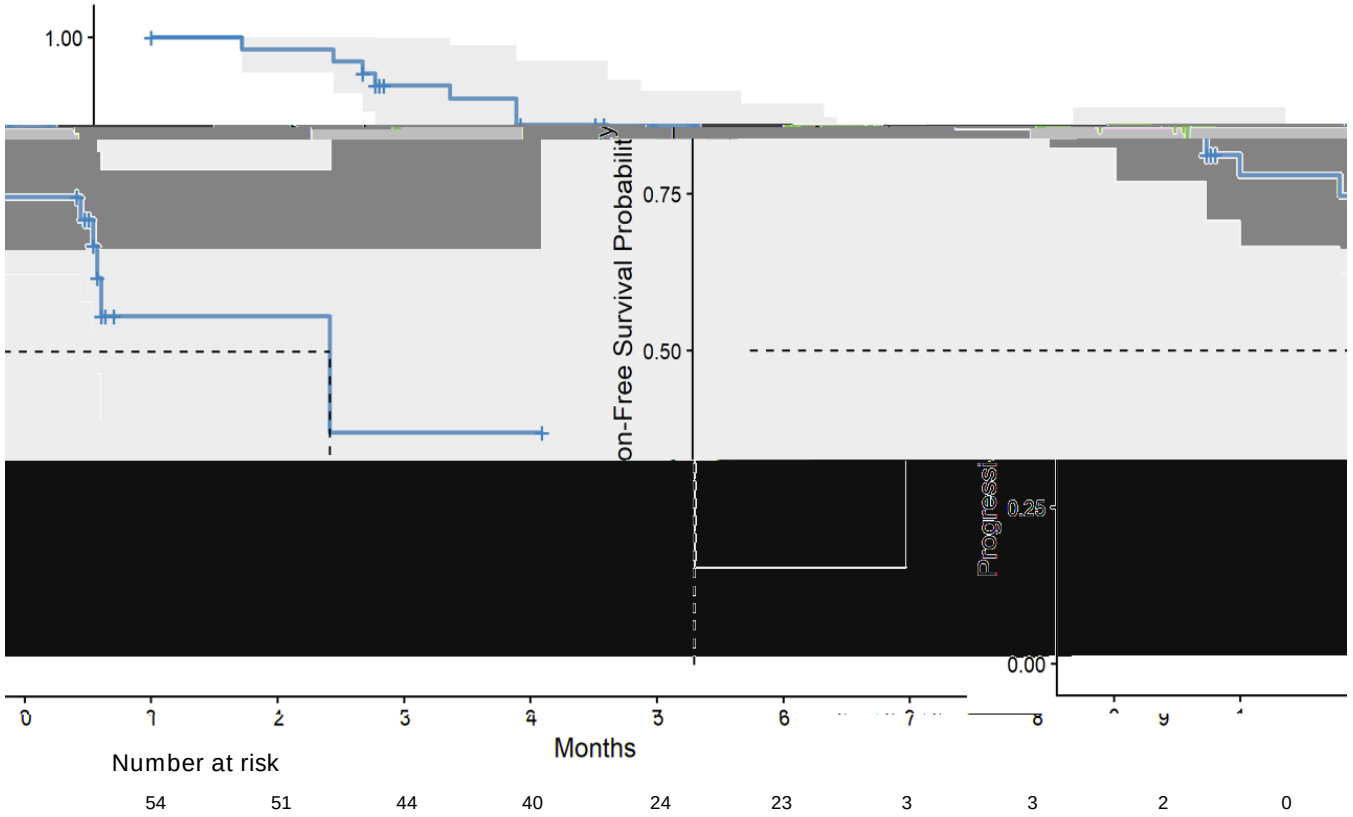


Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Two patients with CRC who lack post-baseline tumor assessments are not displayed in the waterfall but included in the denominator for ORR. Three patients with uPR discontinued treatment: 1 due to PD, 1 per patient decision, and 1 to initiate a new anticancer therapy.

CI, confidence interval; cPR, confirmed partial response; CRC, colorectal cancer; DCR, disease control rate; ORR, overall response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; QD, once daily; Q2W, Quaque 2 weeks; SD, stable disease; uPR, unconfirmed partial response.

PFS in Pretreated KRAS G12D-mutant CRC

- PFS events: n=16, 35 remain on treatment.
- Median PFS was 7.3 months with median follow-up time of 5.4 months.
- 4-months PFS rate, % (95%CI): 78 (62 88).

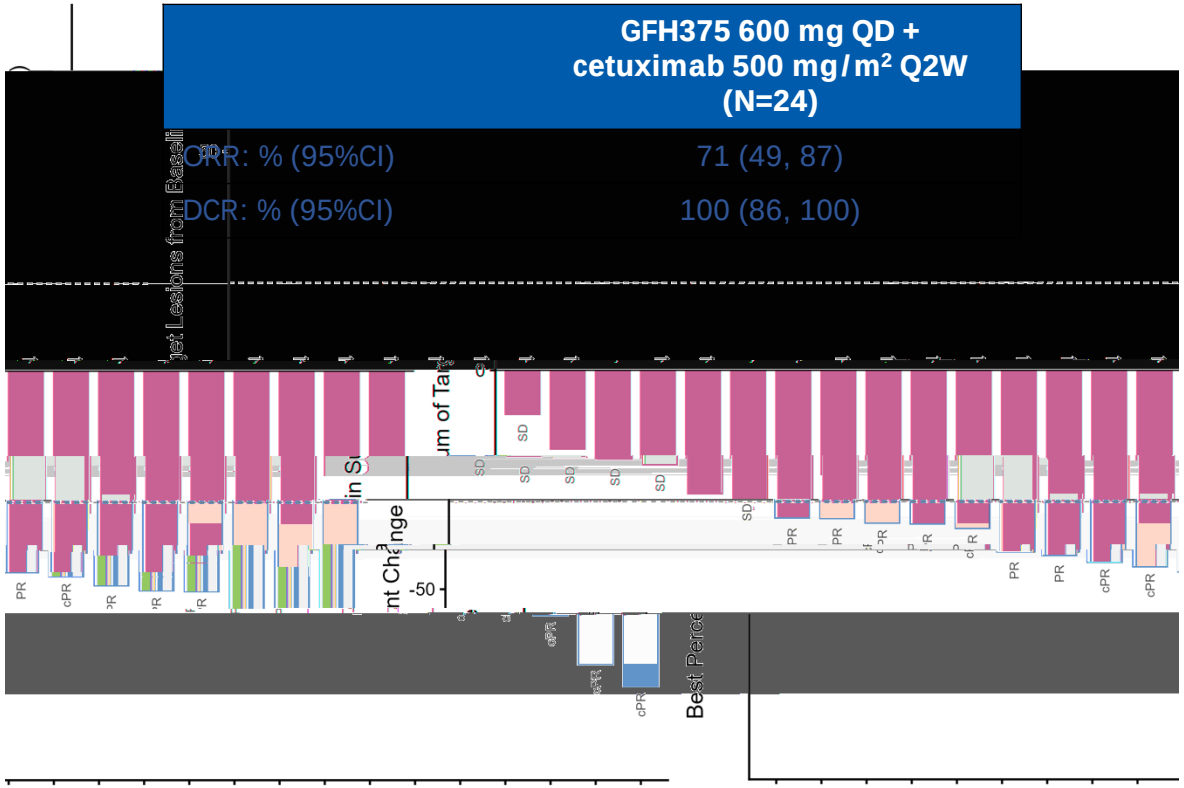


Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Four patients dropped out early, including 3 per patient decision and 1 per investigator decision.

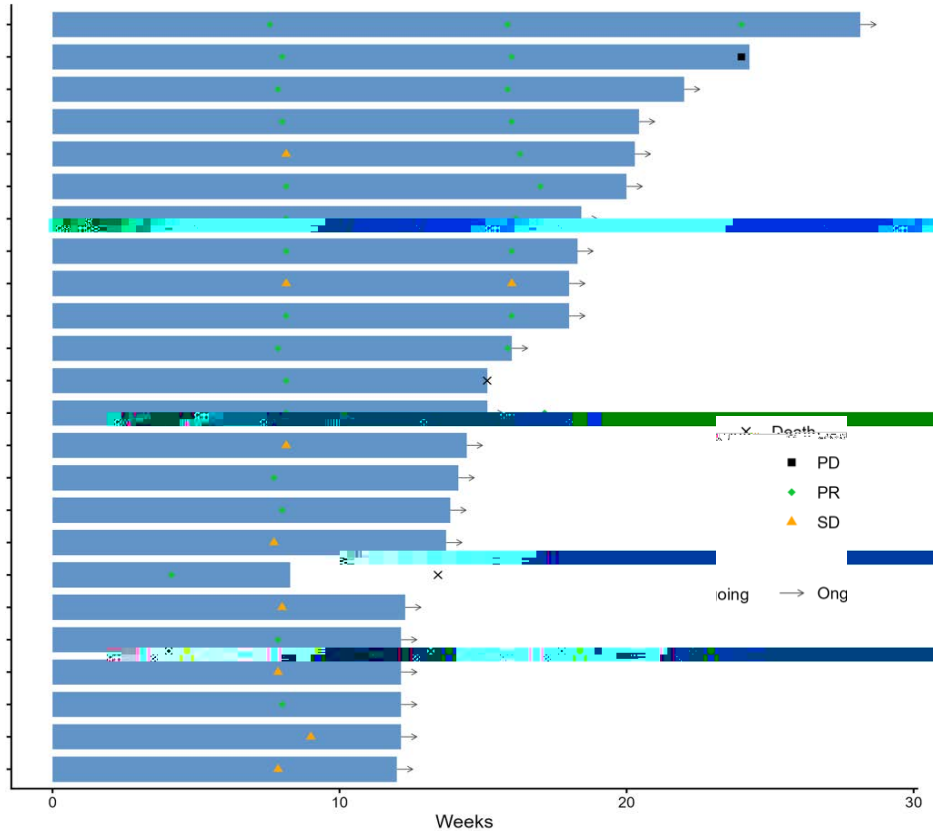
CI, confidence interval; CRC, colorectal cancer; PD, progressive disease; PFS, progression-free survival.

Preliminary Efficacy in 1L KRAS G12D-mutant mPDAC

- Median follow-up: 3.8 months (range: 2.9, 6.5).
- ORR: 71% (17/24), 7 uPRs (5 patients remaining on treatment, 2 EOT).



- 88% (21/24) of patients remain on treatment.
- PFS events: n=3.



Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Two patients with uPR discontinued treatment: 1 per investigator decision and 1 death due to disease progression.

1L, first line; CI, confidence interval; cPR, confirmed partial response; DCR, disease control rate; ORR, overall response rate; PDAC, pancreatic ductal adenocarcinoma; PFS, progression-free survival; PR, partial response; QD, once daily; Q2W, Quaque 2 weeks; SD, stable disease; uPR, unconfirmed partial response.

	2L+ CRC (N = 54)		1L PDAC (N = 24)		Total (N = 78)	
	Any Grade	Grade 3	Any Grade	Grade 3	Any Grade	Grade 3
Any study drug-related AE, n (%)	**54 (100)**	**14 (26)**	**24 (100)**	**5 (21)**	**78 (100)**	**19 (24)**
TRAEs in ≥20% of all patients, n (%)						
Diarrhea	46 (85)	4 (7)	14 (58)	0	60 (77)	4 (5)

PART

03



04

KRAS G12D RAS BTD

突破性治疗申请公示详细信息

受理号	CXHL2400328	药品名称	GFH375片
药品类型	化药	注册分类	1
申请日期	2026-01-30	承办日期	2024-04-03
公示日期	2026-02-13	公示截止日期	2026-02-27
是否为罕见病药物	否		
拟定适应症（或功能主治）	至少接受过一种系统性治疗并具有KRAS G12D突变的非小细胞肺癌（NSCLC）		

	GFH375片
	1
	2024-04-03
	2026-04-08
拟定适应症（或功能主治）	至少接受过一种系统性治疗并具有KRAS G12D突变的转移性胰腺癌

	GFH375片
	1
	2025-07-11
	2026-09-24
拟定适应症（或功能主治）	

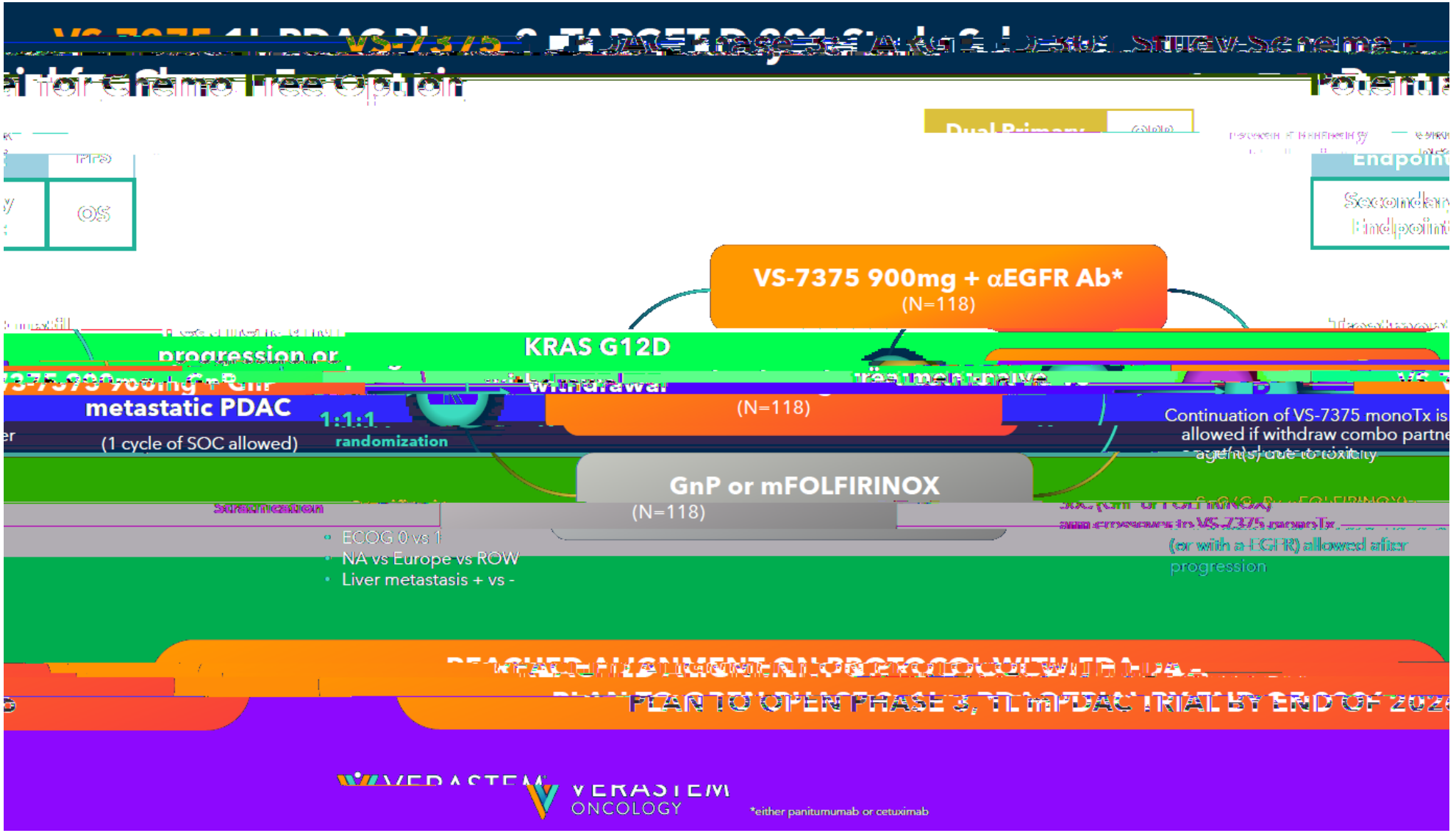
GFH276

ESMO LBA





GFH375/VS-7375 PDAC III




風飛波動・招募願方