



GFH375联合西妥昔单抗 治疗实体瘤研究初步数据

2026年10月

会议议程

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-- 吕强博士，劲方医药董事长

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-- 汪裕博士，劲方医药首席医学官

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-- 吕强博士，劲方医药董事长

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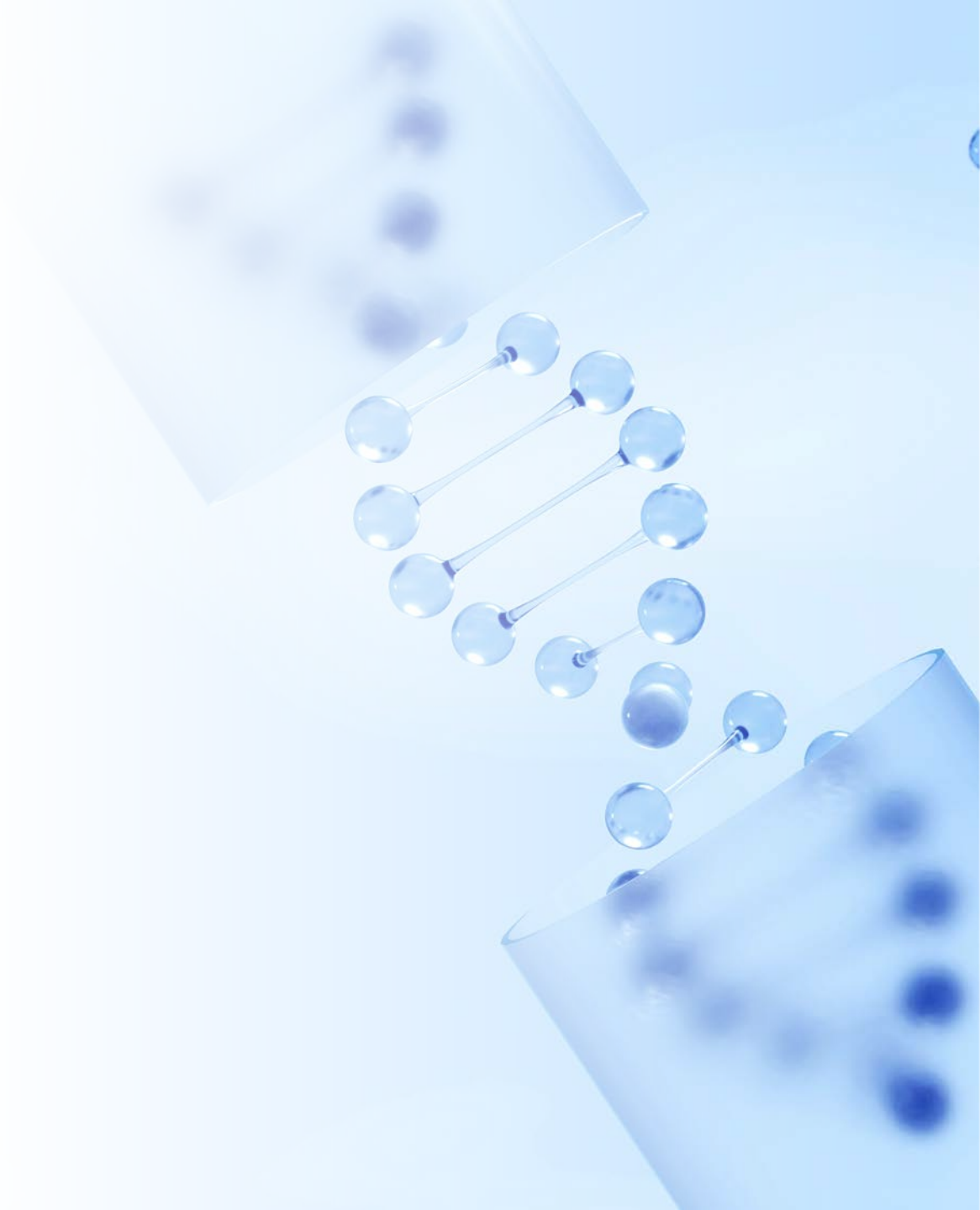
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PART **01**

GFH375治疗各瘤种 研究背景



GFH375拥有全球KRAS G12D抑制剂中最为完善的单药、联合疗法数据



劲方主导的中国临床开发进度：展现优秀成药性及高效执行力

2024

2024.7 FPI

国内I期试验首例患者入组

Start Point of
Clinical Development

D+11Months

2025

2025.6 ASCO Oral

实体瘤研究纳入**66名**患者数据

2025.9 WCLC Oral

实体瘤研究纳入**142名**患者数据

2025.10 ESMO Oral & combo启动

II期PDAC数据入选LBA和口头报告

联合化疗或西妥昔单抗临床研究启动

2025.11 PDAC III期启动

全球**首个**口服KRAS G12Di **III期**研究
D+16M

2026

2026.2 NSCLC BTD

国内率先获得**口服KRAS G12Di BTD**

2026.4 PDAC BTD

单药治疗, KRAS G12D突变型PDAC

2026.6 ASCO Oral

全球首个RAS抑制剂治疗胆管癌专项数据

2026.7 NSCLC III期启动

GFH375**第二项注册性III期**试验
D+24M

2026.8 多项1L或创新combo启动

1L NSCLC、RAS双联、RAS+恶病质双靶向

2026.9 WCLC Oral & BTD

II期NSCLC数据入选WCLC口头报告

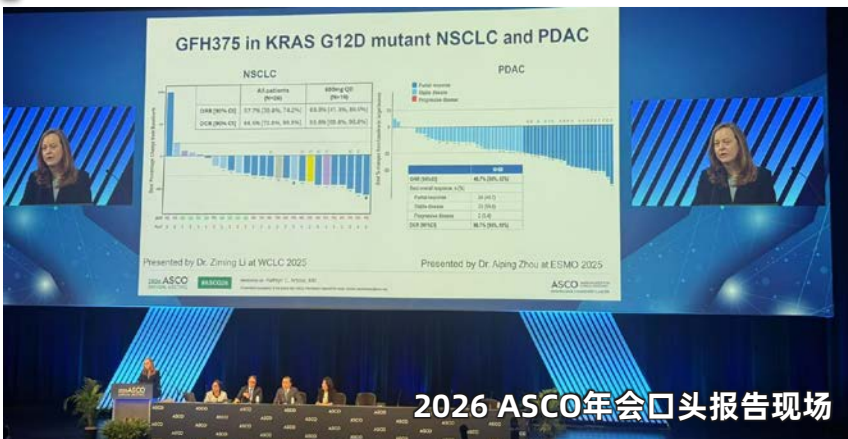
联合cetux, KRAS G12D突变型CRC BTD

nature
medicine

Impact factor: 52.5

I期实体瘤研究数据已发表

GFH375在多个瘤种试验中展现稳定的疗效及安全性



2026 ASCO年会口头报告现场

评论员对GFH375治疗多个瘤种疗效给予高度认可

We see a truly impressive response rate in CCA, a refractory disease. And I will mention that we saw data earlier for this agent in NSCLC and pancreatic cancer, with response rates presented at the same dose 600 mg QD as clearly an active agent.

It is not surprising the response rate is lower in CRC. I really credit the authors for even presenting the data here. We have to understand what the baseline is and to know how much benefit we're really adding to these combos, which will likely be required.

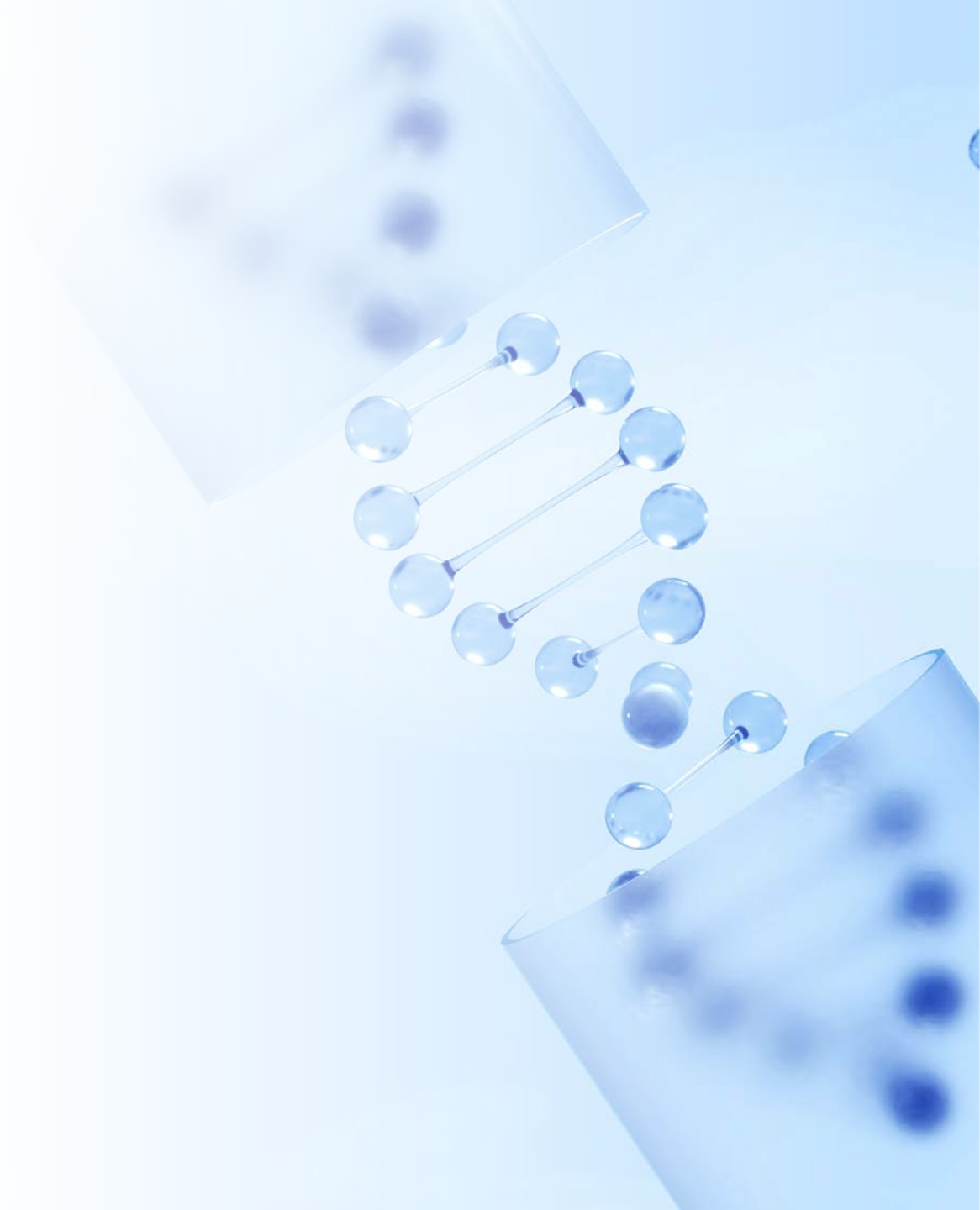
By commentator Kathryn Arbor, M.D., Memorial Sloan Kettering Cancer Center

		NSCLC	CRC			PDAC		Other tumor type
		mono (pretreated pts)	mono (pretreated pts)	combo with cetux (pretreated pts)		mono (pretreated pts)	combo with cetux (1L setting)	CCA mono (pretreated pts)
疗效	600 mg QD	N=71	N=28	N=54		N=59	N=24	N=18
	ORR	59.2% (cORR 52.1%)	11%	44%		40.7%	71%	44.4%
	DCR	93.0%	71%	89%		96.7%	100%	94.4%
	数据截止日	Sept. 4, 2026	Apr, 20, 2026	Sept. 16, 2026		Sept. 27, 2025	Sept. 16, 2026	Apr, 20, 2026
安全性		600 mg QD(N=75)	400-750 mg QD(N=41)	600 mg QD(N=54)		600mg QD(N=66)	600 mg QD(N=24)	400-600 mg QD(N=20)
	TRAEs ≥G3	41.3%	26.8%	26%		31.8%	21%	40%
	Discontinuation	4%	4.9%	0		3%	0	0
	Interruption	37.3%	24.4%	22%		27.3%	17%	40%
	SAEs	21.3%	9.8%	7%		13.6%	8%	5%
	数据截止日	Jun. 17, 2026	Dec. 12, 2025	Jul.22, 2026		Aug. 27, 2025	Jul.22, 2026	Dec. 12, 2025

02

PART

GFH375联合西妥昔单抗 研究初步数据



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

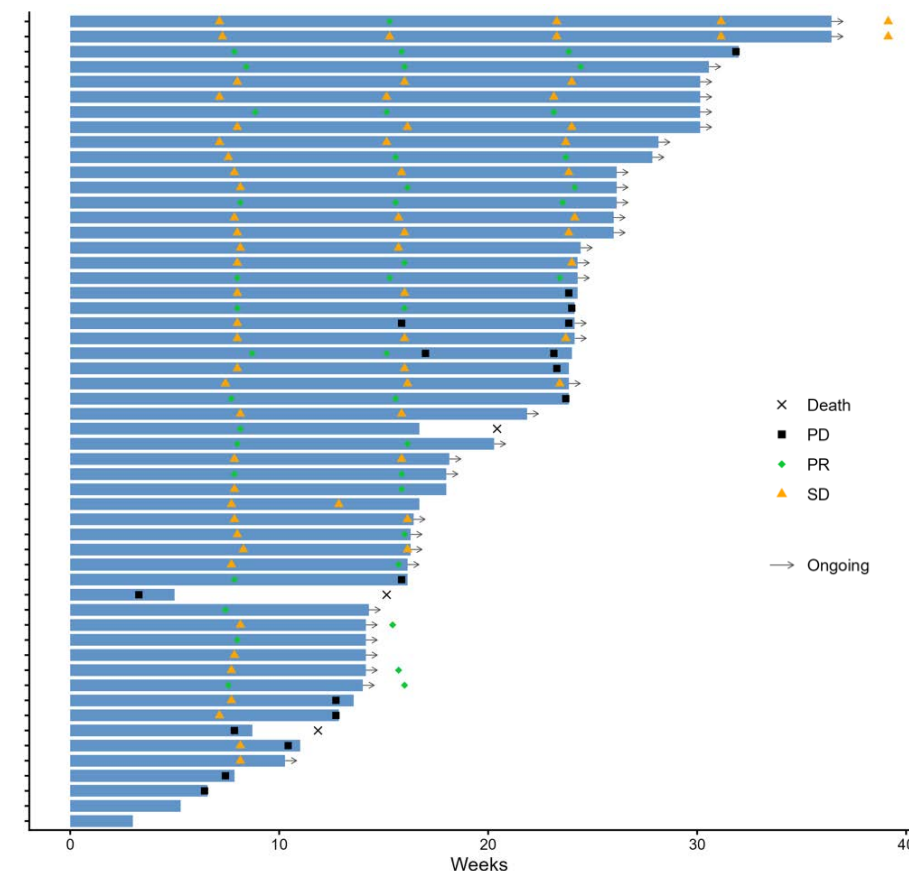
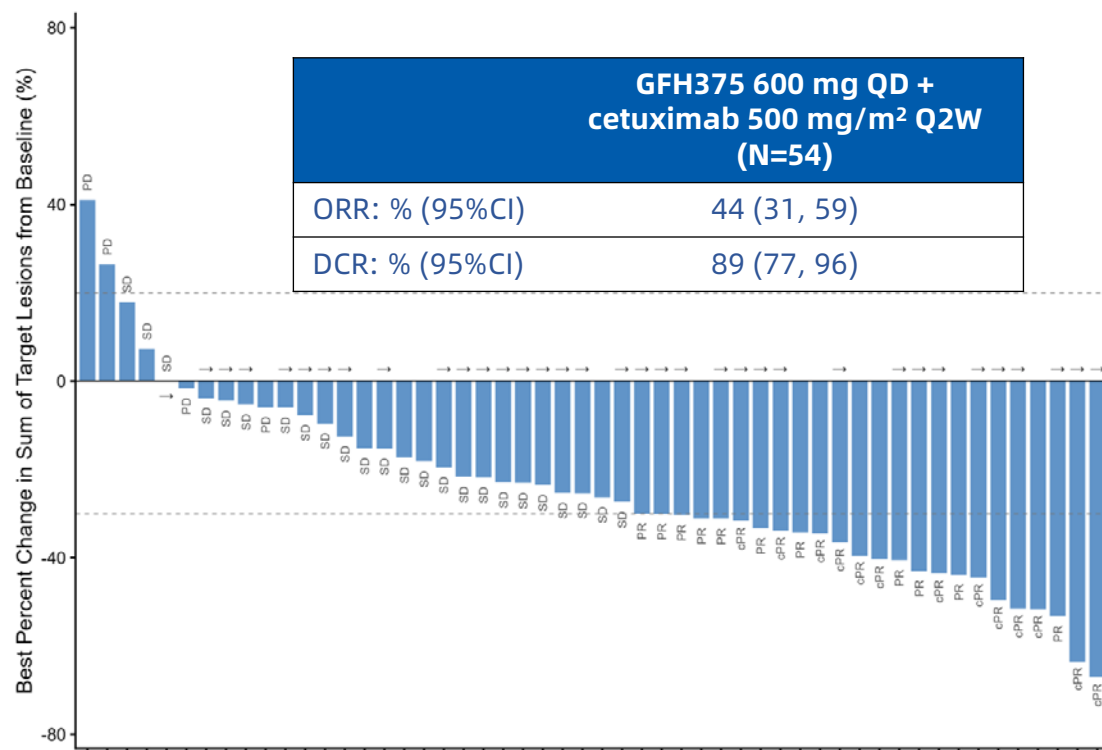
Enrollment cut-off date: 24-Jun-2026.

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).

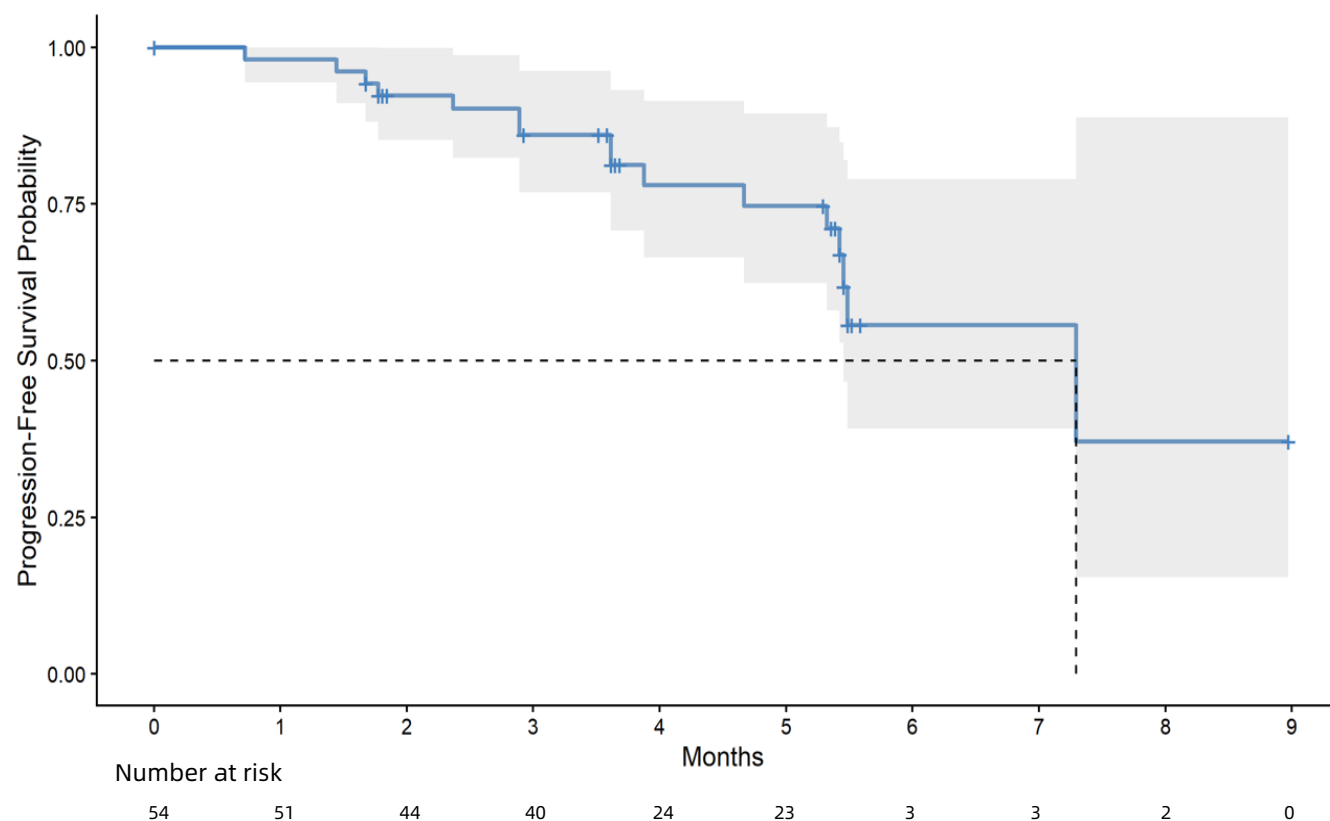
- 65% (35/54) of patients remain on treatment.



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).

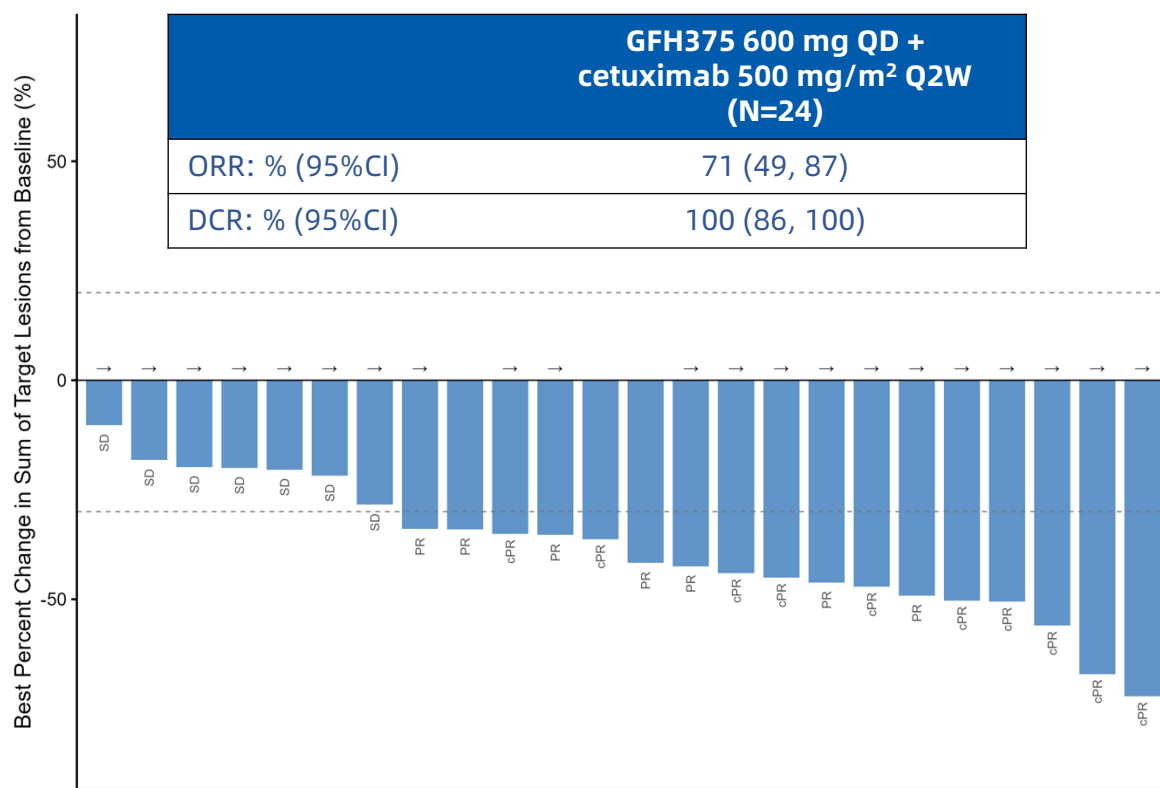


Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Four patients dropped out early, including 3 per patient decision and 1 per investigator decision.

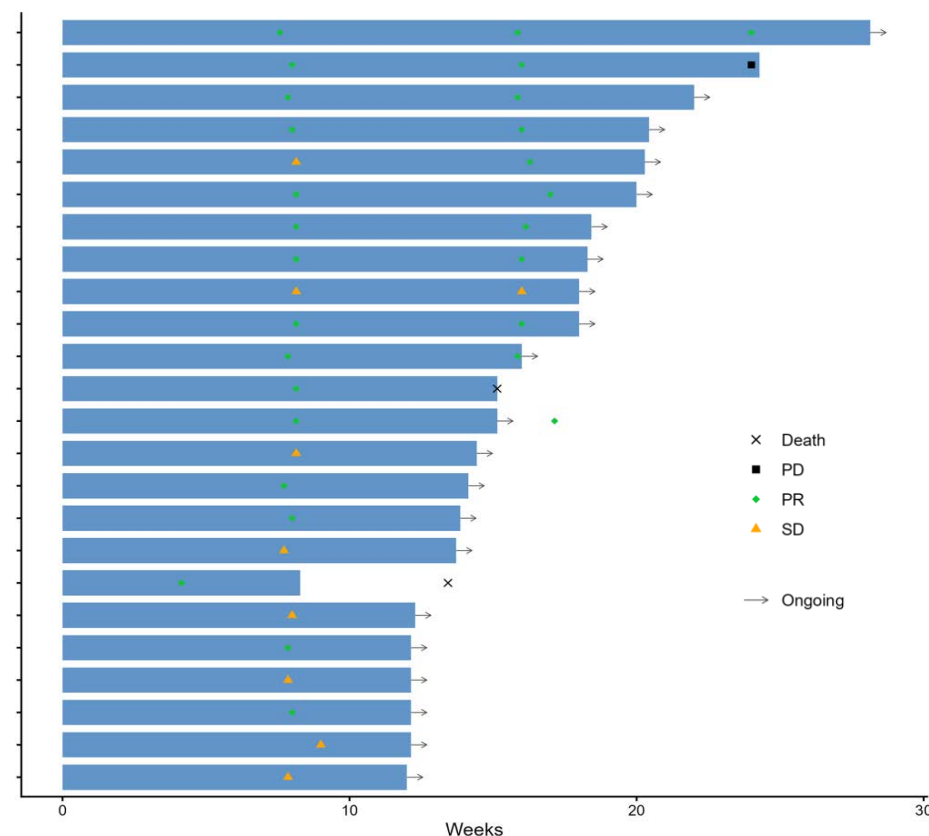
CI, confidence interval; CRC, colorectal cancer; PD, progressive disease; PFS, progression-free survival.

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.

GFH375 + Cetuximab: Design of GFH375X1202

	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)
Nausea	34 (63)	0	10 (42)	0	44 (56)	0
Rash	24 (44)	1 (2)	15 (63)	0	39 (50)	1 (1)
Vomiting	30 (56)	0	7 (29)	0	37 (47)	0
Decreased appetite	22 (41)	1 (2)	9 (38)	1 (4)	31 (40)	2 (3)
Weight decreased	18 (33)	0	9 (38)	0	27 (35)	0
Asthenia	15 (28)	0	9 (38)	0	24 (31)	0
Anaemia	15 (28)	0	8 (33)	1 (4)	23 (30)	1 (1)
Dermatitis acneiform	20 (37)	1 (2)	1 (4)	0	21 (27)	1 (1)
Alanine aminotransferase increased	13 (24)	0	7 (29)	0	20 (26)	0
Lipase increased	17 (32)	1 (2)	2 (8)	1 (4)	19 (24)	2 (3)
Amylase increased	14 (26)	1 (2)	3 (13)	0	17 (22)	1 (1)
Hypoalbuminaemia	9 (17)	0	8 (33)	0	17 (22)	0
Treatment related SAEs, n (%)	4 (7)		2 (8)		6 (8)	
Dose modification of any study drug due to TRAEs, n (%)						
Dose interruption	12 (22)		4 (17)		16 (21)	
Dose reduction	3 (6)		1 (4)		4 (5)	
Dose discontinuation	0		0		0	

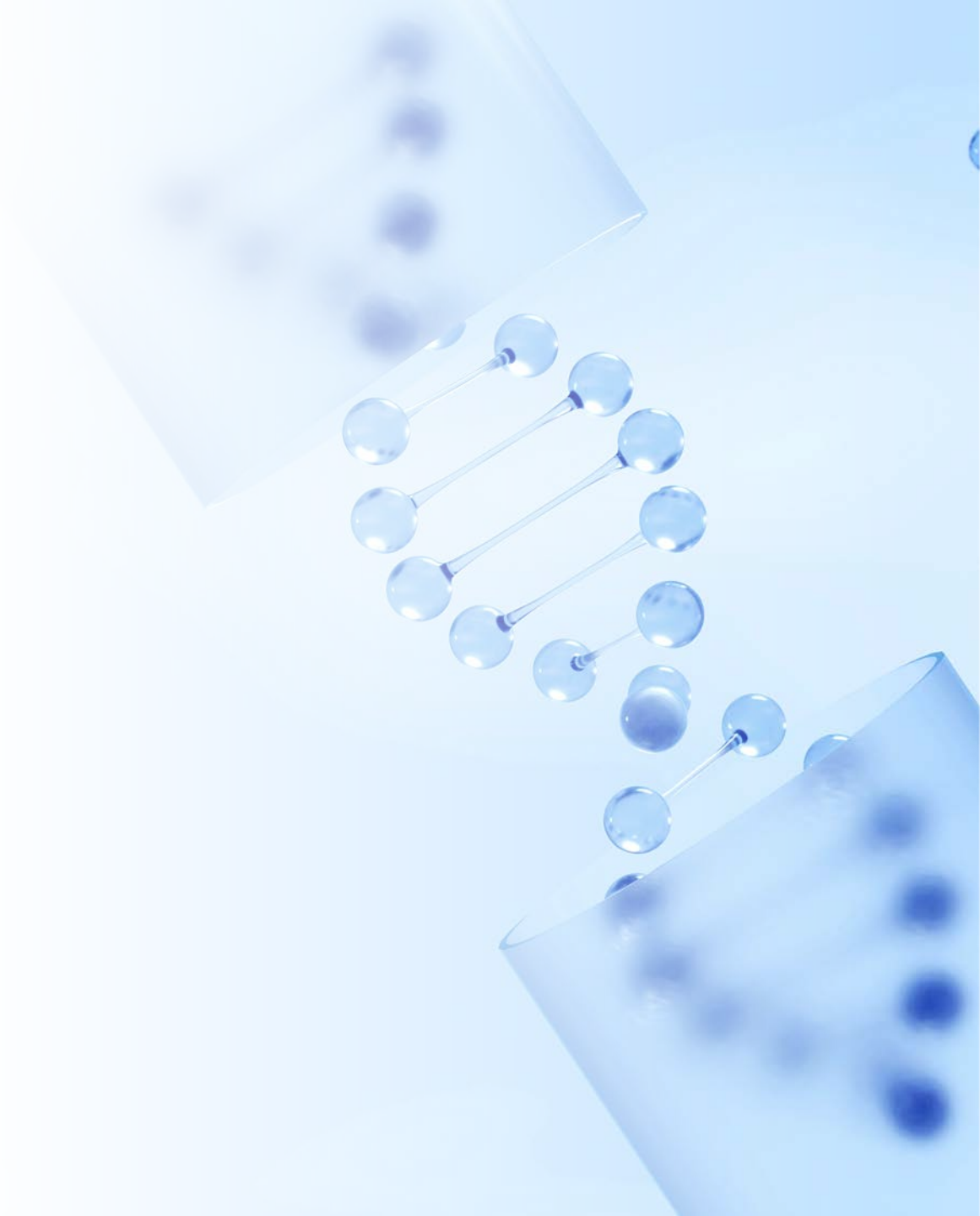
- No Grade 4/5 TRAEs.
- No dose discontinuation due to TRAEs.
- TRAEs were predominantly cutaneous and gastrointestinal toxicities, mostly Grade 1/2.
- Grade 3 TRAEs occurred in 24%; no individual Grade 3 TRAE exceeded 5% (most commonly diarrhea).
- Less frequency and severity of hepatic and hematologic TRAEs comparing to GFH375 monotherapy.

Data cutoff: 22-Jul-2026. All patients received a first dose of GFH375 600 mg QD in combination with cetuximab 500 mg/m² Q2W at least 4 weeks prior to data cutoff date.

CRC, colorectal cancer; PDAC, pancreatic ductal adenocarcinoma; QD, once daily; Q2W, Quaque 2 weeks; SAE, serious adverse event; TRAE, treatment related adverse event.

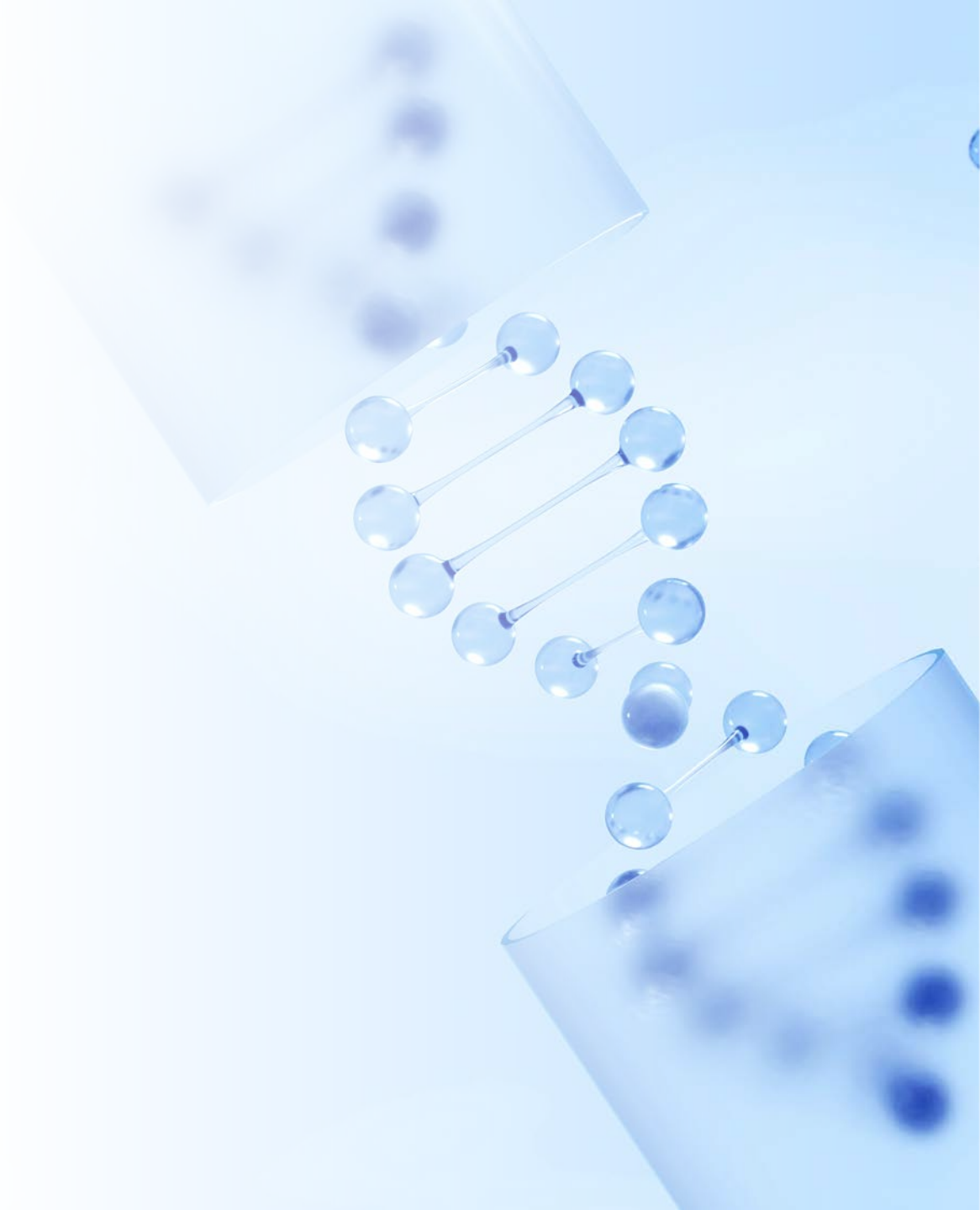
PART **03**

会前问题解答 及现场互动



04 PART

总结及展望



国内率先获得口服KRAS G12D抑制剂治疗三大RAS突变瘤种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	GFH375片
2024-04-03	1
2026-04-08	2025-07-11
	2026-09-24

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
拟定适应症（或功能主治）	联合西妥昔单抗用于携带KRAS G12D突变的既往奥沙利铂、氟尿嘧啶类和伊利替康为基础的化疗失败的转移性结直肠癌

2026/2027期间六项注册性临床试验规划

GFH375 (KRAS G12D抑制剂)

PDAC

后线/单药治疗

一线/联合化疗

NSCLC

后线/单药治疗

CRC

三线/联合西妥昔单抗

GFH276 (Pan RAS 抑制剂)

PDAC

后线/单药治疗

一线/联合化疗

GFH276治疗实体瘤初步数据将在ESMO LBA报告中发布

MADRID 2026 **ESMO** congress

MADRID SPAIN
23-27 OCTOBER 2026



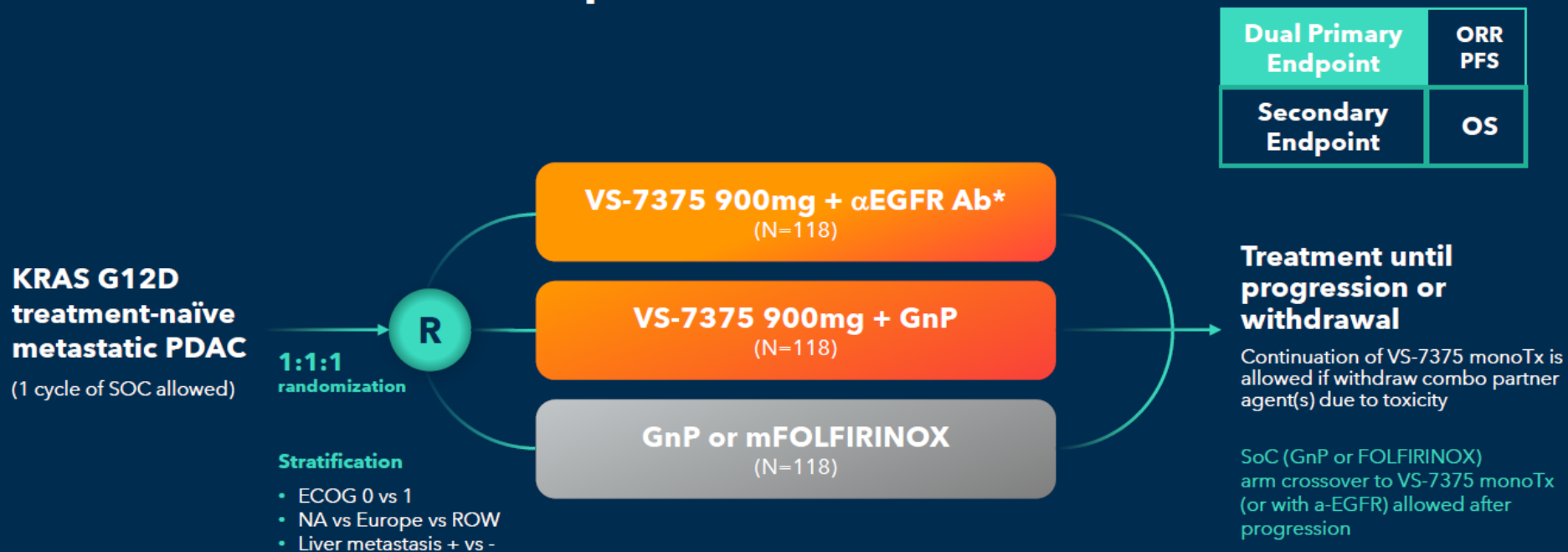
LBA 摘要标题: Safety and efficacy of GFH276 monotherapy in previously treated RAS-mutated advanced solid tumors

*场次: 当地时间2026年10月25日上午8:30-10:00
(Developmental Therapeutic专场)*



GFH375/VS-7375预计今年底进入一线联合疗法PDAC注册性III期研究

VS-7375 1L PDAC Phase 3: TARGET-D 301 Study Schema - Potential for Chemo Free Option



REACHED ALIGNMENT ON PROTOCOL WITH FDA -
PLAN TO OPEN PHASE 3, 1L mPDAC TRIAL BY END OF 2026



風飛浪勁·据義履方