



2026世界肺癌大会 GFH375口头报告数据解读会

2026年9月

会议议程

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-- 吕强博士，劲方医药董事长

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-- 李子明教授，上海市胸科医院

-- 汪裕博士，劲方医药首席医学官

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-- 劲方医药参会管理层

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-- 吕强博士，劲方医药董事长

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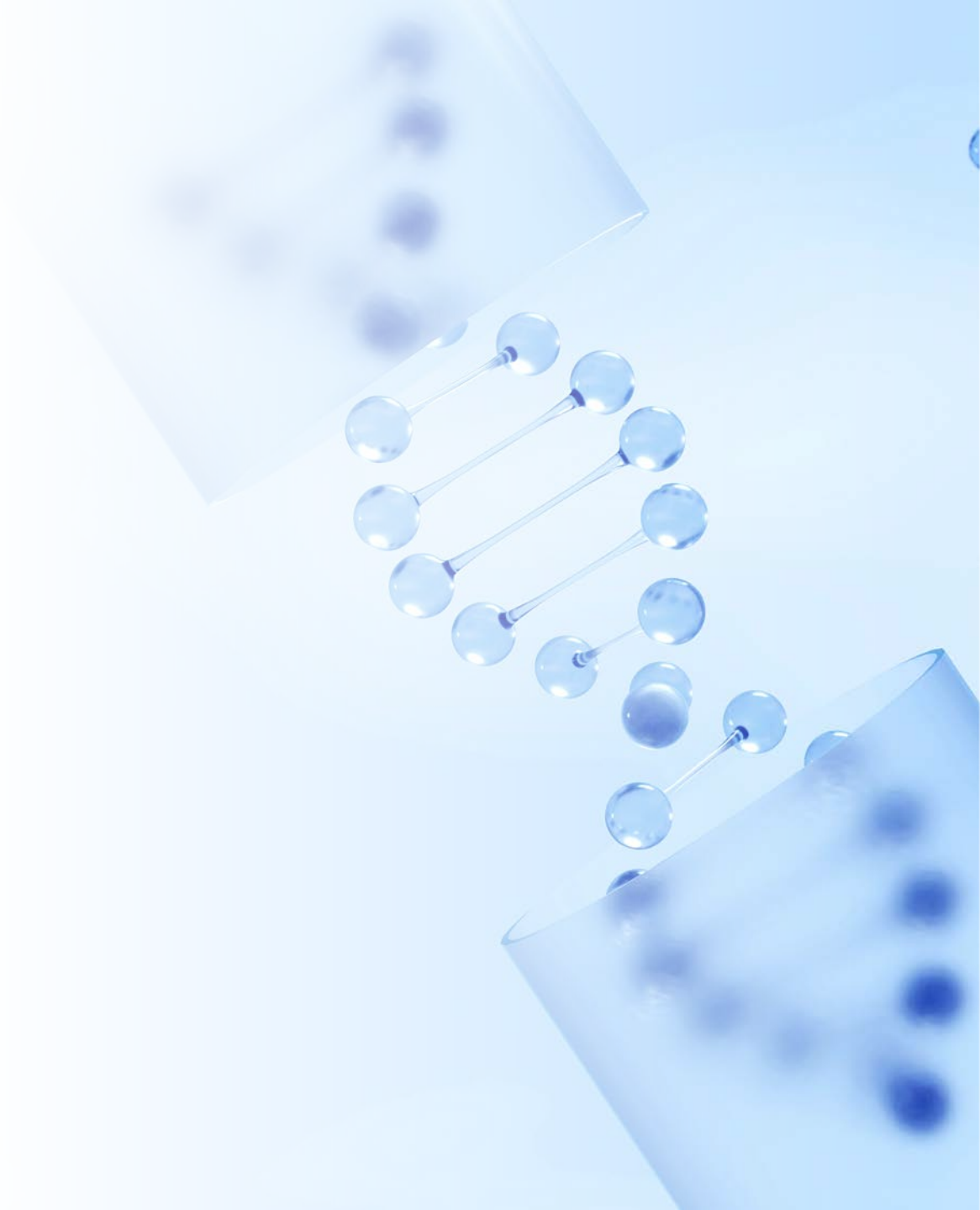
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01 *PART*

GFH375治疗各瘤种 研究背景



从FPI到国际会议口头报告：化合物成药性 + 执行力

2024

2024.7 FPI

国内I期试验首例患者入组

Start Point of
Clinical Development

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

II期PDAC数据入选LBA和口头报告

2025.11 PDAC III期启动

全球**首个**口服KRAS G12D抑制剂
III期研究

D+16M

2026

2026.2 NSCLC BTD

国内率先获得口服KRAS G12D抑制剂BTD

2026.4 PDAC BTD

口服KRAS G12D抑制剂治疗胰腺癌BTD

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

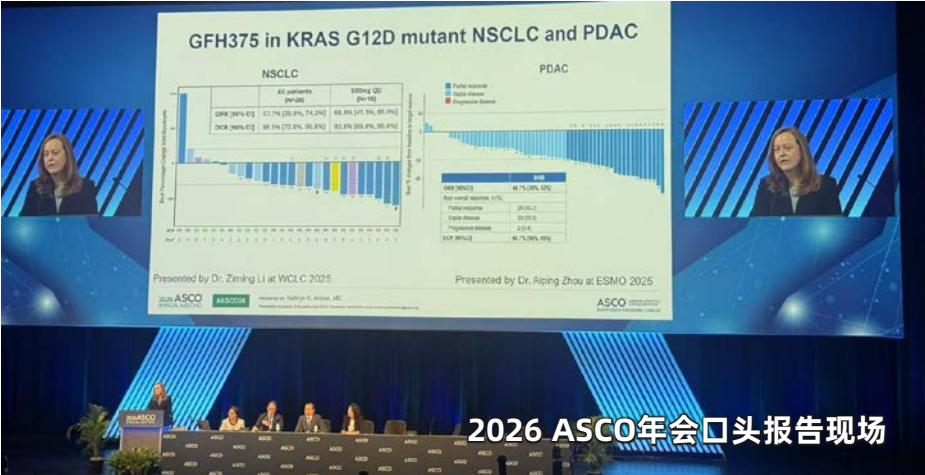
GFH375**第二项**注册性III期试验

D+24M

2026.9 WCLC Oral

II期NSCLC数据入选口头报告

GFH375在多个瘤种试验中展现稳定的疗效及安全性



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.

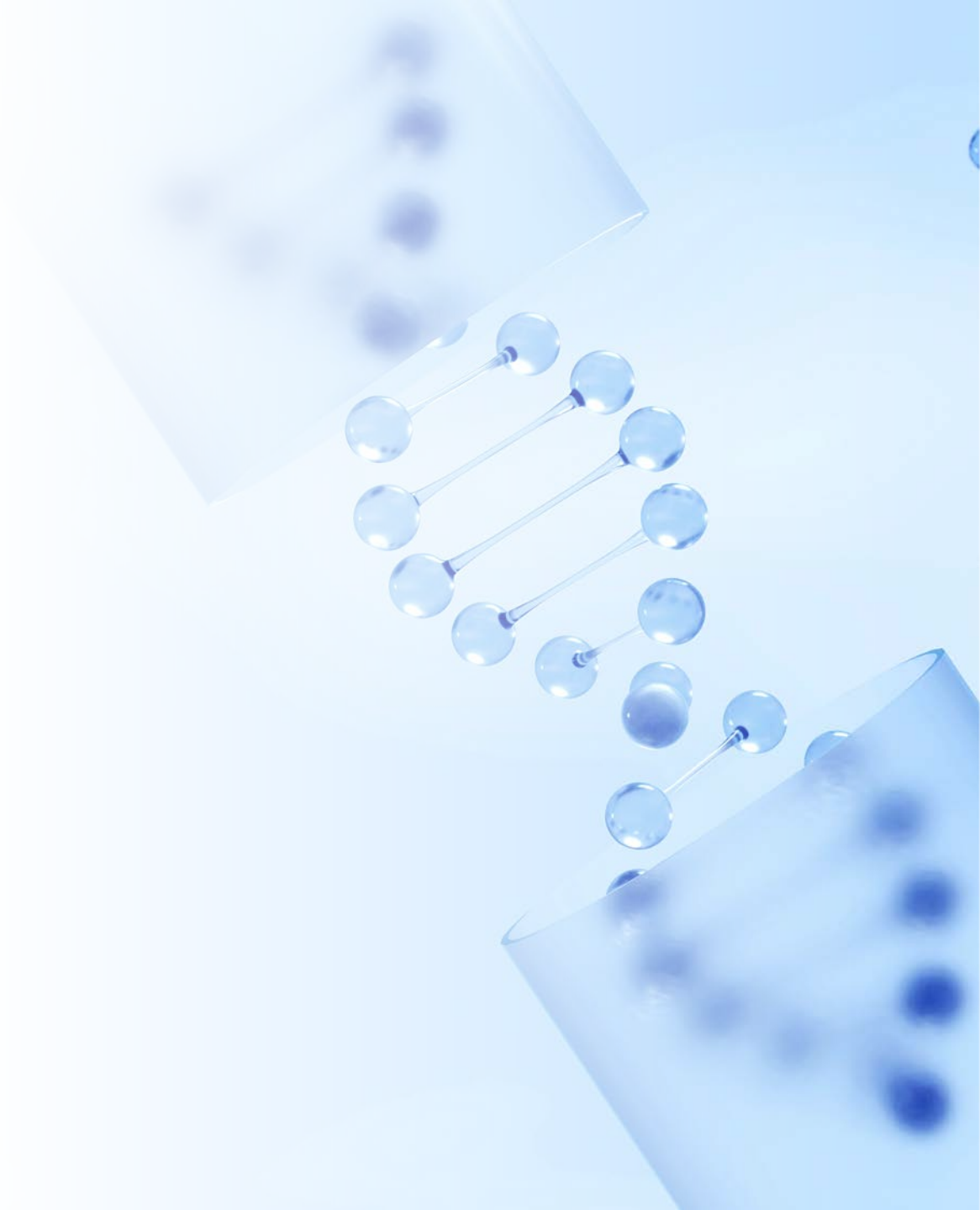
It is not surprising the response rate is lower in CRC. I really credit the authors for even presenting the data here. We have to understand what the baseline is and to know how much benefit we're really adding to these combos, which will likely be required.

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

		2025 ESMO: PDAC	2026 ASCO: CCA	2026 ASCO: CRC	2026 WCLC: NSCLC
疗效	600 mg QD (RP2D)	N=59	N=18	N=28	N=71
	ORR	40.7%	44.4%	11%	59.2% (cORR 52.1%)
	DCR	96.7%	94.4%	71%	93.0%
	数据截止日	Sept. 27, 2025	Apr. 20, 2026		Sept. 4, 2026
安全性		600mg QD (N=66)	400-600 mg QD (N=20)	400-750 mg QD (N=41)	600 mg QD (N=75)
	TRAEs ≥ Grade 3	31.8%	40%	26.8%	41.3%
	TRAEs leading to discontinuation	3%	0	4.9%	4%
	TRAEs leading to dose interruption	27.3%	40%	24.4%	37.3%
	SAEs	13.6%	5%	9.8%	21.3%
	数据截止日	Aug. 27, 2025	Dec. 12, 2025		Jun. 17, 2026

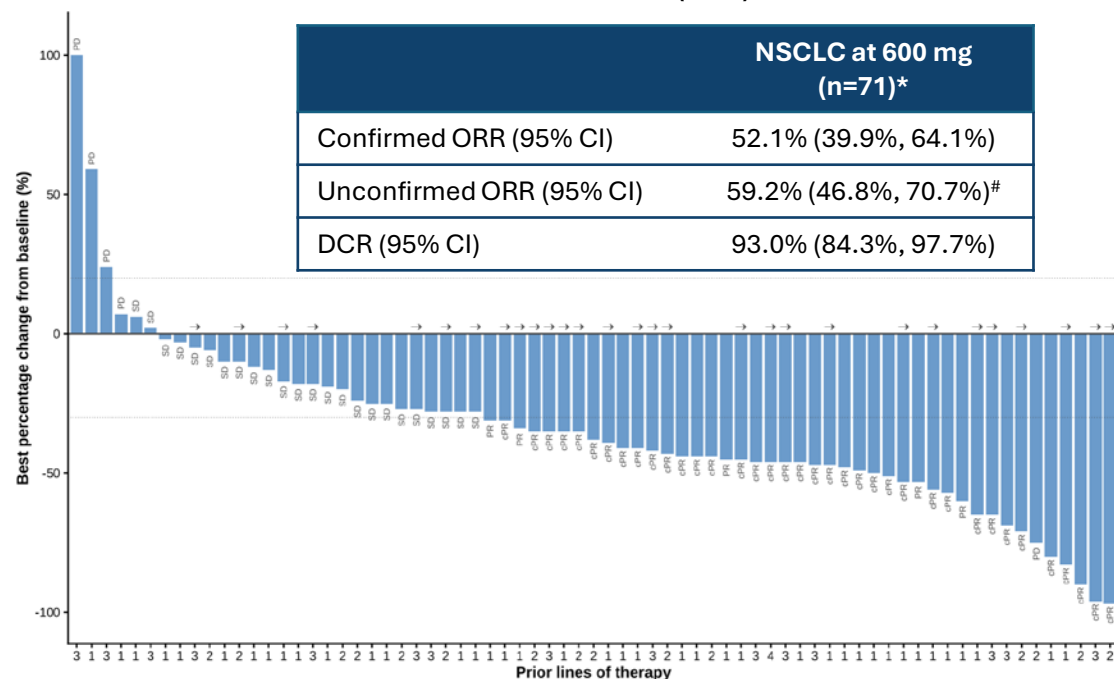
PART 02

375口头报告 重点解读



Objective Response

- Among the 71 patients with at least one post-treatment efficacy evaluation, ORR was 59.2% (42/71), confirmed ORR was 52.1% (37/71).
- Among the 9 patients with brain metastases and at least one post-treatment evaluation, ORR was 55.6% (5/9)[&].
- Median (range) time to response: 1.4 months (1.4-8.3 months)
- Median duration of response: 8.3 months (95% CI: 6.3, NA)



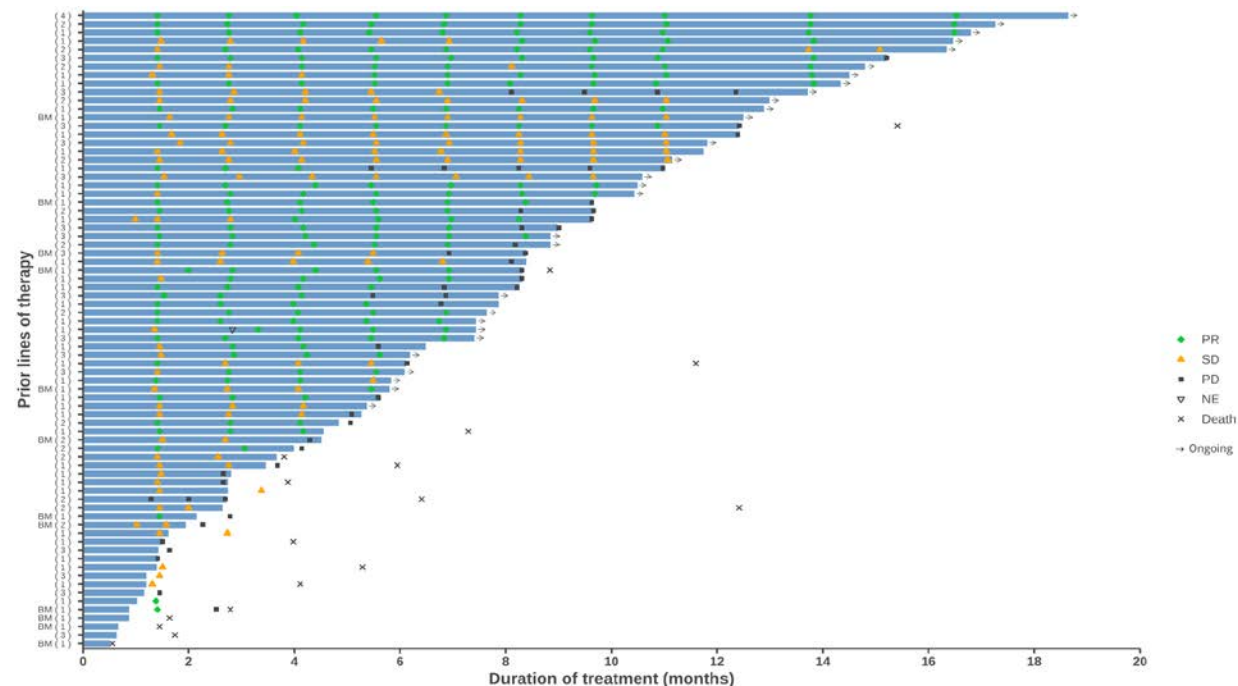
Data cut-off date: 04 Sep 2026.

* Four patient dropped out early without post-baseline tumor assessment (2 due to death, 1 due to patient's global deterioration of health, and 1 due to physician's decision), 3 among whom had baseline brain metastases.

[#] One was ongoing and pending for confirmed PR. Four patients achieved PR but discontinued before response confirmation: 1 dropped out due to AE (G4 hepatic function abnormal and recovered after discontinuation), 2 had disease progression at the second assessment, and 1 had stable disease at the later assessments.

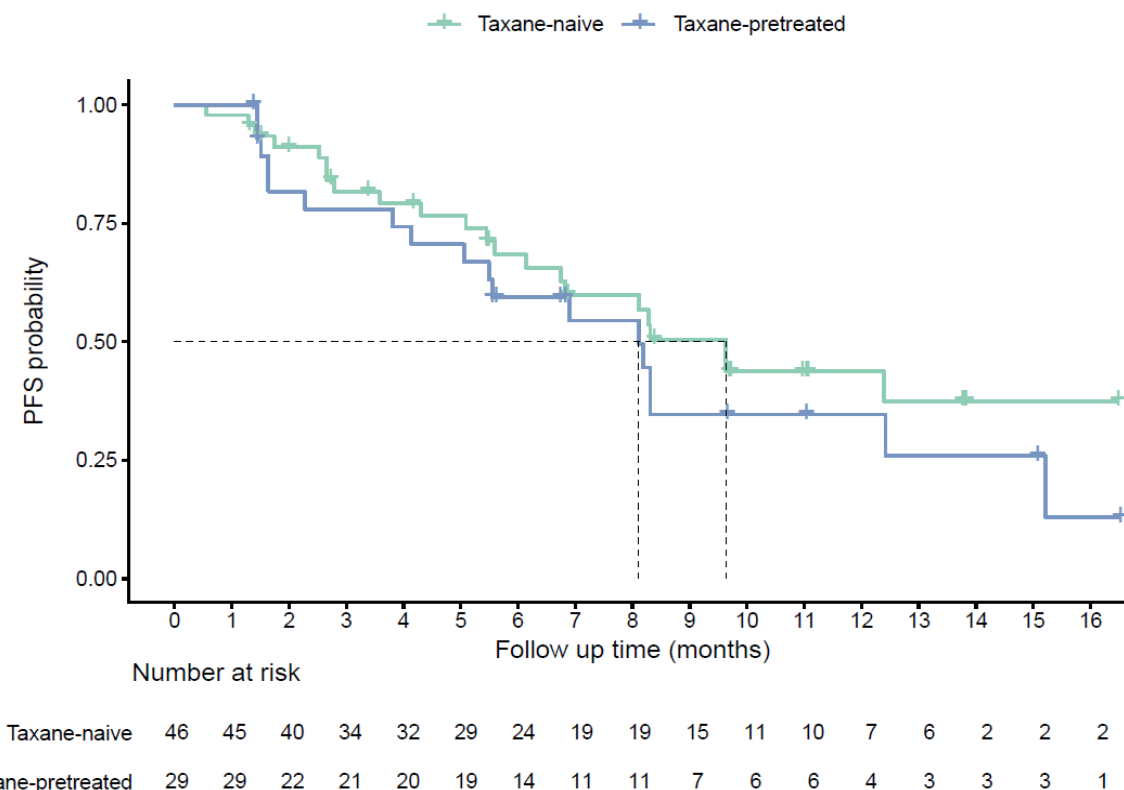
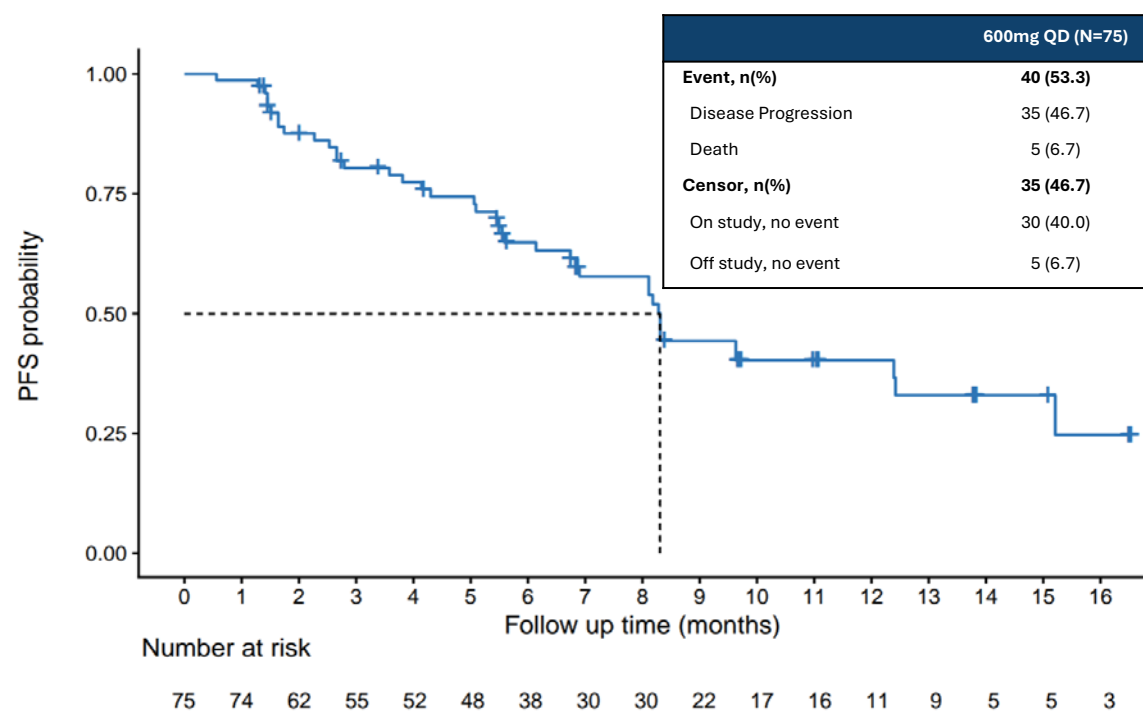
[&] No cerebral metastatic lesions were chosen as target lesions among the patients.

Abbreviation: BM, brain metastases; CI, confidence interval; cPR, confirmed partial response; DCR, disease control rate; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.



PFS and OS

- Median PFS was 8.3 months (95% CI: 6.8, NA) with median follow-up time 11.0 months.
 - Among taxane-naïve patients, median PFS was 9.6 months (95% CI: 6.7, NA)
 - Among taxane-pretreated patients, median PFS was 8.1 months (95% CI: 5.5, NA)
- Median OS was not reached (95% CI: 15.4 m, NA) with median follow-up time 11.2 months. 12-months OS rate was 77.0% (95% CI: 66.9%, 88.7%).



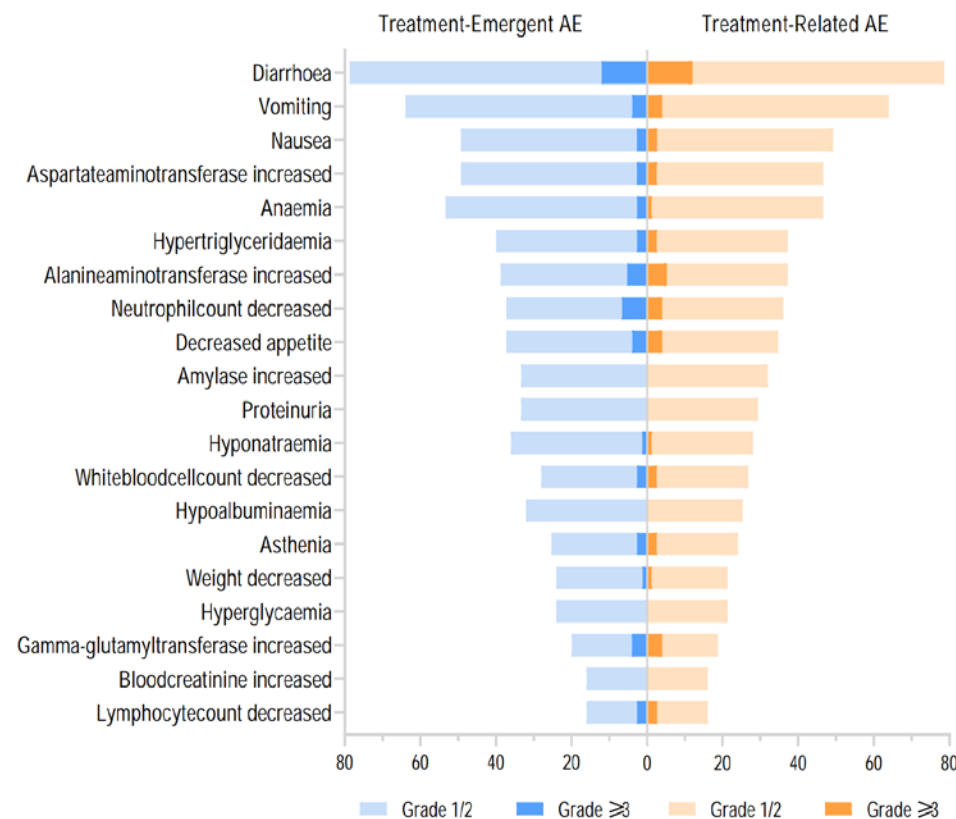
Data cut-off date: 04 Sep 2026.

Safety in Patients with NSCLC

- GFH375 presented a manageable safety profile in pretreated NSCLC patients.
- The safety profile was consistent with prior reports¹⁻³, without new safety signals.
- Common TRAEs were gastrointestinal, hematological AEs and transaminitis; most were grade 1 or 2 and recovered with supportive treatment.

Adverse events, n(%)	600 mg QD (N=75)
TEAEs	
All grades	75 (100)
Grade ≥ 3	42 (56.0)
Leading to discontinuation	6 (8.0)
Leading to reduction	19 (25.3)
Leading to interruption	33 (44.0)
SAE	27 (36.0)
Leading to death	5 (6.7)
TRAEs	
All grades	75 (100)
Grade ≥ 3	31 (41.3)
Leading to discontinuation	3 (4.0)
Leading to reduction	19 (25.3)
Leading to interruption	28 (37.3)
SAE	16 (21.3)
Leading to death	0

Data cut-off date: 17 June 2026.



TEAEs and TRAEs occurred in $\geq 15\%$ of patients

The median exposure time to GFH375 in all NSCLC patients at 600 mg was 5.3 months (range: 0.5-16.1) by the cut-off date. The mean relative dose intensity was 89.8%.

Abbreviations: SAE, serious adverse event; TEAE, treatment emergent adverse event; TRAE, treatment related adverse event.

¹Lu S, et al. MA02.07. Journal of Thoracic Oncology, 20, S59-S60. ²Zhou A, et al. LBA84. Annals of Oncology, 36S1626. ³Zhu L, et al. J Clin Oncol 44, 3008-3008(2026).

三款KRAS G12D抑制剂进入III期临床研究治疗NSCLC

企业	产品	I/II期单药治疗2L+ NSCLC疗效					III期 (NSCLC) 启动
		RP2D	疗效 样本量	Confirmed ORR	DCR	截止日期及 数据来源	
劲方	GFH375	600 mg QD	71	52.1%	93%	Sept. 4, 2026 (2026 WCLC)	2026.7 (单药)
RevMed	RMC-9805 (zoldonrasib)	1200 mg QD	27	52%	93%	Dec. 1, 2025 (2026 AACR)	2026.8 (联合K药+含铂 化疗+培美曲塞)
Astellas	ASP3082 (setidegrasib) (注射)	600 mg QW	45	33%	NE	Nov. 10 (2026 NEJM)	2026.5 (单药)

KRAS G12D抑制剂单药治疗2L+ NSCLC研究基线特征对比

	GFH375 600 mg QD (N=75)	RMC-9805 1200 mg QD (N=27)
研究名称	NCT06500676	NCT06040541
既往治疗线数	1-4 (42.7%既往接受≥2线治疗, 22.7% ≥3线治疗)	1-2 (67%既往接受1线治疗, 33%既往接受2线治疗)
既往接受治疗	- 免疫检查点抑制剂 - 含铂化疗 - 多西他赛等紫杉类药物 (38.7%的患者既往使用)	- 免疫检查点抑制剂 - 含铂化疗 (既往未曾使用多西他赛)
入组转移情况	脑转移 (16%), 骨转移 (37.3%), 肝转移 (13.3%)	脑转移 (19%)
截止日期及数据来源	Sept. 4, 2026 (2026 WCLC)	Dec. 1, 2025 (2026 AACR)

KRAS G12D抑制剂单药治疗2L+ NSCLC研究疗效对比

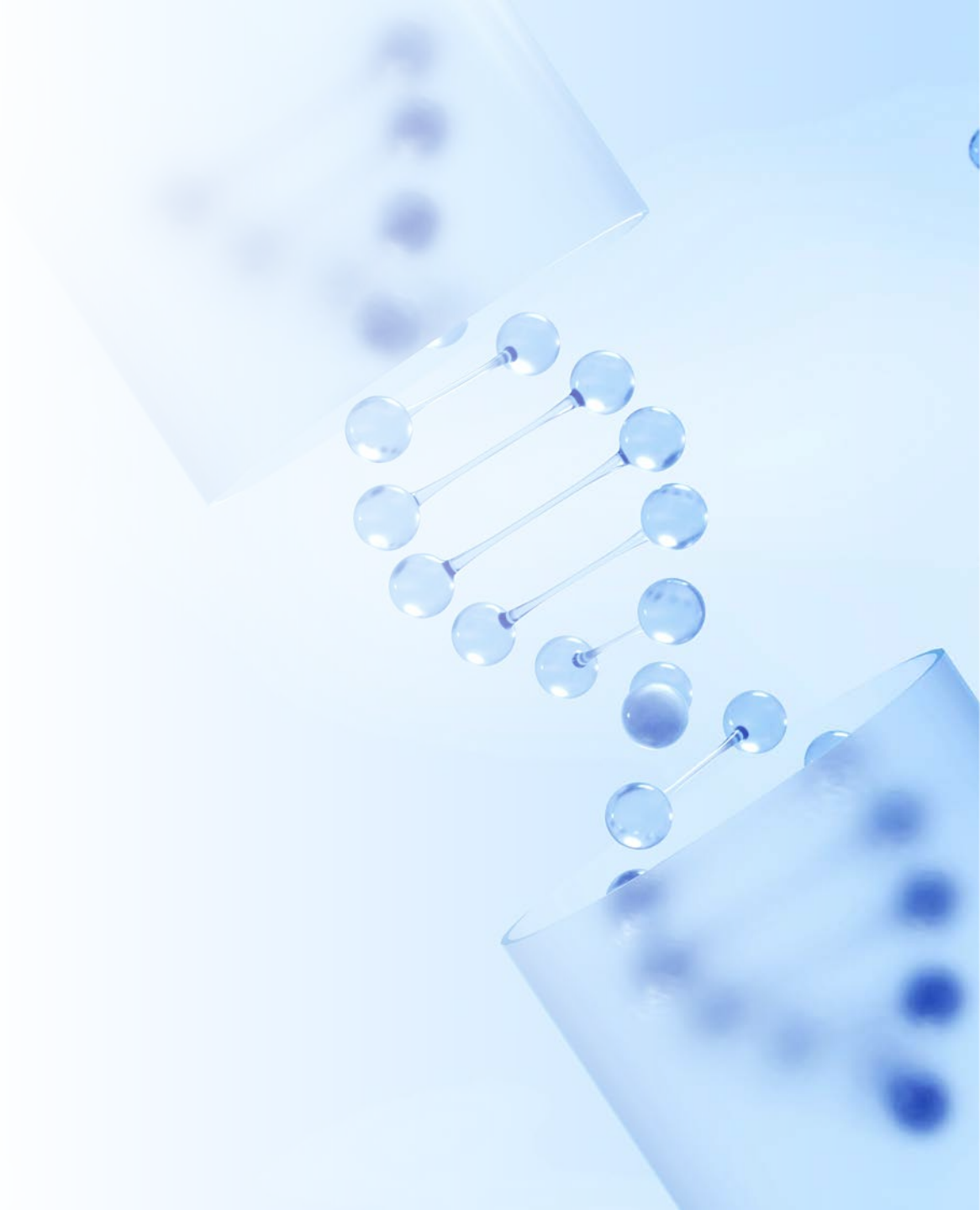
	GFH375 600 mg QD	RMC-9805 1200 mg QD
Confirmed ORR	52.1% (95%CI: 39.9%, 64.1%)	52% (95%CI: 32%, 71%)
DCR	93% (95% CI: 84.3%, 97.7%)	93% (95%CI: 76%, 99%)
中位随访时间	11m	13.1m
PFS	9.6m (95% CI: 6.7, NA) - 既往未曾使用多西他赛等紫杉类药物 8.3m (95% CI: 6.8, NA) - 所有患者, 包括既往使用紫杉类药物 8.1m (95% CI: 5.5, NA) - 既往使用紫杉类药物	11.1m (95% CI: 5.3, NE) - 既往未曾使用多西他赛
12m OS-rate	77% (95% CI: 66.9%, 88.7%)	73% (95% CI: 52%, 86%)
截止日期及数据来源	Sept. 4, 2026 (2026 WCLC)	Dec. 1, 2025 (2026 AACR)

KRAS G12D抑制剂单药疗法安全性对比（含中美患者）

		GFH375 600 mg QD (N=75, 中国NSCLC患者)	GFH375/VS-7375 600-900 mg QD (美国多种实体瘤患者, 给药1个周期以上、≥29天)		RMC-9805 1200 mg QD (N=40)
			600 mg QD (N=51)	900 mg QD (N=22)	
TRAEs (Any grade)	腹泻	78.7%	24%	18%	30%
	呕吐	64%	20%	9%	33%
	恶心	49.3%	18%	14%	43%
	贫血	46.7%	6%	5%	10%
	AST升高	46.7%	无临床意义的药物相关肝脏毒性		10%
	皮疹	未达到统计阈值	未达到统计阈值		18%
TRAE≥3级		41.3%	腹泻 4%	恶心 5%	13%
给药终止		4%	NE		5%
截止日期及数据来源		Jun. 17, 2026 (2026 WCLC)	Jun.12, 2026 (VSTM官网)		Dec. 1, 2025 (2026 AACR)

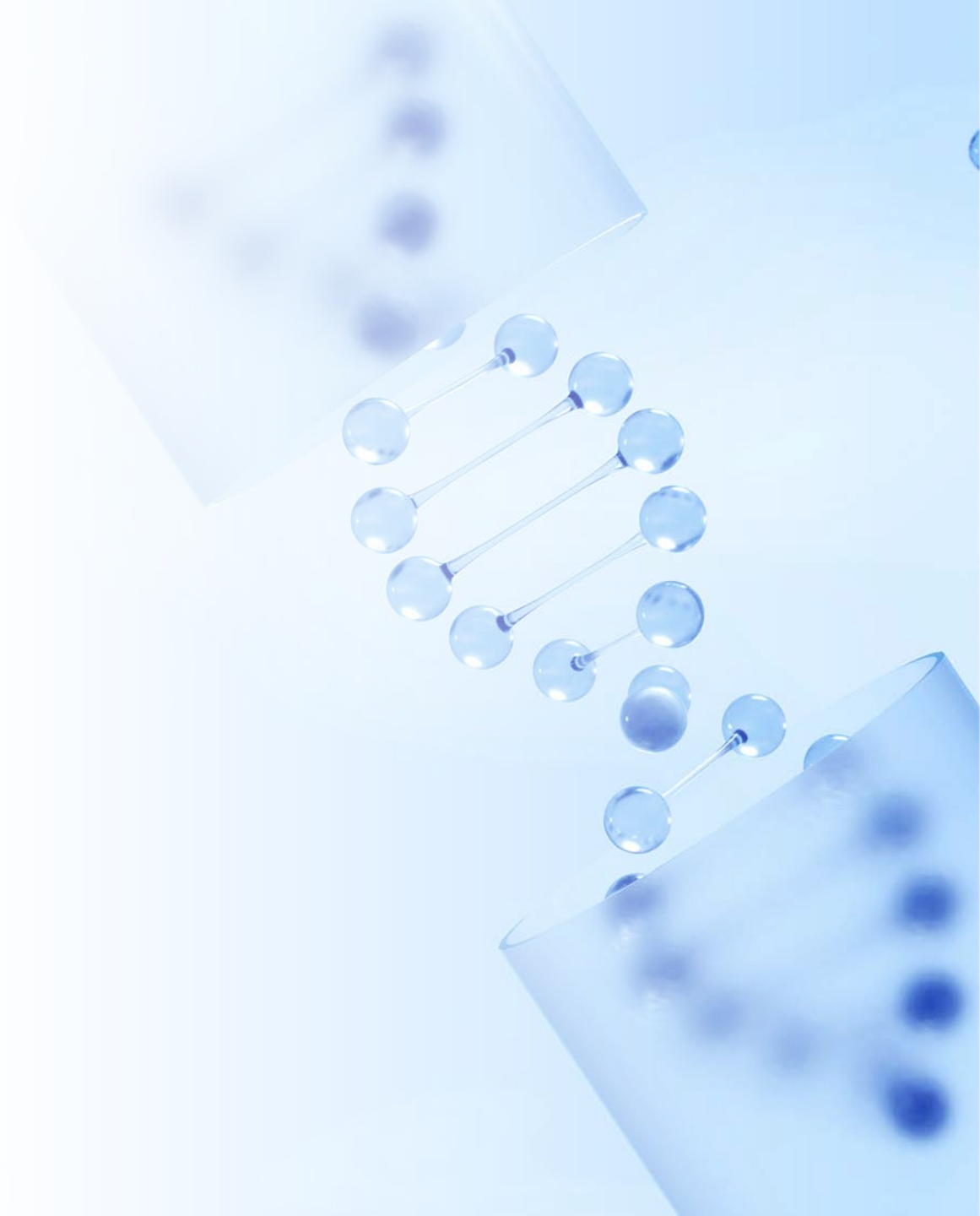
PART 03

会前问题解答 及现场互动



04 PART

总结及展望



劲方两款RAS疗法研究数据获得2026 ESMO LBA资格



GFH375联合西妥昔单抗
KRAS + EGFR

联合疗法治疗PDAC、CRC

GFH276
Pan RAS 抑制剂

单药治疗实体瘤

GFH375早期（Phase I）临床数据回顾：即将发表于国际顶级期刊



论文
成果

nature
medicine

52.5
Impact Factor

相关研究：I 期治疗KRAS G12D突变型实体瘤
发布时间：9月15日 16:00（伦敦时间）

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



風飛浪勁·据義履方