GFH375及GFH276
最新临床进展交流会

2026年11月

会议议程

1	GFH375临床进展更新	-- 吕强博士，劲方医药董事长
2	GFH276临床进展更新	-- 吕强博士，劲方医药董事长
3	GFH276注册路径	-- 汪裕博士，劲方医药首席医学官
4	会前问题解答及现场互动	-- 劲方医药参会管理层

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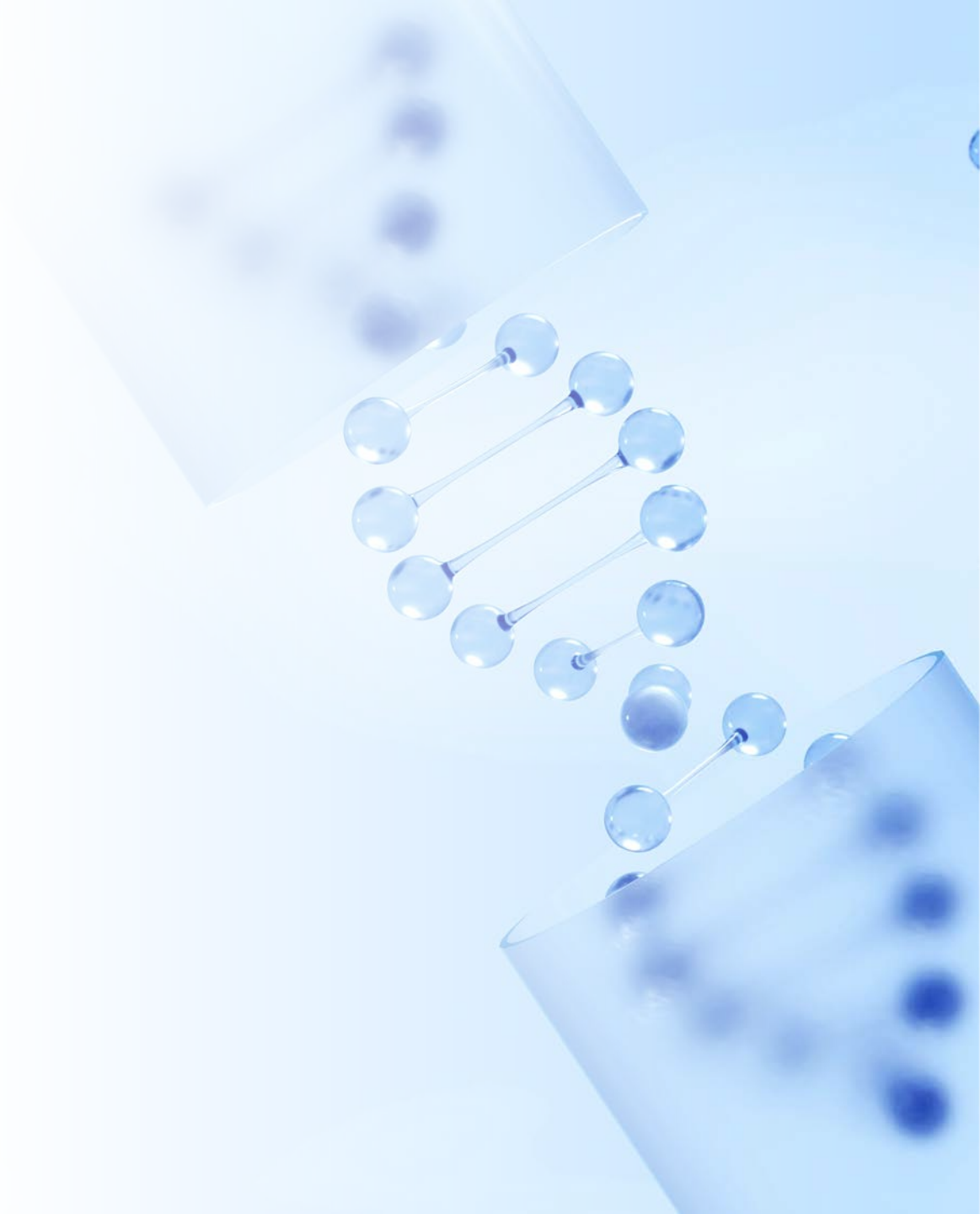
PART 01

GFH375临床进展更新



2026.10.15 线上交流会：关于GFH375的临床进展

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

GFH375已获准进入CRC注册性临床研究

在国内率先获得口服KRAS G12D抑制剂治疗NSCLC、PDAC、CRC的三项BTD

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

（现已完成所有患者入组）

2026

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期研究

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

2026.10 CRC III期试验正式开始

GFH375 第三项注册性III期研究

D+27M

GFH375联合西妥昔单抗在同类CRC联用方案中初步疗效数据领先

企业	方案	KRAS G12D抑制剂剂量	样本量	ORR	DCR	PFS	中位随访时间	Cutoff
GenFleet	GFH375+cetux	600 mg QD	54	44%	89%	7.3 m	5.4 m	2026.9.16
Incyte	INCB161734+cetux	1200 mg QD	22	36%	100%	7.2 m	Not reported	2026.7.6
Quanta	QTX3034+cetux	1200 mg QD	21	25%	75%	Not reported	Not reported	2026.8.31

PART 02

GFH276临床进展更新

GFH276临床开发位于国内Pan RAS抑制剂第一梯队

- **在国内同靶点产品中，率先在国际学术会议发表临床数据（2026 ESMO LBA）**
- **已在国内、海外获批开展多项一线及后线联合疗法试验，覆盖多个大适应症瘤种**

2025

2025.9 FPI

国内I期试验首例患者入组

Start Point of
Clinical Development

2026

2026.7 PDAC combo IND获批

联合化疗或EGFR单抗（一线，中国、澳洲）

中国试验：80、120 mg QD剂量水平
均已招募患者入组

2026.7 PDAC combo IND获批

联合GFH375，**全球首个**不同机制的双RAS疗法

2026.8 NSCLC combo IND获批

联合PD-1及化疗，**国内首个**Pan RAS抑制剂一线肺癌研究

2026.10 CRC combo IND获批

联合化疗（±VEGF单抗）或联合EGFR单抗

D+13Months

2026.10 ESMO LBA

I期单药研究纳入**98名**患者数据

PDAC Cross-trial Efficacy Comparison

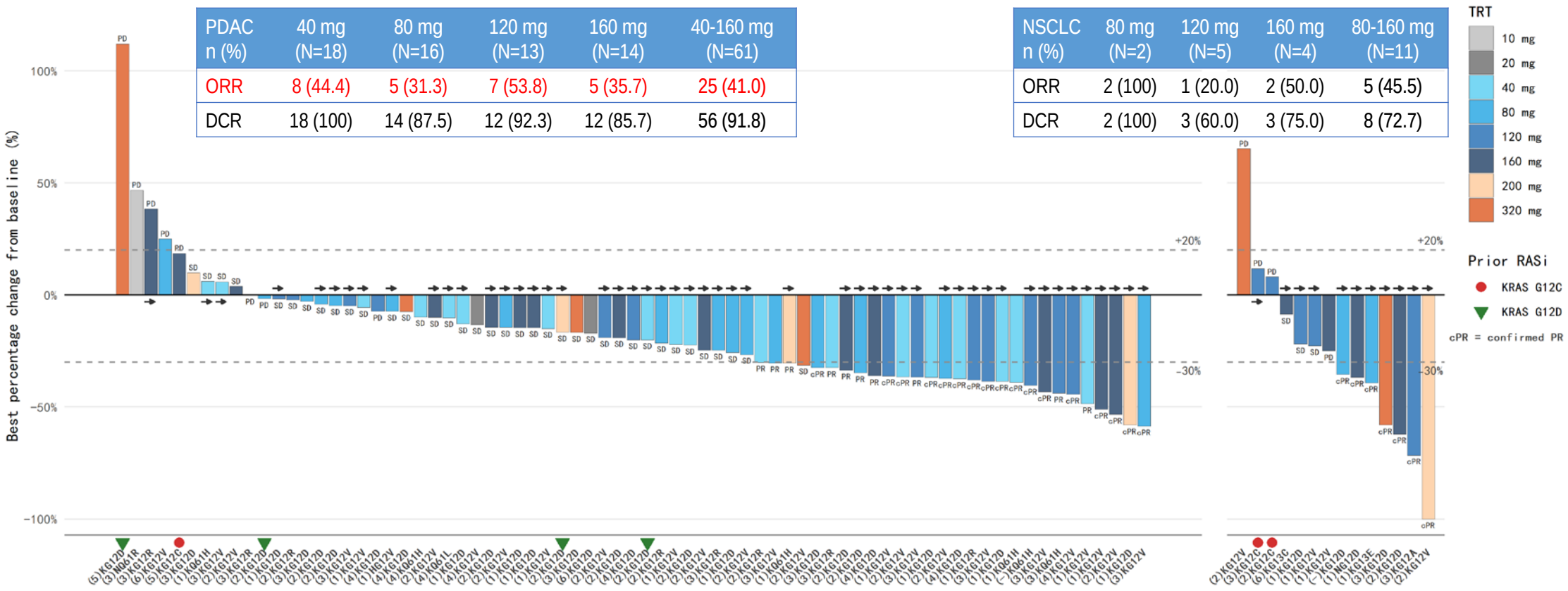
		GFH276	RMC-6236		
数据对应的试验阶段		Phase I	Phase I/II		Phase III
剂量		40-160 mg QD	300 mg QD（以下ORR均为confirmed）		
整体疗效	类型	All RAS mutations	All RAS mutations		
	人数	N=61（2L+）	N=38（2L）	N=45（3L+）	N=237（2L）
	ORR	41%	29%	20%	31.6%
	DCR	91.8%	95%	84%	Not reported
亚组疗效	类型	RAS inhibitor naïve	KRAS G12X-mutant		
	人数	N=58（2L+）	N=26（2L）	N=38（3L+）	N=217 (2L)
	ORR	43.1%	35%	21%	33.2%
	DCR	94.8%	92%	87%	Not reported
截止日期 及数据来源		Cutoff: 2026.9.15 Source: 2026 ESMO	Cutoff: 2025.6.30 Source: 2026 NEJM		Cutoff: 2026.2.10 Source: 2026 ASCO

Objective Response

- Partial responses were observed starting from the 40 mg dose cohort.
- 61 PDAC and 14 NSCLC received 40~160 mg:
  - ORR was 41.0% (25/61, 90% CI: 30.3-52.3) in PDAC, and 45.5% (5/11, 90%CI: 20.0-72.9) in NSCLC.
  - In RAS inhibitor naïve patients, ORR was 43.1% (25/58) in PDAC, and 55.6% (5/9) in NSCLC.

PDAC n (%)	40 mg (N=18)	80 mg (N=16)	120 mg (N=13)	160 mg (N=14)	40-160 mg (N=61)
ORR	8 (44.4)	5 (31.3)	7 (53.8)	5 (35.7)	25 (41.0)
DCR	18 (100)	14 (87.5)	12 (92.3)	12 (85.7)	56 (91.8)

NSCLC n (%)	80 mg (N=2)	120 mg (N=5)	160 mg (N=4)	80-160 mg (N=11)
ORR	2 (100)	1 (20.0)	2 (50.0)	5 (45.5)
DCR	2 (100)	3 (60.0)	3 (75.0)	8 (72.7)



Data cutoff date: 15 September 2026

ORR and DCR were calculated in the evaluable population, defined as patients with target lesions at baseline and at least one post-dose evaluable tumor assessment. Among the 14 NSCLC, 3 were not evaluable: 1 at 40 mg had no baseline target lesions; 1 at 120 mg had no evaluable post-dose tumor assessment but was still on treatment; 1 at 160 mg dropped out without post-dose tumor assessment due to G3 stomatitis.

Yuxiang Ma, MD

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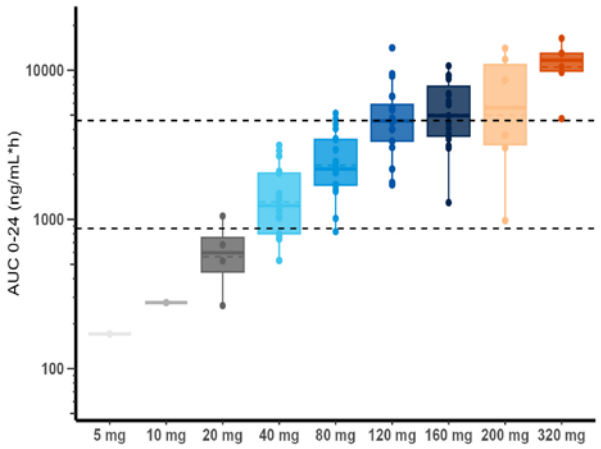
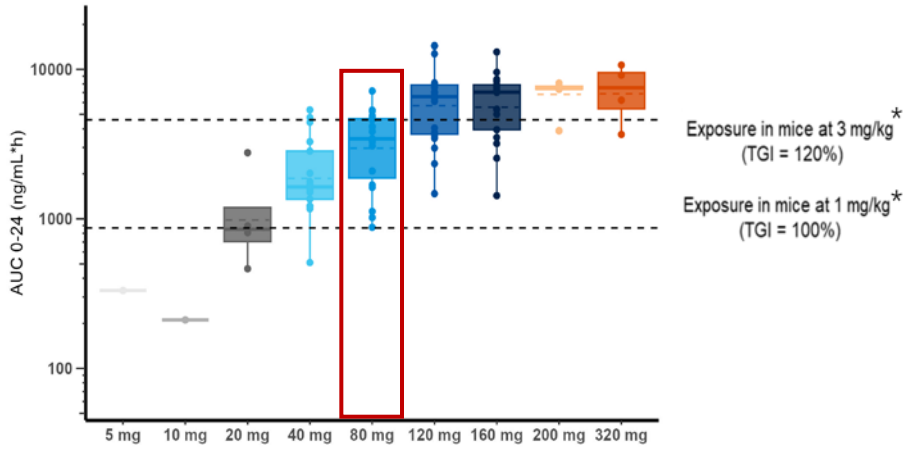
GFH276: Linear PK Exposure with No Exposure Plateau

- Approximately **linear PK** exposure with half-life 10.3-19.1 hours.
- **No exposure plateau** or significant accumulation observed.
- Exposure of 40 mg and 120 mg achieved target levels of 100% and 120% TGI in mice AsPC-1 CDX model, respectively.
- Lower dose (GFH276 80mg vs. RMC-6236 300mg) to achieve target exposure

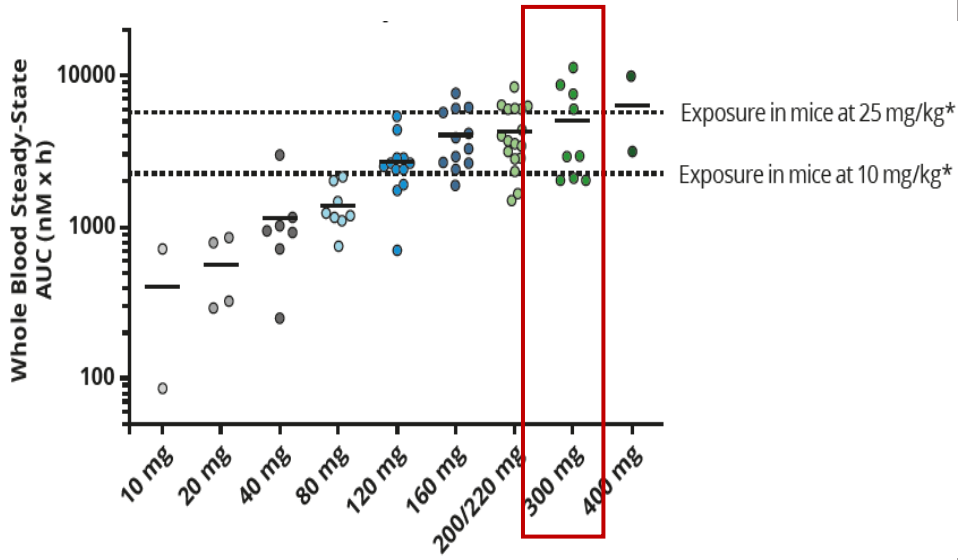
Single Dose AUC_{0-24} boxplot of GFH276-



Steady State AUC_{tau} boxplot of GFH276



Individual AUC After Multiple Administration of RMC-6236#



*Exposure corrected with cross-species protein binding and blood/plasma partitioning.
*RMC-6236 10mg/kg QD induces tumor regressions in sensitive models.
*RMC-6236 25mg/kg QD induces tumor regressions in the majority of models.
#RVM 2023 AACR Poster
GFH276 human BP ratio=1.05

Preferred Safety & Tolerability vs. RMC-6236 at Similar Range of Exposures in PDAC

Adverse Event N (%)	GFH276										RMC-6236			
	40 mg (N=18)		80 mg (N=16)		120 mg (N=13)		160 mg (N=14)		120-160 mg (N=27)		160-220 mg (N=51)		300 mg (N=83)	
	Any	G ≥3	Any	G ≥3	Any	G ≥3	Any	G ≥3	Any	G ≥3	Any	G ≥3	Any	G ≥3
Follow-up duration, median (range)	9.3 w (5.1-31.1)		12.6 w (5.0-27.3)		6.3 w (5.1-11.3)		8.6 w (4.6-22.9)		8.1 w (4.1-22.9)		UN		17 m (10.3-24.6)#	
Treatment-related adverse event														
Any	17 (94)	0	16 (100)	3 (19)	13 (100)	2 (15)	14 (100)	4 (29)	27 (100)	6 (22)	51 (100)	13 (25)	80 (96)	28 (34)
Leading to dose modification	1 (6)	0	3 (19)	1 (6)	3 (23)	0	5 (36)	3 (21)	8 (30)	3 (11)	19 (37)	11 (22)	40 (48)	18 (22)
Dose interruption	1 (6)	0	1 (6)	1 (6)	2 (15)	0	4 (29)	2 (14)	6 (22)	2 (7)	18 (35)	11 (22)	36 (43)	17 (20)
Dose reduction	0	0	2 (13)	0	1 (8)	0	3 (21)	1 (7)	4 (15)	1 (4)	7 (14)	5 (10)	25 (30)	11 (13)
Leading to dose discontinuation	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Treatment-related serious adverse event	1 (6)	0	1 (6)	1 (6)	0	0	1 (7)	1 (7)	1 (4)	1 (4)	3 (6)	2 (4)	5 (6)	4 (5)
Specific treatment-related adverse event														
Rash*	11 (61)	**0**	12 (75)	**0**	12 (92)	**0**	13 (93)	1 (7)	25 (93)	1 (4)	46 (90)	5 (10)	75 (90)	6 (7)
Diarrhea	7 (39)	0	5 (31)	0	4 (31)	0	9 (64)	1 (7)	13 (48)	1 (4)	21 (41)	0	43 (52)	3 (4)
Nausea	2 (11)	0	1 (6)	0	3 (23)	0	0	0	3 (11)	0	27 (53)	0	32 (39)	0
Stomatitis or mucositis/ mouth ulceration	4 (22)	0	9 (56)	0	7 (54)	0	9 (64)	0	16 (59)	0	18 (35)	2 (4)	45 (54)	3 (4)
Vomiting	4 (22)	0	1 (6)	0	2 (15)	0	1 (7)	0	3 (11)	0	12 (24)	0	30 (36)	0
Fatigue/ asthenia	0	0	1 (6)	0	1 (8)	0	3 (21)	0	4 (15)	0	14 (27)	2 (4)	14 (17)	1 (1)
Paronychia	1 (6)	0	4 (25)	0	4 (31)	0	3 (21)	0	7 (26)	0	8 (16)	0	15 (18)	0
Decreased appetite	0	0	1 (6)	0	3 (23)	0	1 (7)	0	4 (15)	0	4 (8)	1 (2)	10 (12)	0
Dry Skin	0	0	2 (13)	0	1 (8)	0	1 (7)	0	2 (7)	0	4 (8)	0	12 (14)	0

* The category of rash includes dermatitis (RMC-6236 only), **dermatitis acneiform**, **dermatitis exfoliative generalized** (GFH276 only), dermatitis bullous (RMC-6236 only), eczema (RMC-6236 only), erythema, **erythema nodosum** (GFH276 only), **rash**, rash erythematous (RMC-6236 only), rash macular (RMC-6236 only), rash maculopapular (RMC-6236 only), **drug eruption** (GFH276 only), **papule** (GFH276 only) and **rash pustular**.

Data for the study patients who received 300 mg of RMC-6236 daily as second-line therapy

Data cutoff date: **July. 15, 2026.**

Objective Response

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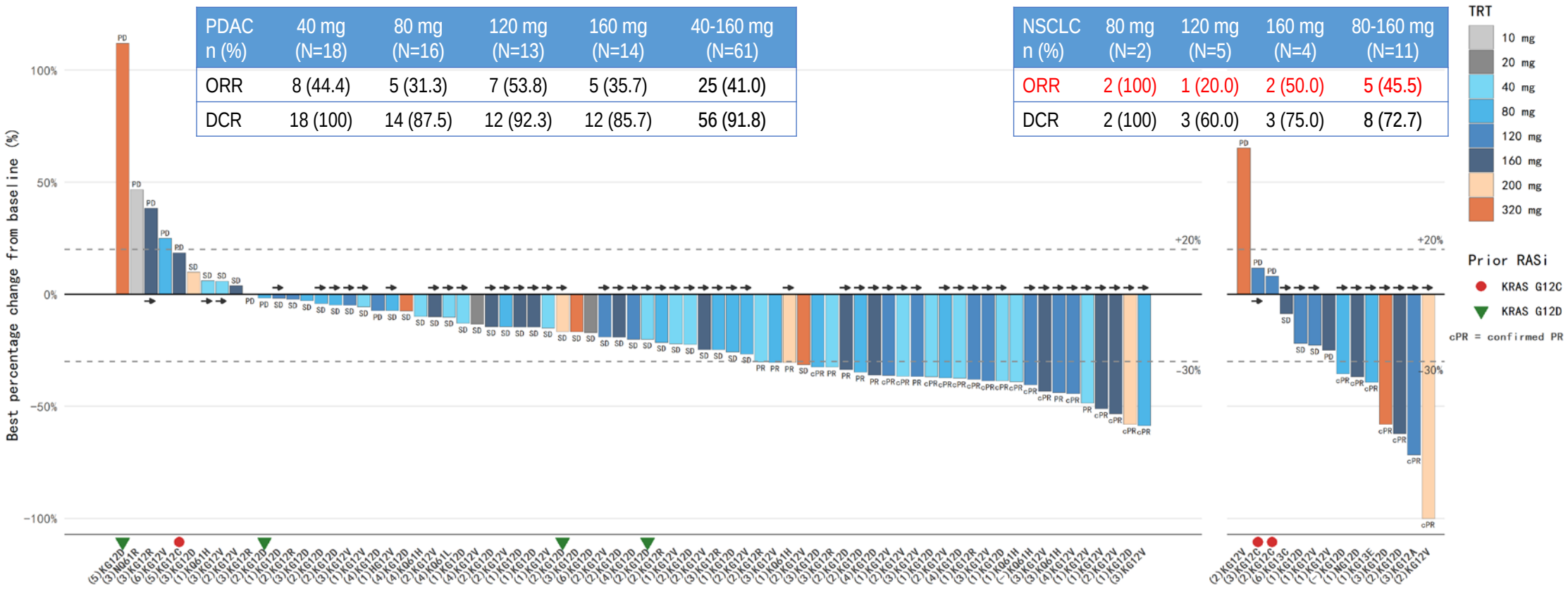

Data cutoff date: 15 September 2026

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Rash TRAEs in NSCLC across 5-320 mg QD Dose Levels

	5 mg (N=1)	10 mg (N=0)	20 mg (N=0)	40 mg (N=1)	80 mg (N=2)	120 mg (N=6)	160 mg (N=5)	200 mg (N=1)	320 mg (N=2)	5-20 mg (N=1)	40-160 mg (N=14)
All grades	0	0	0	1 (100.0%)	2 (100.0%)	6 (100.0%)	5 (100.0%)	1 (100.0%)	2 (100.0%)	0	14 (100.0%)
Grade≥3	0	0	0	0	0	1 (16.7%)	4 (80.0%)	1 (100.0%)	0	0	5 (35.7%)

*The category of rash includes rash, dermatitis acneiform, rash maculopapular, erythema nodosum, dermatitis exfoliative generalized, rash pustular, drug eruption, genital rash. Multiple types of rash may have occurred in the same patient.

PART 03

GFH276注册路径

GFH276注册路径探索全面展开，临床方案获得监管认可

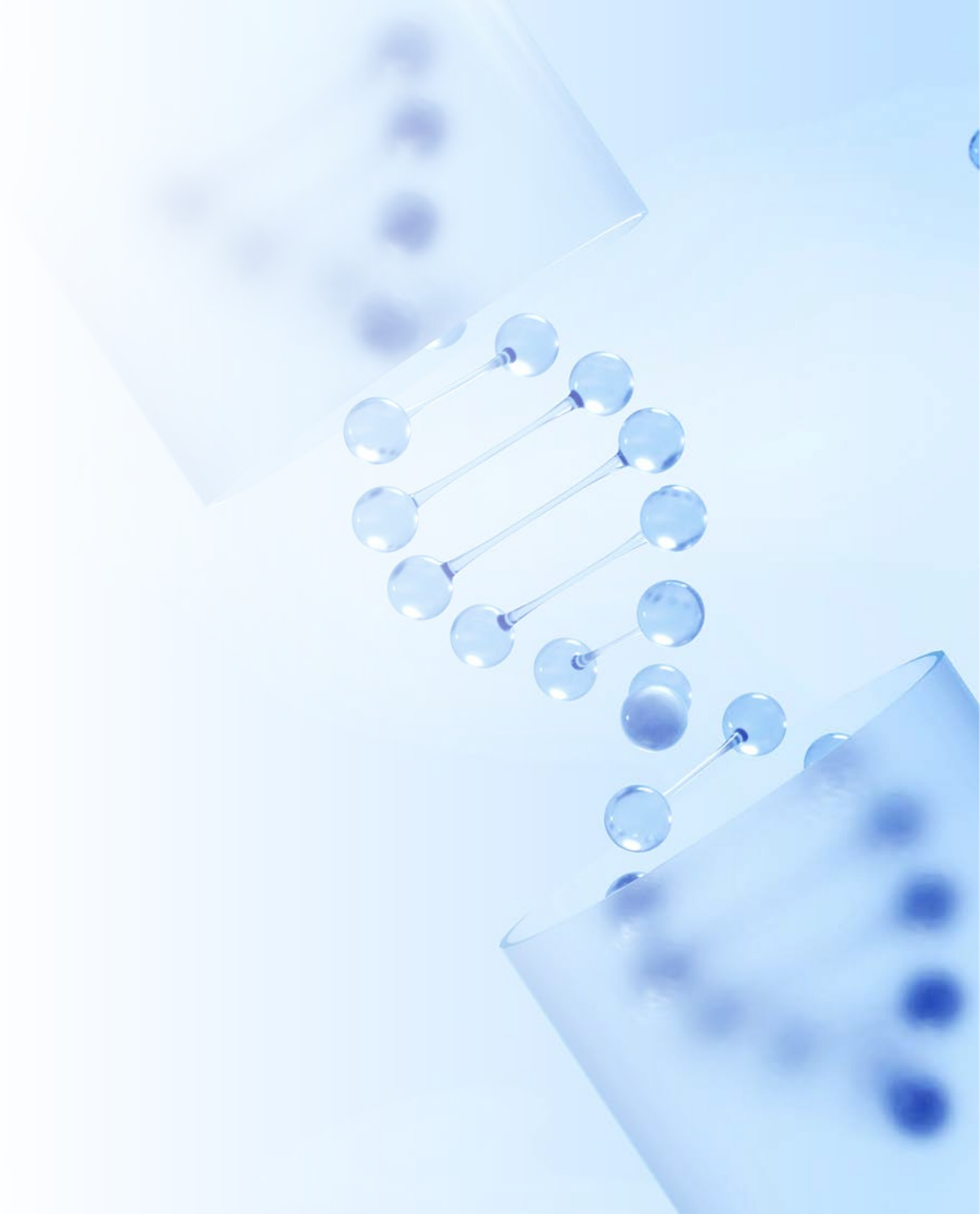
✓ Q3以来
IND获批

	PDAC	NSCLC	CRC
	单药治疗（ 120 /160 mg QD ）		
2L+			*+cetux* ✓ *+化疗（±VEGF单抗）* ✓
1L	**+cetux** ✓ **+chemo** ✓	**+PD-1±chemo** ✓	

*联合疗法剂量：
- GFH276——80/120/160 mg QD
- cetux、PD-1、chemo——均不减量

PART 04

会前问题解答
及现场互动



風飛浪勁·据義履方