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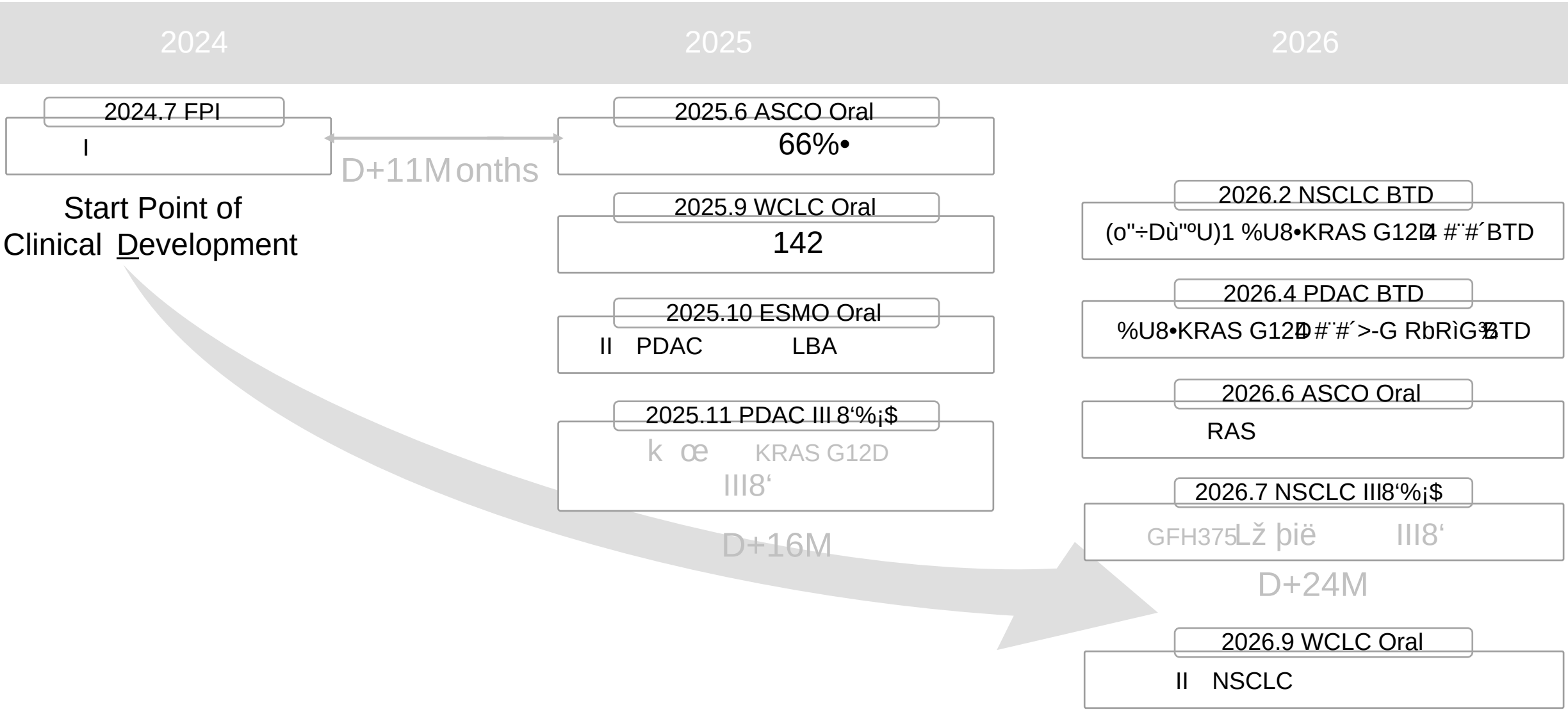
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PART

01

GFH375治疗各瘤种研究背景

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We see a truly impressive response rate , with response rates presented at the same dose 600 mg QD as clearly an active agent .

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

02

PART

375口头报告

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)[&].

	NSCLC at 600 mg (n=71)*
Confirmed ORR (95% CI)	52.1% (39.9%, 64.1%)
Unconfirmed ORR (95% CI)	59.2% (46.8%, 70.7%)[#]
DCR (95% CI)	93.0% (84.3%, 97.7%)

- 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%).

	600mg QD (N=75)
Event, n(%)	**40 (53.3)**
Disease Progression	35 (46.7)
Death	5 (6.7)
Censor, n(%)	**35 (46.7)**
On study, no event	30 (40.0)
Off study, no event	5 (6.7)

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

{<°KRAS G12D 4 #¨#´aM"×III8‘ ¦/ül†Kè>-G NSCLC

s Œ	&3	I/II8‘$ÇTá>-G 2L+ NSCLCŒG 6º					III8‘ ŸNSCLC %¡$
		RP2D	G 6º 9©8žcA	Confirmed ORR	DCR	3œ<Ô7W8‘%< 6â4à8×@	
	GFH375	600 mg QD	71	52.1%	93%	Sept. 4, 2026 2026 WCLC	2026.7
RevMed	RMC-9805 (zoldonrasib)	1200 mg QD	27	52%	93%	Dec. 1, 2025 2026 AACR	2026.8 K + +
Astellas	ASP3082 (setidegrasib) Ÿ>Z-v	600 mg QW	45	33%	NE	Nov. 10 (2026 NEJM)	2026.5

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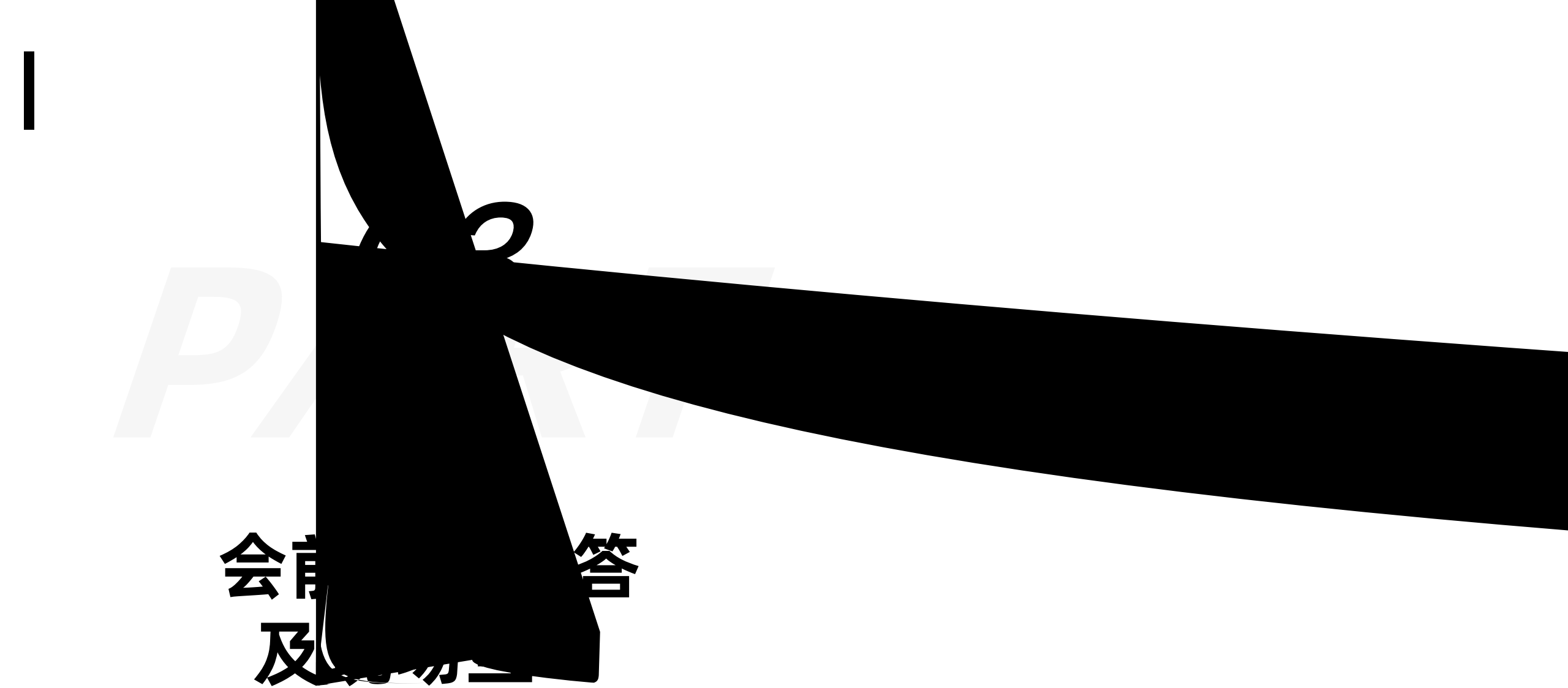
	GFH375 600 mg QD (N=75)	RMC-9805 1200 mg QD (N=27)
	NCT06500676	NCT06040541
7T0ò>-G P16â	1-4 Ÿ42.7%7T0ò5 %I ²P1>-G j 22.7% r3P1>-G 241 520904A0>Tj EMC /P <</MCID 78qMCID 68(980588 3.154 0 Td <0272	

KRAS G12D4 #¨#´$ÇTá>-G 2L+ NSCLCI†KèG 6º-k=F

	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%)
Ÿ ¿h]17hgf	11m	13.1m
PFS	• 9.6m (95% CI: 6.7, NA) - 7T0ò8œ8p ñFš*ŒZñ H^ÍL»N•8»MíTáCÛ • 8.3m (95% CI: 6.8, NA) – • 8.1m (95% CI: 5.5, NA) -	11.1m (95% CI: 5.3, NE) - 7T0ò8œ8p ñFš*ŒZñ H^Í
12m OS-rate	77% (95% CI: 66.9%, 88.7%)	73% (95% CI: 52%, 86%)
	Sept. 4, 2026 2026 WCLC	Dec. 1, 2025 (2026 AACR)

KRAS G12D4 #¨#´$ÇTáG >G,û"Ú1™-k=F Ÿ%• ŸQ 2 Qw

		GFH375 600 mg QD ŸN=75 j Ÿ(oNSCLC 2 Qw	GFH375/VS-7375 600- 900 mg QD ŸQ (o*ŒK?- ÅG–2 Qw jPKTáde%Ú8‘ W | ¹ r29*›		RMC-9805 1200 mg QD (N=40)
			600 mg QD ŸN=51)	900 mg QD (N=22	
TRAEs (Any grade)	Rë>m	78.7%	24%	18%	30%
	%Ç%,	64%	20%	9%	33%
	1è15	49.3%	18%	14%	43%
	^•Y²	46.7%	6%	5%	10%
	AST$¹lJ	46.7%			10%
	H G+				18%
TRAE r3P		41.3%	4%	5%	13%
PKTáP:<Ô		4%	NE		5%
3œ<Ô7W8‘%<6â4à8×@		Jun. 17, 2026 2026 WCLC	Jun.12, 2026 (VSTM)		Dec. 1, 2025 (2026 AACR)



04

PART

总结及展望

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