RC148 (ABBV-1480) monotherapy or in combination with docetaxel in first- or second-line advanced non-small-cell lung cancer (NSCLC) without actionable genomic alterations (AGA): updated results from a Phase 1/2 study

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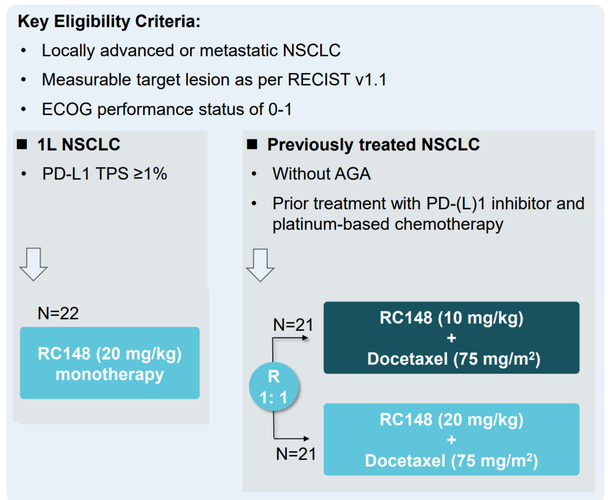
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Background

- RC148 (ABBV-1480) is a novel investigational bispecific antibody with a differentiated molecular design for dual targeting of PD-1 and VEGF.[1]
- RC148 has demonstrated encouraging antitumor activity and manageable safety as first-line (1L) monotherapy in patients with PD-L1-positive locally advanced or metastatic NSCLC, and in combination with docetaxel in patients without AGA who are previously treated with a PD-(L)1 inhibitor and platinum-based chemotherapy based on previous analysis of a Phase 1/2 study (NCT06016062).[2]
- We report here the updated efficacy and safety results with extended follow-up. The data cutoff date for this analysis was August 22, 2026.

Methods

Figure 1. Study design



- All study drugs were administered IV Q3W. Treatment was continued until disease progression, intolerable toxicity, consent withdrawal, or initiation of new anti-cancer treatment, or for up to 24 months (mo), whichever occurred first.
- Tumors were assessed as per RECIST v1.1 at baseline and thereafter every 6 weeks until disease progression, consent withdrawal, or initiation of new anti-cancer treatment, whichever occurred first.

Primary endpoint

- ORR assessed by investigators as per RECIST v1.1, and safety

Abbreviations: PD-1: programmed death-1; VEGF: vascular endothelial growth factor; RECIST v1.1: Response Evaluation Criteria in Solid Tumors version 1.1; ECOG: Eastern Cooperative Oncology Group; R: randomized; TPS: tumor proportion score; IV: intravenously; Q3W: once every 3 weeks; mo: months; ORR: objective response rate; DoR: duration of response; PFS: progression-free survival; IQR: interquartile range; NE: not estimable; NR: not reached; CPI: checkpoint inhibitor; RP3D: recommended phase 3 dose.

Efficacy Results – 1L NSCLC

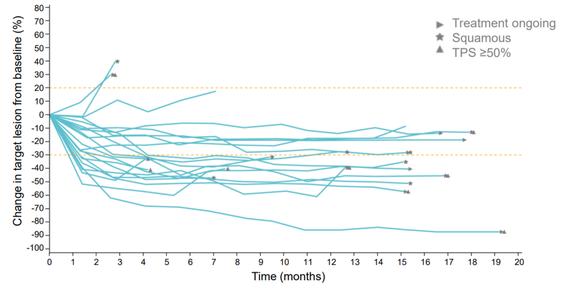
Patients

- 22 patients were enrolled (median age: 65.0 years; sqNSCLC: 54.5%; clinical stage IV: 63.6%). The median follow-up duration was 15.61 mo (IQR: 9.20-17.35); 6 (27.3%) patients remained on treatment.

Antitumor activity

- The confirmed ORR (cORR) was 57.1% (95% CI: 34.0-78.2) among the 21 patients with at least one post-baseline tumor assessment. Durable tumor response was observed in all patients (median DoR: 12.52 mo [95% CI: 4.14-NE]) and across subgroups.

Figure 2. Spider plot of tumor change in 1L NSCLC

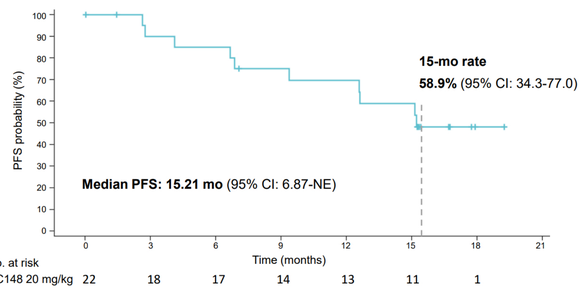


	sqNSCLC (N = 12)	nsqNSCLC (N = 9)	TPS 1%-49% (N = 13)	TPS ≥50% (N = 9)
cORR (95% CI)	63.6 (30.8-89.1)	44.4 (13.7-78.8)	50.0 (21.1-78.9)	66.7 (29.9-92.5)
Median DoR (95% CI), mo	12.52 (4.14-NE)	NR	12.52 (4.14-NE)	NR

PFS

- PFS data was immature, with 10 (45.5%) events reported. The median PFS was 15.21 mo in all patients, and the PFS benefit was consistently observed in the subgroups.

Figure 3. PFS in 1L NSCLC



	sqNSCLC (N = 12)	nsqNSCLC (N = 9)	TPS 1%-49% (N = 13)	TPS ≥50% (N = 9)
Median PFS (95% CI), mo	12.62 (2.76-NE)	NR	15.21 (6.87-NE)	NR
15-mo PFS rate (95% CI)	45.5 (16.7-70.7)	87.5 (38.7-98.1)	64.8 (31.0-85.2)	50.0 (15.2-77.5)

Efficacy Results – Previously Treated NSCLC

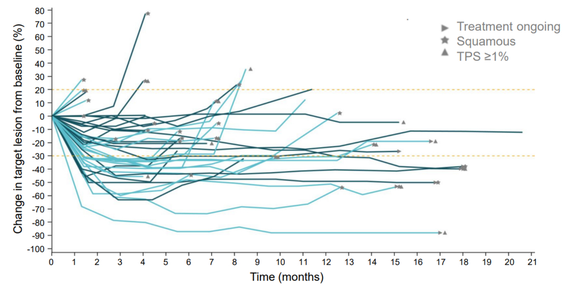
Patients

- 21 patients were randomized to each group (median age: 61.0 vs 66.0 years for the 10 vs 20 mg/kg groups; sqNSCLC: 52.4% vs 66.7%; stage IV: 95.2% vs 85.7%). The median follow-up was 16.33 mo (IQR: 8.61-17.68).

Antitumor activity

- In a checkpoint inhibitor (CPI)-experienced setting, the 20 mg/kg group exhibited higher cORR versus the 10 mg/kg group (66.7% [95% CI: 43.0-85.4] vs 33.3% [95% CI: 14.6-57.0]), with durable response observed (median DoR: 8.38 mo [95% CI: 5.65-12.68] vs not reached).

Figure 4. Spider plot of tumor change in previously treated NSCLC

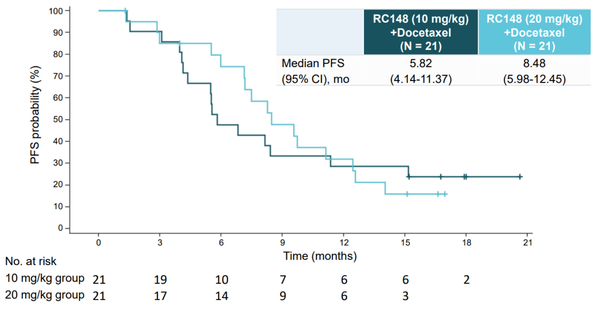


	RC148 (20 mg/kg) + Docetaxel			
	sqNSCLC (N = 14)	nsqNSCLC (N = 7)	TPS <1% (N = 11)	TPS ≥1% (N = 10)
cORR (95% CI)	64.3 (35.1-87.2)	71.4 (29.0-96.3)	54.5 (23.4-83.3)	80.0 (44.4-97.5)
Median DoR (95% CI), mo	8.38 (4.07-12.68)	NR	6.98 (4.07-NE)	12.68 (5.65-NE)

PFS

- In a CPI-experienced setting, the 20 mg/kg group achieved a longer median PFS than the 10 mg/kg group (8.48 vs 5.82 mo), with promising benefit observed across subgroups.

Figure 5. PFS in previously treated NSCLC



	RC148 (20 mg/kg) + Docetaxel			
	sqNSCLC (N = 14)	nsqNSCLC (N = 7)	TPS <1% (N = 11)	TPS ≥1% (N = 10)
Median PFS (95% CI), mo	7.16 (2.99-12.45)	10.35 (8.28-NE)	7.16 (2.86-11.14)	11.88 (7.13-NE)

Safety Results – Overall

Safety

- The safety profiles for both RC148 monotherapy and RC148 in combination with docetaxel were consistent with the previous report.[2]
- RC148 in combination with docetaxel did not increase the overall safety risk as compared with docetaxel monotherapy.
- The most common (incidence ≥10.0%) grade ≥3 treatment-related adverse events (TRAEs) for monotherapy were hypertension and proteinuria; for combination therapy were neutrophil count decreased and white blood cell count decreased.
- Most VEGF- and immune-related TRAEs were grade 1-2 and were consistent with previous report.

Table 1. Safety summary

n (%)	1L NSCLC	Previously treated NSCLC	
	RC148 (20 mg/kg) Monotherapy (N = 22)	RC148 (10 mg/kg) + Docetaxel (N = 21)	RC148 (20 mg/kg) + Docetaxel (N = 21)
Any TRAE*	22 (100)	21 (100)	21 (100)
≥ Grade 3	14 (63.6)	18 (85.7)	16 (76.2)
Leading to treatment discontinuation	1 (4.5)	2 (9.5)	4 (19.0)
Leading to death	0	0	0
Any VEGF-related TRAEs	16 (72.7)	9 (42.9)	13 (61.9)
≥ Grade 3	9 (40.9)	1 (4.8)	1 (4.8)
Any immune-related TRAEs	17 (77.3)	2 (9.5)	9 (42.9)
≥ Grade 3	6 (27.3)	0	1 (4.8)

*Related to any study drug

Conclusion

- RC148, alone and with docetaxel, showed durable efficacy and manageable safety in advanced NSCLC, supporting pivotal studies.
- In a CPI-experienced setting, NSCLC 20 mg/kg seems to provide superior efficacy as compared to 10 mg/kg and needs further investigation, while 10 mg/kg is RP3D in 1L NSCLC.
- RC148 is being evaluated in three Phase 3 studies in NSCLC, both in China and globally (RC148-C301: NCT07416474; RC148-C304: NCT07829549; AMUR-Lung-01: NCT07756645).

References

1. Fang J, et al. AACR 2024 (2734). 2. Yu J., et al. ESMO IO Congress 2025 (249P).

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