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Raludotatug deruxtecan (R-DXd) + bevacizumab (Bev) in participants (Pts) with platinum-resistant recurrent ovarian cancer (PROC): Results for cohort B-1 of the phase 1b/2 REJOICE-ovarian02 study

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Background

R-DXd is an ADC consisting of a humanized anti–cadherin-6 antibody, enzymatically cleavable peptide linker, and cytotoxic topoisomerase I inhibitor. In REJOICE-Ovarian01, R-DXd showed manageable safety and promising antitumor activity in pts with PROC (ORR, 50%). We describe safety and efficacy results from the dose escalation portion of the phase 1b/2 REJOICE-Ovarian02 study (NCT06843447) in pts with PROC who received R-DXd + Bev (cohort B-1).

Methods

Pts had high-grade serous epithelial OC, primary peritoneal, or fallopian tube cancer, measurable disease per RECIST v1.1, and had relapsed disease after 1–3 prior lines of therapy and radiographic PD <6 mo after the last dose of platinum-based therapy. Pts with primary platinum-refractory OC were ineligible. Pts received R-DXd 4.8 (n=10) or 5.6 (n=20) mg/kg IV Q3W + Bev 15 mg/kg IV Q3W until PD or unacceptable toxicity. Primary endpoints were DLTs, AEs, and treatment discontinuations due to AEs. Secondary endpoint was ORR per RECIST v1.1 by BICR.

Results

As of Feb 3, 2026, 30 pts received R-DXd + Bev. Median follow-up was 4.5 (range, 0.8–8.8) mo. Safety results are summarized in the table. Grade ≥3 AEs improved with dose modification and standard of care. One pt had drug-related grade 1 ILD (4.8 mg/kg) and another had grade 5 aspiration pneumonia per investigator which was adjudicated later as drug-related ILD (5.6 mg/kg). No DLTs or synergistic toxicities occurred; the safety profile was consistent with those of each drug. Confirmed ORR was 80% (n=8/10; 95% CI, 44%–98%; 1 CR, 7 PR) and 53% (n=8/15; 95% CI, 27%–79%; 8 PR) in the 4.8- and 5.6-mg/kg groups, respectively. All pts had disease control and tumor shrinkage. Treatment continued in 25 pts at data cutoff.Table: 1247R0

n (%)	R-DXd 4.8 mg/kg + Bev n = 10	R-DXd 5.6 mg/kg + Bev n = 20
Any AE	10 (100)	19 (95)
Grade ≥3	0	9 (45)
Led to treatment interruption	5 (50)	9 (45)
Led to dose reduction	0	2 (10)
R-DXd	0	2 (10) ^a
Bev	0	0
Led to treatment discontinuation	1 (10)	2 (10)
R-DXd	0	1 (5) ^b
Bev	1 (10) ^c	2 (10) ^{b,d}

n (%)	R-DXd 4.8 mg/kg + Bev n = 10	R-DXd 5.6 mg/kg + Bev n = 20
Led to death	0	1 (5) ^b
TRAEs	10 (10)	19 (95)
Grade ≥3	0	8 (40)
Led to treatment interruption	4 (40)	7 (35)
Led to dose reduction	0	2 (10)
R-DXd	0	2 (10) ^a
Bev	0	0
Led to treatment discontinuation	1 (10)	0
R-DXd	0	0
Bev	1 (10) ^c	0
Led to death	0	0

^aGrade 3 anemia and grade 3 fatigue (n = 1 each). ^bGrade 5 pneumonia aspiration (not drug related per investigator but adjudicated to drug-related ILD). ^cGrade 2 proteinuria. ^dGrade 2 gastrointestinal fistula.

Conclusions

R-DXd + Bev showed manageable safety and preliminary evidence of promising antitumor activity in PROC at the R-DXd 4.8- and 5.6-mg/kg doses.

Clinical trial identification

NCT06843447.

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Legal entity responsible for the study

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Disclosure

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