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Tisotumab vedotin (TV) + carboplatin (Carbo) in first-line (1L) or + pembrolizumab (Pembro) in previously treated (2L/3L) recurrent or metastatic cervical cancer (r/mCC): Interim results of ENGOT-Cx8/GOG-3024/innovaTV 205 study

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Background

TV demonstrated durable activity (objective response rate [ORR]=24%; median duration of response [mDOR]=8.3 mo) with manageable safety in previously treated r/mCC (Lancet Oncol. 2021; 22:609-619). Here we report results for the 1L TV + carbo and 2L/3L TV + pembro cohorts of the 2-part, multi-cohort phase Ib/II trial ENGOT-cx8/GOG-3024/innovaTV 205 clinical trial in r/mCC.

Methods

In the 1L TV + carbo cohort, pts with no prior systemic therapy (excluding chemoradiation) for r/mCC received TV 2.0 mg/kg + carbo AUC 5 IV every 3 weeks (Q3W). In the 2L/3L TV + pembro cohort, pts with r/mCC, with disease progression on/after 1–2 prior systemic therapies, received TV 2.0 mg/kg + pembro 200 mg IV Q3W. The primary endpoint was ORR per RECIST v1.1.

Results

There were 33 pts treated with 1L TV + carbo (median 5 cycles). Confirmed ORR was 55% (Table). All treated pts had adverse events (AEs) with 76% reporting grade (gr) ≥3 AEs regardless of causality. Prespecified AEs of interest (gr 1-2/ gr ≥3) included ocular (55%/3%), peripheral neuropathy (27%/12%) and bleeding events (48%/6%). There were 35 pts treated with 2L/3L TV + pembro (median 6 cycles), with most having received 1 prior systemic treatment for r/mCC (57%) and prior bevacizumab (57%). Confirmed ORR was 35% (Table). All treated pts had AEs with 74% reporting gr ≥3 AEs regardless of causality. AEs of interest included (gr 1-2/ gr ≥3) ocular (51%/3%), peripheral neuropathy (37%/3%) and bleeding events (54%/9%). There were no treatment-related deaths in either cohort.

Conclusions

Both 1L TV + carbo and 2L/3L TV + pembro had encouraging antitumor activity with acceptable safety profiles in pts with r/mCC.Table: 723MO

Summary of efficacy

Parameters	1L TV + Carbo (N = 33) Median FU: 4.8 months	2L/3L TV + Pembro (N = 34)[a] Median FU: 10.2 months
Objective response rate, n (%) [95% CI]Complete response, n (%)Partial response, n (%)	18 (55) [36–72]2 (6)16 (48)	12 (35) [20–54]2 (6)10 (29)

Parameters	1L TV + Carbo (N = 33) Median FU: 4.8 months	2L/3L TV + Pembro (N = 34)[a] Median FU: 10.2 months
Median duration of response, months (range)	5.6 (2.7-NE)	NE
Median time to response, months (range)	1.4 (1.1–4.4)	1.4 (1.3–5.8)
Median PFS, months (range)	6.9 (3.9–NE)	5.6 (2.7–9.6)

NE, not estimable. [a]1 pt was excluded from the full analysis set as they didn't have any target or non-target lesions at baseline. Response ongoing in 13/18 pts with 1L TV + carbo and 8/12 pts with 2L/3L TV + pembro.

Clinical trial identification

NCT03786081.

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Legal entity responsible for the study

Genmab A/S and Seagen Inc.

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Disclosure

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