18:30 - 20:00 Genmab - Advancing Antibody-Drug Conjugates Into the Future of Gynecologic Malignancies

CHAIR: CHRISTIAN MARTH

Advancing Care in Cervical Cancer: The Role of Tisotumab Vedotin

Linn Wölber

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Cervical cancer is the 4th most frequently diagnosed cancer in women worldwide[1]

It is also the 4th most common cause of cancer morbidity and mortality among women globally[1]

US estimates for 2025[2]
13,360 new cases
4,320 deaths

EU estimates for 2022[3]
28,211 new cases
13,636 deaths

Japan estimates for 2022[4]
10,958 new cases
3,864 deaths

Worldwide estimates for 2022:[1] >662,000 new cases; >348,700 deaths

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EU, European Union.
1. Wu J, et al. *J Natl Cancer Center*. 2025;11:20. **2.** Siegel RL, et al. *CA Cancer J Clin*. 2025;75:10-45. **3.** European Cancer Information System. Accessed: September 22, 2025. https://ecis.jrc.ec.europa.eu/explorer.php?$0-0$1-All$4-2$3-30$6-0,85$5-2022,2022$7-7$2-All$CEstByCountry$X0_8-3$X0_19-AE27$X0_20-No$CEstBySexByCountry$X1_8-3$X1_19-AE27$X1_-1-1$CEstByIndiByCountry$X2_8-3$X2_19-AE27$X2_20-No$CEstRelative$X3_8-3$X3_9-AE27$X3_19-AE27$CEstByCountryTable$X4_19-AE27 **4.** International Agency for Research on Cancer/World Health Organization. Accessed: September 23, 2025. https://gco.iarc.who.int/media/globocan/factsheets/populations/392-japan-fact-sheet.pdf

Recurrent/metastatic cervical cancer has poor overall survival

When diagnosed at early stages, cervical cancer can be treated with **curative intent**[1]

15% to 61% of patients with earlier stage disease will **experience metastatic disease** within **2 years** of completing therapy[1]

Metastatic disease at diagnosis[a,2-4]
US: **15%**
EU-5: **23%**
Japan: **18%**

5-year survival rates for metastatic disease[2-4]
US: **20%**
EU-5: **19%**
Japan: **27%**

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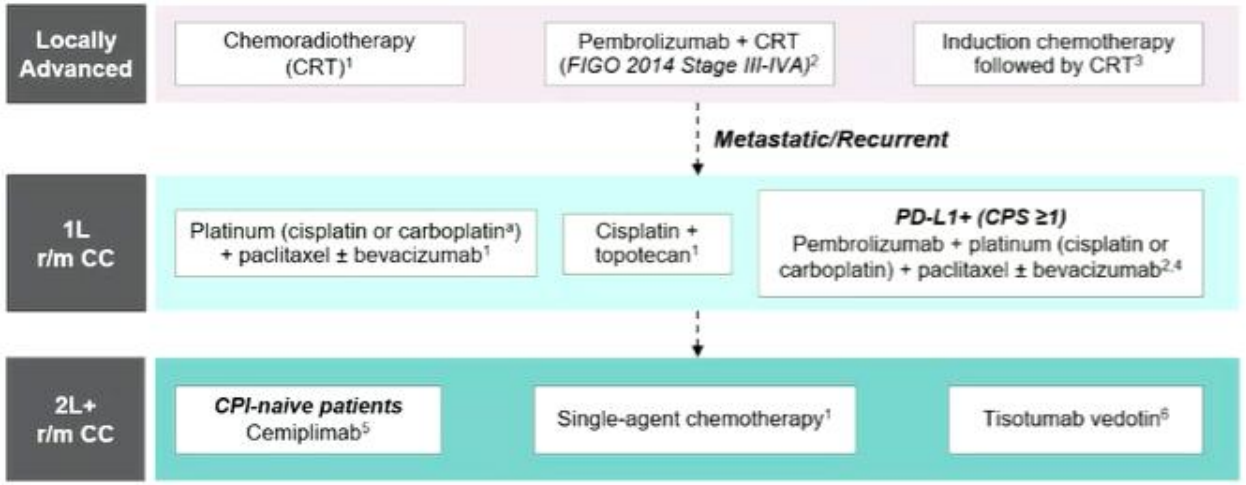
EU-5, France, Germany, Italy, Spain, United Kingdom.
[a]US, distant (disease has metastasized), EU-5 and Japan, Stage IVB.
1. Pfaendler KS, Tewari KS. *Am J Obstet Gynecol*. 2016;214:22-30. **2.** SEER Cancer Stat Facts: *Cervical Cancer*. Accessed September 23, 2025. https://seer.cancer.gov/statfacts/html/cervix.html **3.** CancerMPact® Treatment Architecture Cervical Cancer, EU5. Published May 2025. **4.** CancerMPact® Treatment Architecture Cervical Cancer, Japan. Published May 2025.

Overview of Treatment for Cervical Cancer

Based on EU guidelines, EU approvals, and local practice



- The recent evolution of the treatment landscape for locally advanced and r/m CC has raised new questions around optimal sequencing in the post-immunotherapy era[7,8]
- Limited treatment options available for r/m CC when disease progression occurs after first-line combination therapy[9]

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1L, first-line; 2L, second-line; CC, cervical cancer; CPI, checkpoint inhibitor; CPS, combined positive score; CRT, chemoradiotherapy Checkpoint inhibitor; EU, European Union; FIGO, International Federation of Gynecology and Obstetrics; r/m, recurrent/metastatic.
[a]Carboplatin preferred for patients previously treated with cisplatin therapy.

1. Marth C, et al. *Ann Oncol* 2017;28(Suppl 4):iv72-iv83. **2.** Keytruda. Summary of Product Characteristics. Last updated June 2025. **3.** McCormack M, et al. *Lancet* 2024;404:525-1535. **4.** Cibula D, et al. *Int J Gynecol Cancer* 2023;33:649-666. **5.** Libtayo. Summary of Product Characteristics. Last updated September 2024. **6.** Tivdak. Summary of Product Characteristics. Last updated June 2025. **7.** García E, Ayoub N, Tewari KS. *J Gynecol Oncol* 2024;35:e30. **8.** Giudice E, Mirza MR, Lorusso D. *Curr Oncol Rep* 2023;25:1307-1326. **9.** Vergote I, et al. *N Engl J Med* 2024;391:44-55. **10.** FDA approves tisotumab vedotin-tftv for recurrent or metastatic cervical cancer. Accessed September 23, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tisotumab-vedotin-tftv-recurrent-or-metastatic-cervical-cancer **11.** European Medicines Agency. Tivdak. https://www.ema.europa.eu/en/medicines/human/EPAR/tivdak Last updated June 2025. **12.** TIVDAK® Approved by Japan Ministry of Health, Labour and Welfare. Accessed September 23, 2025. https://ir.genmab.com/news-releases/news-release-details/tivdakr-tisotumab-vedotin-approved-japan-ministry-health-labour

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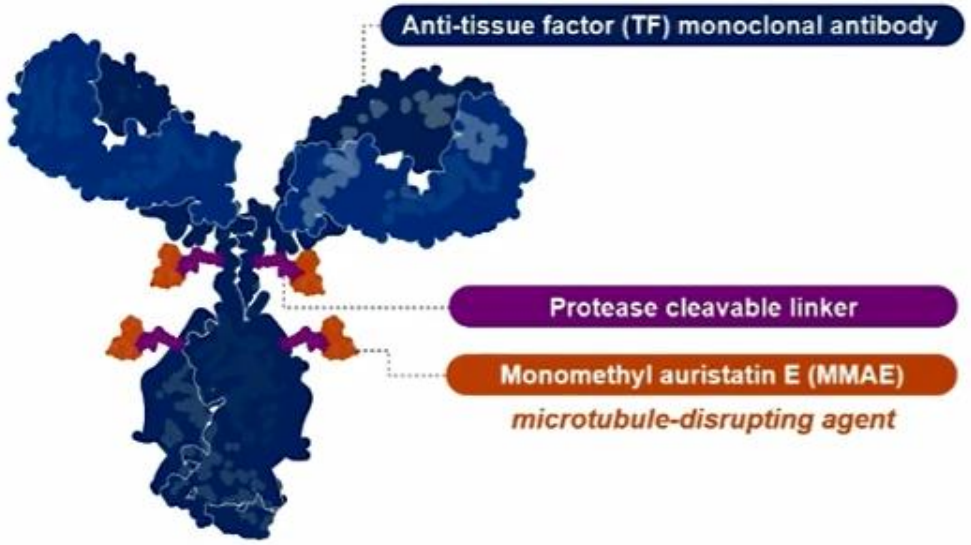
Key Elements of Tisotumab Vedotin (TV)

TV is a Human IgG1 monoclonal antibody conjugated to MMAE[1]



Tisotumab vedotin

Tisotumab vedotin is an antibody-drug conjugate composed of:

- **Antibody:** fully human IgG1 monoclonal antibody targeting a unique epitope of tissue factor (TF) – HuMax-TF
- **Linker:** protease-cleavable valine-citrulline linker
- **Payload:** microtubule-disrupting agent monomethyl auristatin E (MMAE)

Tisotumab vedotin was developed by Genmab in collaboration with Pfizer utilizing their antibody-drug linker technology[2]

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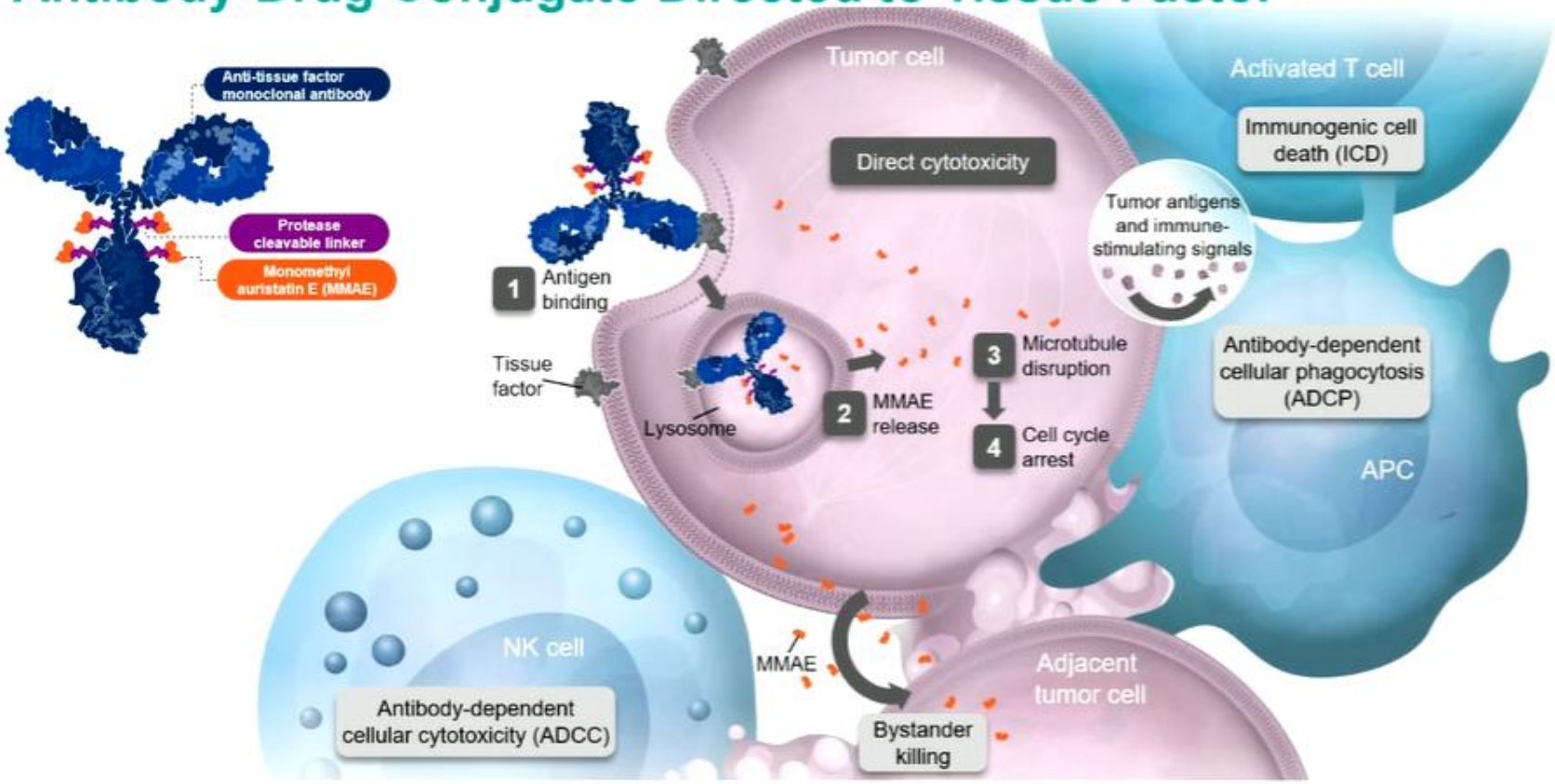
1. Breij ECW, et al. *Cancer Res*. 2014;4:1214-1226. 2. Genmab. [News release]. Accessed August 9, 2025. https://ir.genmab.com/news-releases/news-release-details/tivdak-tisotumab-vedotin-approved-european-commission

Tisotumab Vedotin Proposed Mechanism of Action for an Antibody-Drug Conjugate Directed to Tissue Factor[a,1-4]



APC, antigen-presenting cell; NK, natural killer.
[a]Tisotumab vedotin is an investigational agent in some settings, and its safety and efficacy have not been established.

1. Breij ECW, et al. *Cancer Res*. 2014;4:1214-1226. **2.** De Goeij BECG, et al. *Mol Cancer Ther*. 2015;14:1130-1140. **3.** Alley SC, et al. *Cancer Res*. 2019;7(13_Suppl): 221.
4. Tivdak. Summary of Product Characteristics. Last updated June 2025.

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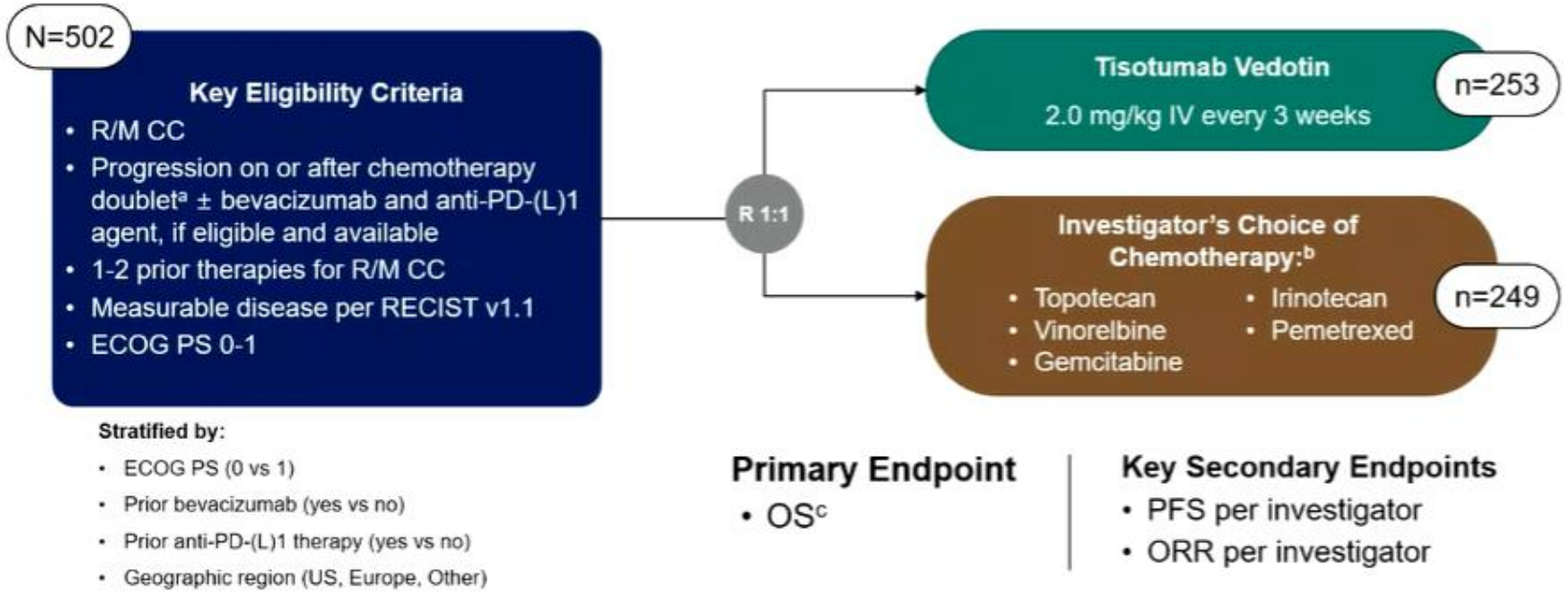
innovaTV 301 Study Design[1,2]

innovaTV 301 is a global, randomized, open-label, phase 3 trial of tisotumab vedotin vs chemotherapy in patients with 2L/3L R/M CC



Stratified by:

- ECOG PS (0 vs 1)
- Prior bevacizumab (yes vs no)
- Prior anti-PD-(L)1 therapy (yes vs no)
- Geographic region (US, Europe, Other)

Primary Endpoint

- OS[c]

Key Secondary Endpoints

- PFS per investigator
- ORR per investigator

2L, second-line; 3L, third-line; CC, cervical cancer; ECOG, Eastern Cooperative Oncology Group; IV, intravenous; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand; PFS, progression-free survival; PS, performance status; R, randomized; RECIST, Response Evaluation Criteria in Solid Tumors; R/M, recurrent or metastatic.

[a]Standard-of-care systemic chemotherapy doublet defined as paclitaxel + cisplatin, or paclitaxel + topotecan/nogitecan. [b]Chemotherapy regimens were given at the following doses: topotecan: 1 or 1.25 mg/m² IV on Days 1 to 5, every 21 days; vinorelbine: 30 mg/m² IV on Days 1 and 8, every 21 days; gemcitabine: 1000 mg/m² IV on Days 1 and 8, every 21 days; irinotecan: 100 or 125 mg/m² IV weekly for 28 days, every 42 days; pemetrexed: 500 mg/m² on Day 1, every 21 days. [c]OS was defined as the time from the date of randomization to the date of death due to any cause.

Modified from: **1.** Vergote I, et al. *N Engl J Med*. 2024;391:44-55. **2.** Tivdak. Summary of Product Characteristics. Last updated June 2025.

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innovaTV 301: Baseline Demographic and Disease Characteristics[1,2]

	Tisotumab vedotin (n=253)	Chemotherapy (n=249)
Age, median (range), years	51 (26-80)	50 (27-78)
Region, n (%)		
US	16 (6.3)	14 (5.6)
Europe	106 (41.9)	104 (41.8)
Asia	85 (33.6)	88 (35.3)
Other	46 (18.2)	43 (17.3)
Baseline ECOG PS, n (%)		
0	137 (54.2)	136 (54.6)
1	116 (45.8)	113 (45.4)
Biopsy evaluable, n (%)	210 (83.0)	194 (77.9)
Positive membrane TF expression[a]	194 (92.4)	183 (94.3)
Prior systemic therapy or radiation for cervical cancer, n (%)	253 (100)	249 (100)
Prior bevacizumab	164 (64.8)	157 (63.1)
Prior anti–PD-(L)1 therapy	71 (28.1)	67 (26.9)
Prior radiation therapy for cervical cancer	205 (81.0)	203 (81.5)
Prior recurrent/metastatic systemic regimens, n (%)[b]		
1	159 (62.8)	149 (59.8)
2	93 (36.8)	100 (40.2)

Data cutoff: July 24, 2023.
ECOG, Eastern Cooperative Oncoloty Group; PD-(L)1, programmed cell death (ligand) 1; PS, performance status; TF, tissue factor.
[a]TF expression is defined as TF membrane expression ≥1% with immunohistochemistry; percentages are calculated based on number of evaluable biopsies. [b]One patient in the tisotumab vedotin arm had an unknown number of prior systemic regimens.
Modified from: **1.** Vergote I, et al. *N Engl J Med*. 2024;391:44-55. **2.** Slomovitz BM, et al. 2024 SGO Annual Meeting; March 16-18, 2024, San Diego, California, USA. From The New England Journal of Medicine, I. Vergote, et al. Tisotumab Vedotin as Second- or Third-Line Therapy for Recurrent Cervical Cancer, Volume 391, Pages 44-55. Copyright © 2024 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

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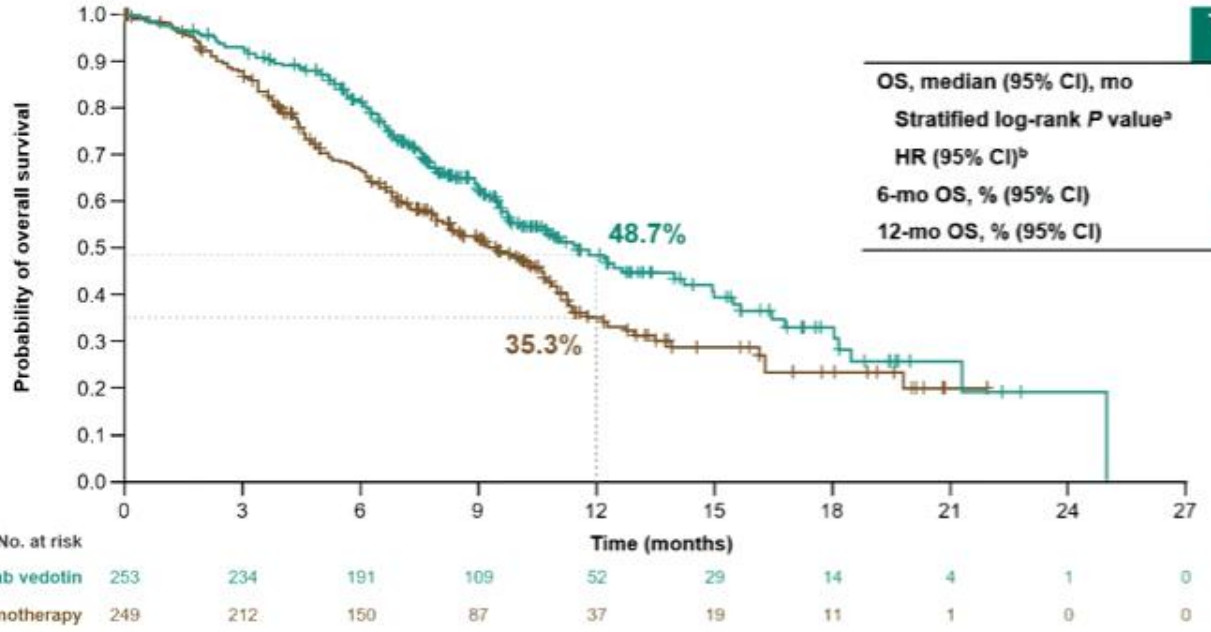
innovaTV 301: Overall Survival (Primary Endpoint)[1]

Tisotumab vedotin demonstrated a statistically significant improvement in OS, with a 30% reduction in the risk of death (HR 0.70 [95% CI 0.54-0.89]; *P*=0.004)



	Tisotumab vedotin (n=253)	Chemotherapy (n=249)
OS, median (95% CI), mo	11.5 (9.8–14.9)	9.5 (7.9–10.7)
Stratified log-rank *P* value[a]	0.004	
HR (95% CI)[b]	0.70 (0.54–0.89)	
6-mo OS, % (95% CI)	81.4 (75.9–85.7)	66.9 (60.5–72.5)
12-mo OS, % (95% CI)	48.7 (41.0–55.8)	35.3 (28.0–42.7)

Data cut off: July 24, 2023. Median follow-up time of 10.8 months (95% CI 10.3–11.6).
CI, confidence interval; HR, hazard ratio; IC, investigator's choice; OS, overall survival.
[a]The threshold for statistical significance was 0.0226 (two-sided) on the basis of the actual number of deaths at the interim analysis according to the Lan–DeMets spending function with an O'Brien–Fleming boundary. [b]HR was computed from the stratified Cox proportional hazards model using stratification factors at randomization, excluding region. Censored data are indicated as tick marks.

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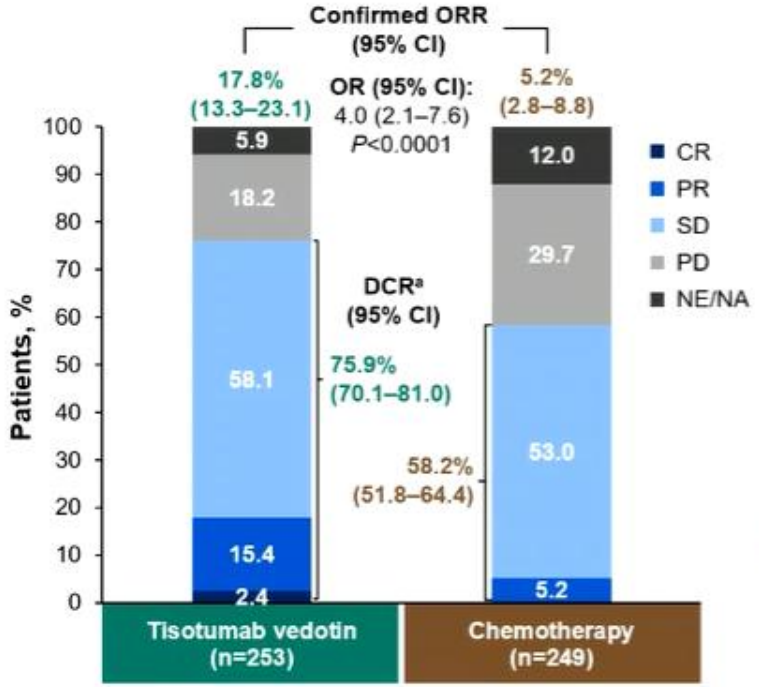
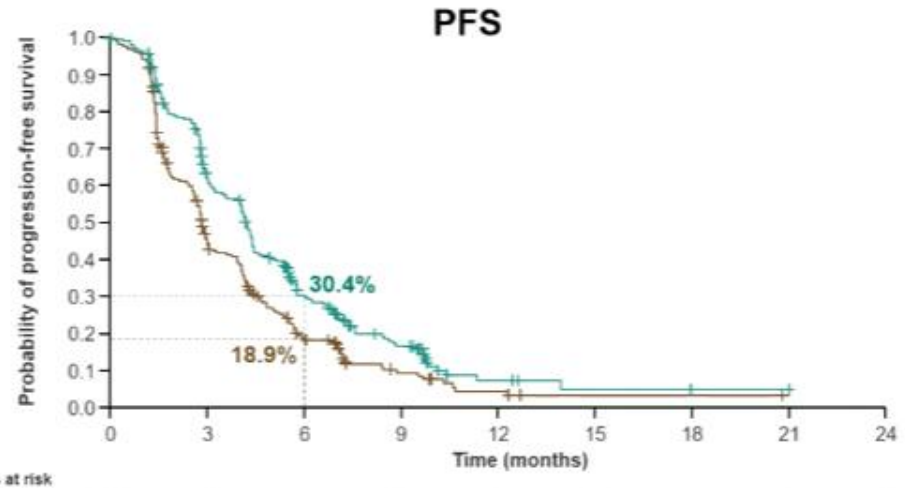
innovaTV 301: Response and PFS[1]





	Tisotumab vedotin (n=253)	Chemotherapy (n=249)
PFS, median (95% CI), mo	4.2 (4.0–4.4)	2.9 (2.6–3.1)
Stratified log-rank *P* value[b]	<0.001	
HR (95% CI)[c]	0.67 (0.54–0.82)	

Data cut off: July 24, 2023.
CR, complete response; DCR, disease control rate; DOR, duration of response; HR, hazard ratio; OR, odds ratio; ORR, objective response rate; NA, not available; NE, not evaluable; PD, progressive disease; PFS, progression-free survival; PR, partial response; SD, stable disease.
[a]DCR defined as CR+PR+SD; CR and PR were confirmed responses. The minimum criteria for SD duration was ≥5 weeks after the date of randomization. [b]The threshold for statistical significance was 0.0453 (two-sided) on the basis of the actual number of progression-free survival events at the interim analysis according to Lan–DeMets spending function with a Pocock boundary. [c]HR was computed from the stratified Cox proportional hazards model using stratification factors at randomization, excluding region. Censored data are indicated as tick marks.
Modified from: 1. Vergote I, et al. *N Engl J Med*. 2024;391:44-55. From The New England Journal of Medicine, I. Vergote, et al. Tisotumab Vedotin as Second- or Third-Line Therapy for Recurrent Cervical Cancer, Volume 391, Pages 44-55. Copyright © 2024 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

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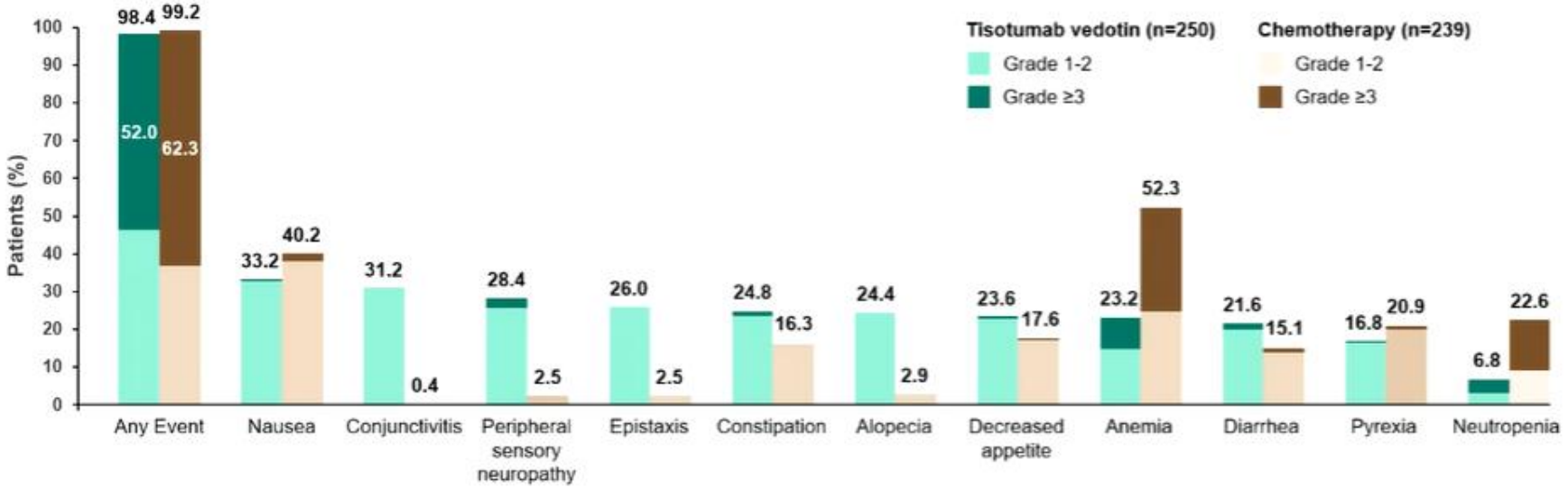
innovaTV 301: Most Common TEAEs (≥20% in Either Arm)[1]



- Overall, the incidence of any grade TRAEs was similar across arms (tisotumab vedotin: 87.6% vs chemotherapy: 85.4%)
  - 29.2% of patients experienced grades ≥3 TRAEs on the tisotumab vedotin arm vs 45.2% on the chemotherapy arm

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Reported by preferred term. Adverse events that led to death occurred in 4 (1.6%) and 5 (2.1%) patients in the tisotumab vedotin and chemotherapy arms, respectively.
TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

1. Vergote I, et al. *N Engl J Med*. 2024;391:44-55.

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innovaTV 301: AESIs Associated With Tisotumab Vedotin[1,2]

- The only grade 4 AESIs were bleeding events that occurred in 1 patient in each arm
- No grade 5 AESIs and no grade 4 ocular or peripheral neuropathy events were observed

	Tisotumab vedotin (n=250)			
Treatment-emergent AESI, n (%)	**Grade 1**	**Grade 2**	**Grade ≥3**	**Any grade**
Any ocular event	**49 (19.6)**	**73 (29.2)**	**10 (4.0)**	**132 (52.8)**
Conjunctivitis	37 (14.8)	41 (16.4)	0	
Keratitis	9 (3.6)	25 (10.0)	5 (2.0)	
Dry eye	23 (9.2)	10 (4.0)	0	
Time to onset of first ocular event, median (range), mo				**1.22 (0–4.9)**
Time to resolution[a] of first ocular event, median (range), mo				**0.59 (0.1–12.6)**
Any peripheral neuropathy event	**32 (12.8)**	**50 (20.0)**	**14 (5.6)**	**96 (38.4)**
Peripheral sensory neuropathy	21 (8.4)	43 (17.2)	7 (2.8)	
Time to onset of first PN event, median (range), mo				**2.38 (0–9.3)**
Time to resolution[a] of first PN event, median (range), mo				**1.12 (0–12.1)**
Any bleeding event	**80 (32.0)**	**19 (7.6)**	**6 (2.4)**	**105 (42.0)**
Epistaxis	62 (24.8)	3 (1.2)	0	
Vaginal hemorrhage	18 (7.2)	4 (1.6)	3 (1.2)	
Hematuria	12 (4.8)	5 (2.0)	1 (0.4)	
Time to onset of first bleeding event, median (range), mo				**0.43 (0–10.4)**
Time to resolution[a] of first bleeding event, median (range), mo				**0.26 (0–7.2)**

AESI, adverse event of special interest; PN, peripheral neuropathy.
Most common (≥5%) preferred terms for each AESI category are shown for each category.
[a]Time to resolution is defined as time from the start date of the event to the end date of the same event.
Modified from: **1.** Vergote I, et al. *N Engl J Med*. 2024;391:44-55. **2.** Sánchez LM. ASCO 2024, May 31–June 14, 2024, Chicago, IL, USA. Poster 5531.

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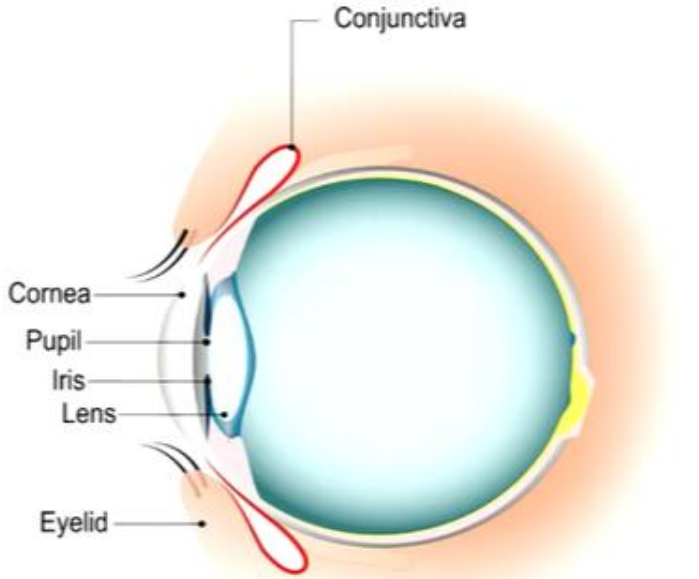
Mechanism of Ocular AEs with Tisotumab Vedotin

- Tissue factor levels have been demonstrated in the ocular epithelium, including the conjunctiva[1]
- Ocular AEs are likely driven by **targeted delivery of MMAE to TF-expressing cells in the ocular epithelium**[1]
  - Different mechanism from keratopathies seen with non-antigen–mediated ADC uptake
- innovaTV 204 and 301 trials showed these ocular AEs were primarily mild to moderate and confined to the ocular surface[a,1-3]



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ADC, antibody-drug conjugate; AE, adverse event; MMAE, monomethyl auristatin E; TF, tissue factor.
[a]Grade 3 ocular adverse reactions occurred in 3% of patients. Cases of grade 3 ulcerative keratitis were reported in 1.2% of patients. Grade 4 ocular adverse reactions occurred in 0.2% of patients, including ulcerative keratitis.[4]

1. Kim SK, et al. *Gynecol Oncol*. 2022;165:385-392. **2.** Coleman RL, et al. *Lancet Oncol*. 2021;22:609-619. **3.** Vergote I, et al. *N Engl J Med*. 2024;391:44-55. **4.** Tivdak. Summary of Product Characteristics. Last updated June 2025.

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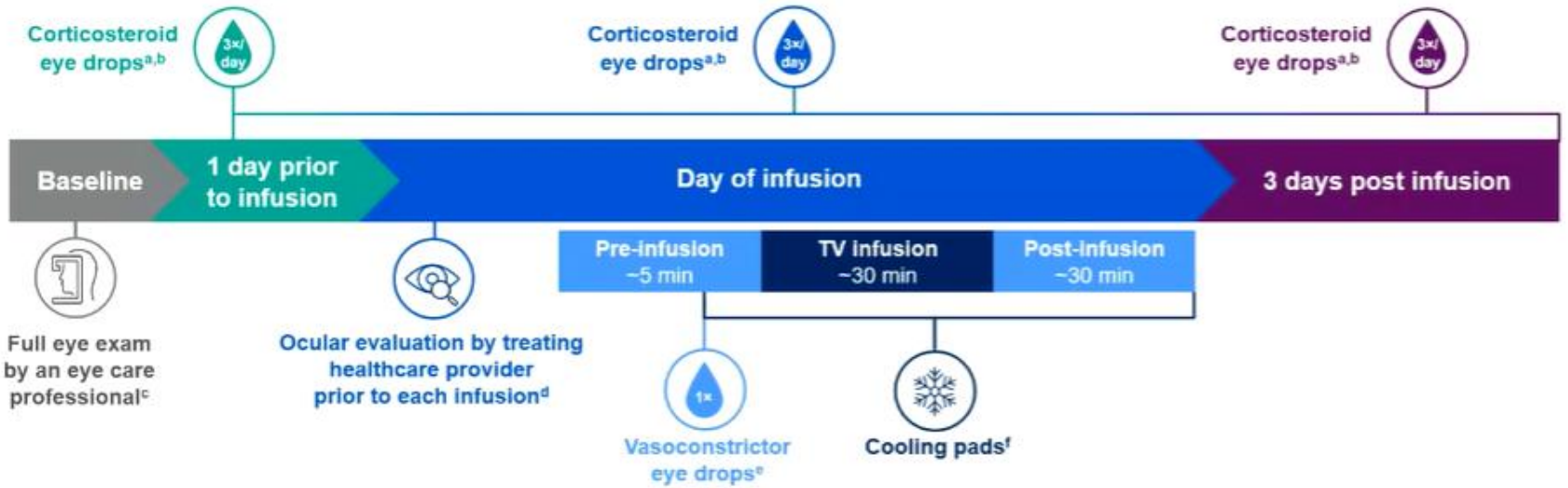
Required Eye Care Management in Patients Receiving Tisotumab Vedotin Monotherapy[1,2]



- **Lubricating eye drops:** multiple times every day throughout treatment and for 30 days after the last dose
- **Avoid contact lens use** for the entire duration of therapy

[a]All eye drops (corticosteroid, vasoconstrictor, and lubricating) should be preservative-free. [b]Administer steroid eye drops (dexamethasone 0.1% or equivalent) before and after each infusion for a total of 4 days, starting 24 hours prior to start of each infusion. Continue treatment for 72 hours thereafter. Steroid eye drops should be administered as 1 drop in each eye, 3 times daily, or used in accordance with the product prescribing information.[1,2] [c]At baseline and as clinically indicated. Eye exam should include visual acuity and slit lamp exam. [d]Eye inspection should include visual inspection of the eyes, including control of normal eye movement. Patients should be asked about any ocular signs or symptoms and monitored for new or worsening ocular signs and symptoms. Refer to an eye care professional if warranted. [e]Administer ocular vasoconstrictor, brimonidine tartrate 0.2%, 3 drops (or equivalent) in each eye immediately prior to start of infusion.[1,2] [f]Cooling pads must cover both eyes (such as an eye mask or cold pack/s) and should be applied prior to start of infusion in accordance with the instructions provided with the eye cooling pads. The cooling pads must remain on the patient's eyes during the entire 30-minute infusion and for as long as 30 minutes afterward.[1,2] Change as needed to ensure eye area remains cold.

1. Tivdak. Summary of Product Characteristics. Last updated June 2025. Modified from: **2.** Kim SK, et al. *Gynecol Oncol*. 2022;165:385-392. Reprinted from Gynecologic Oncology, Vol 165, Stella K Kim, et al, Mitigation and management strategies for ocular events associated with tisotumab vedotin, pp385-392, Copyright 2022, with permission from Elsevier.

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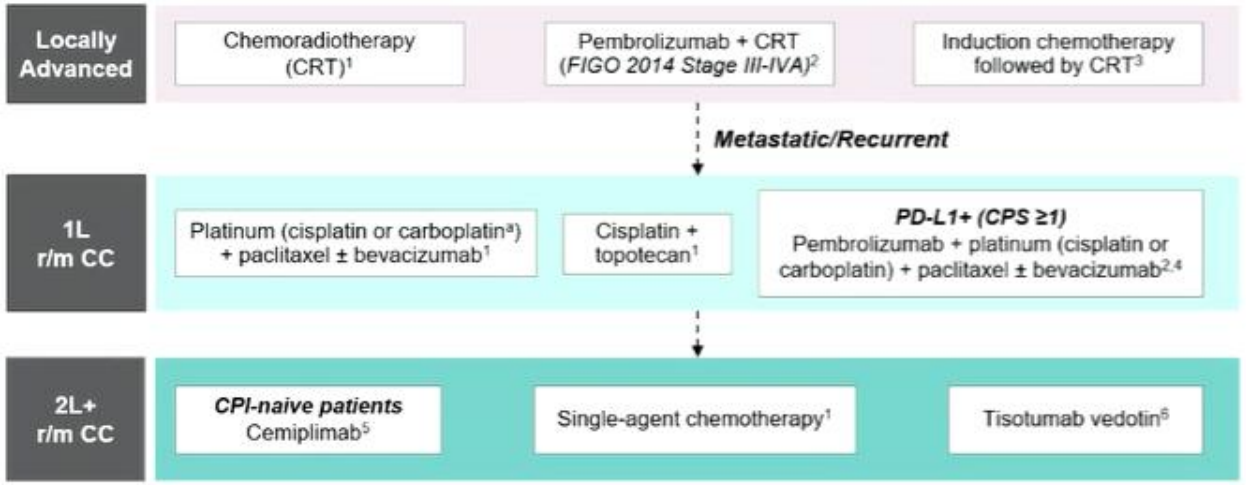
Overview of Treatment for Cervical Cancer

Based on EU guidelines, EU approvals, and local practice



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- Limited treatment options available for r/m CC when disease progression occurs after first-line combination therapy[9]

1L, first-line; 2L, second-line; CC, cervical cancer; CPI, checkpoint inhibitor; CPS, combined positive score; CRT, chemoradiotherapy Checkpoint inhibitor; EU, European Union; FIGO, International Federation of Gynecology and Obstetrics; r/m, recurrent/metastatic.
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1. Marth C, et al. *Ann Oncol*. 2017;28(Suppl 4):iv72-iv83. **2.** Keytruda. Summary of Product Characteristics. Last updated June 2025. **3.** McCormack M, et al. *Lancet*. 2024;404:525-1535. **4.** Cibula D, et al. *Int J Gynecol Cancer*. 2023;33:649-666. **5.** Libtayo. Summary of Product Characteristics. Last updated September 2024. **6.** Tivdak. Summary of Product Characteristics. Last updated June 2025. **7.** García E, Ayoub N, Tewari KS. *J Gynecol Oncol*. 2024;35:e30. **8.** Giudice E, Mirza MR, Lorusso D. *Curr Oncol Rep*. 2023;25:1307-1326. **9.** Vergote I, et al. *N Engl J Med*. 2024;391:44-55.

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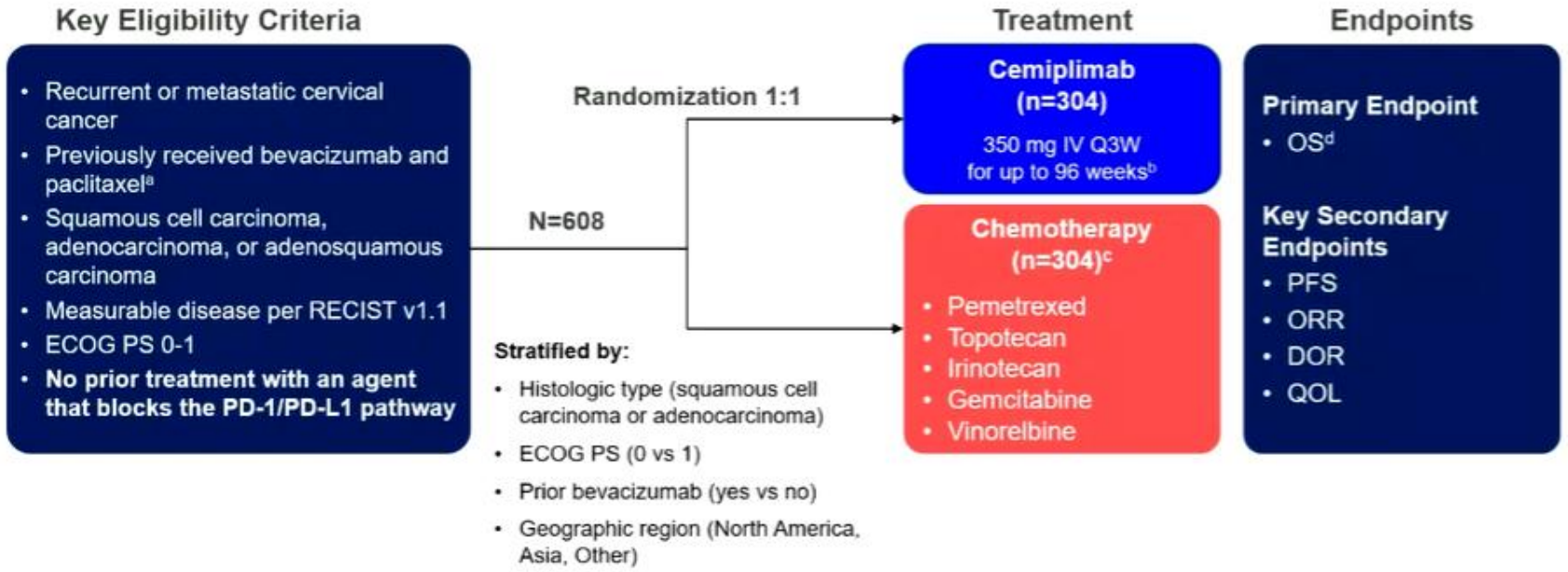
EMPOWER-Cervical 1: Study Design[1,2]

Randomized, open-label, phase 3 trial of cemiplimab vs chemotherapy in patients with 2L+ anti-PD-1/anti-PD-L1–naive R/M CC



2L, second-line; CC, cervical cancer; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; IV, intravenous; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand; PFS, progression-free survival; PS, performance status; QOL, quality of life; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; R/M, recurrent or metastatic.
[a]Unless declined, unsuitable, or unable to access. [b]Patients had option for repeat treatment if 16 treatment cycles had been completed and then had progressive disease in post-treatment follow-up period. [c]Chemotherapy regimens were given at the following doses: pemetrexed: 500 mg/m^2 on Day 1, every 21 days; topotecan: 1 or 1.25 mg/m^2 IV on Days 1 to 5, every 21 days; irinotecan: 100 mg/m^2 IV weekly for 28 days, every 6 weeks; gemcitabine: 1000 mg/m^2 IV on Days 1 and 8, every 21 days; vinorelbine: 30 mg/m^2 IV on Days 1 and 8, every 21 days. [d]OS was defined as the time from randomization to the date of death. A patient who had not died was censored at the last known alive date.

1. Tewari KS, et al. *N Engl J Med*. 2022;386:544-555. 2. Libtayo. Summary of Product Characteristics. Last updated September 2024.

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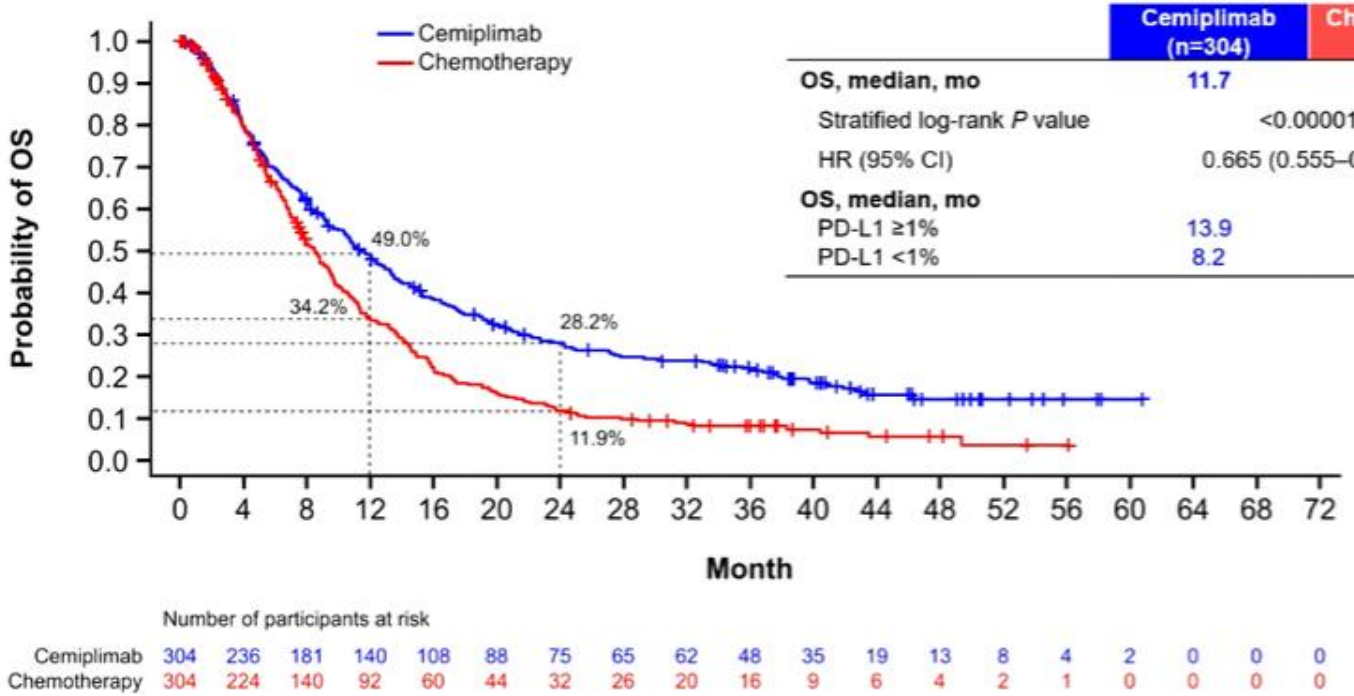
EMPOWER-Cervical 1: Final Analysis of OS[1]



	Cemiplimab (n=304)	Chemotherapy (n=304)
OS, median, mo	11.7	8.5
Stratified log-rank *P* value	<0.00001	
HR (95% CI)	0.665 (0.555–0.796)	
OS, median, mo		
PD-L1 ≥1%	13.9	9.3
PD-L1 <1%	8.2	6.7

Data cut-off: April 20, 2023.
CI, confidence interval; HR, hazard ratio; OS, overall survival; PD-L1, programmed cell death ligand 1.
Modified from: **1.** Oaknin A, et al. *Eur J Cancer*. 2025;216:115146. Reprinted from European Journal of Cancer, Vol 216, Ana Oaknin, et al, Cemiplimab in recurrent cervical cancer: Final analysis of overall survival in the phase III EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9 trial, 115146, Copyright 2025, with permission from Elsevier.

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EMPOWER-Cervical 1: Safety Overview[1]

Any TEAE, n (%)	Cemiplimab (n=300)	Chemotherapy (n=290)
Overall	269 (89.7)	266 (91.7)
Grade ≥3	141 (47.0)	156 (53.8)
Grade 3-4	136 (45.3)	154 (53.1)
Grade 5	5 (1.7)	2 (0.7)
Led to discontinuation	27 (9.0)	15 (5.2)
Led to death	5 (1.7)	2 (0.7)

For the cemiplimab vs chemotherapy arm:

- Treatment-related AEs occurred in 57.3% vs 81.7% of patients
- AESIs occurred in 12% vs 0 patients

Occurred in ≥10% in either group, n (%)	Cemiplimab (n=300)	Chemotherapy (n=290)
Gastrointestinal disorders		
Nausea	57 (19.0)	99 (34.1)
Vomiting	50 (16.7)	68 (23.4)
Constipation	45 (15.0)	58 (20.0)
Diarrhea	34 (11.3)	39 (13.4)
Abdominal pain	30 (10.0)	33 (11.4)
General disorders and administration-site conditions		
Fatigue	51 (17.0)	45 (15.5)
Pyrexia	39 (13.0)	62 (21.4)
Asthenia	35 (11.7)	44 (15.2)
Metabolism and nutrition disorders		
Decreased appetite	46 (15.3)	46 (15.9)
Blood and lymphatic system disorders		
Anemia	77 (25.7)	128 (44.1)
Neutropenia	6 (2.0)	45 (15.5)
Musculoskeletal and connective tissue disorders		
Arthralgia	33 (11.0)	8 (2.8)
Back pain	32 (10.7)	28 (9.7)

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Data cut-off: April 20, 2023.
AE, adverse event, AESI, adverse event of special interest; TEAE, treatment-emergent adverse event.
Modified from: **1.** Oaknin A, et al. *Eur J Cancer*. 2025;216:115146. Supplementary Material. Reprinted from European Journal of Cancer, Vol 216, Ana Oaknin, et al, Cemiplimab in recurrent cervical cancer: Final analysis of overall survival in the phase III EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9 trial, 115146, Copyright 2025, with permission from Elsevier.

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Summary

Treatment options for r/m CC are limited following progression on 1L combination therapy, particularly after prior CPI exposure[1,2]

Tisotumab vedotin is a human IgG1 monoclonal antibody targeting tissue factor conjugated to MMAE via a protease-cleavable linker[1,3]

- In a phase 3 trial comparing tisotumab vedotin vs chemotherapy in 2L/3L r/m CC, including patients exposed to an anti–PD-(L)1 agent:[1]
  - Tisotumab vedotin demonstrated a statistically significant improvement in OS, reducing the risk of death by 30%
  - There was a similar incidence of any-grade TEAEs: 98.4% vs 99.2%; there were no grade 5 AESIs or grade 4 ocular or peripheral neuropathy events observed with tisotumab vedotin[a]
  - Implementation of an eye care plan has shown reduction in the risk of ocular adverse events[4]

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1L, first-line; 2L, second-line; 3L, third-line; AESI, adverse event of special interest; CC, cervical cancer; CPI, checkpoint inhibitor; IgG1, immunoglobulin G1; MMAE, monomethyl auristatin; OS, overall survival; PD-L1, programmed death-ligand; R/M, recurrent or metastatic; TEAE, treatment-emergent adverse event.
[a]The only grade 4 AESIs were bleeding events that occurred in 1 patient in each arm.
1. Vergote I, et al. *N Engl J Med*. 2024;391:44-55. **2.** Giudice E, Mirza MR, Lorusso D. *Curr Oncol Rep*. 2023;25:1307-1326. **3.** Breij ECW, et al. *Cancer Res*. 2014;4:1214-1226. **4.** Kim SK, et al. *Gynecol Oncol*. 2022;165:385-392.

For Additional Information & Educational Materials

For any additional information regarding Tisotumab Vedotin, or requests for available educational materials including those on adverse event management, please contact Medical Information at **EURmedinfo@genmab.com**

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