1L TV+pembrolizumab (pembro, arm E), and second-line/third-line (2L/3L) TV +pembro (arm F). Primary endpoint was investigator-assessed overall response rate (ORR). Secondary endpoints were duration of response (DOR), progression-free survival (PFS), OS, and adverse events (AEs).

Results: As of February 12, 2025, 101 patients with r/mCC were enrolled in arms D (n=33), E (n=33), and F (n=35) (median FU: 51, 58, and 58 mo, respectively). ORR and median DOR, respectively, were 54.5% and 8.6 mo in arm D, 40.6% mo and not reached (NR) in arm E, and 35.3% and 14.1 mo in arm F. As previously reported, median PFS was 6.9, 5.3, and 5.6 mo in arms D, E, and F, respectively. Median OS was 25.5 mo (OS previously NR), 30.7 mo (OS previously NR), and 15.3 mo in arms D, E, and F, respectively. The most common grade $\geq$3 AE was anemia (12–39% across all arms). One grade 2 ocular AE led to TV discontinuation in arm D shortly after prior report; no new AEs led to discontinuation in arms E and F.

Conclusions: In one of the longest survival FU for a prospective study of patients with r/mCC, TV-doublets led to long-term clinical benefit in 1L and 2L/3L r/mCC, with notable median OS >2 y with 1L TV+carbo and >2.5 y with 1L TV+pembro. No new safety signals were observed. Further investigation of these TV-doublets in r/mCC is warranted.

Clinical trial identification: NCT03786081, 2018-12-24.

Editorial acknowledgement: Medical writing assistance was provided by Braden Roth and Amy Zannikos of Peloton Advantage, LLC, an OPEN Health company, and funded by Genmab A/S and Pfizer Inc.

Legal entity responsible for the study: Genmab A/S and Pfizer Inc.

Funding: Genmab A/S and Pfizer Inc.

Disclosure: B.J. Monk: Financial Interests, Personal, Speaker, Consultant, Advisor: Acrivon, Adaptimmune, Agenus, Akeso, Amgen, Aravive, AstraZeneca, Bayer, Clovis Oncology, Eisai, Elevar, EMD Serono/Merck, Genmab, Seagen, GSK/Tesaro, GOG Foundation, Gradalis, Hengrui, ImmunoGen, Karyopharm, Iovance, Laekna, MacroGenics, Merck, Mersana, Myriad, Novartis, Novocure, OncoC4, Panavance, Pieris, Pfizer, Puma, Regeneron, Roche/Genentech, Sorrento, US Oncology Research, VBL, Verastem, Zentalis; Financial Interests, Personal, Other, Payment or honoraria for lectures, presentations, speaker bureaus, manuscript writing, or educational events: AstraZeneca, Eisai, GSK/Tesaro, Myriad, Roche/Genentech. E. 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No personal compensation received: AstraZeneca, Genmab, Cercept; Non-Financial Interests, Principal Investigator, PI of clinical trial. No personal compensation received: Clovis Oncology, Immunogen, Incyte, Roche; Non-Financial Interests, Principal Investigator, PI of several trials, no compensation received: GSK; Non-Financial Interests, Principal Investigator, PI in several trials. No personal compensation received: MSD; Non-Financial Interests, Principal Investigator, PI of several trials, no personal compensation received: Novartis; Non-Financial Interests, Principal Investigator, PI of clinical trials, no personal compensation received: PharmaMar; Non-Financial Interests, Principal Investigator, PI of clinical trial, no personal compensation received: Seagen; Non-Financial Interests, Member, Board of Directors: GCIG; Non-Financial Interests, Member, President Elected: MITO; Non-Financial Interests, Member, Coordinating: ENGOT; Other, Grants for traveling: AstraZeneca, Menarini, Clovis Oncology, GSK. R.E. 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D.C. Collins: Financial Interests, Personal, Speaker, Consultant, Advisor: Genmab, GSK, MSD Oncology, Seagen; Financial Interests, Personal, Research Funding: Pfizer, Roche; Financial Interests, Personal, Other, Honoraria: Amgen, AZAD, GSK, Janssen, MSD Oncology, Pfizer. A.L. Jackson: Financial Interests, Personal, Invited Speaker: Onclive; Financial Interests, Personal, Advisory Board: Ethicon; Financial Interests, Personal, Other, Variance provider: Planned Parenthood. K. Madsen: Financial Interests, Personal, Other, Travel expenses: GSK/Tesaro, Pierre Fabre Norden, Roche; Financial Interests, Personal, Other, Deputy medical director at NSGO-CTU and/or principal investigator/sub-principal investigator working on pharmaceutical studies: Apexigen, AstraZeneca, Genmab, GSK/Tesaro, Kancera, Mersana, MSD, Novartis, Roche, Seagen, Spago Nanomedical. C. 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U. Conte: Financial Interests, Personal, Other, Employee: Pfizer. K. Windfeld, H. Hansen: Financial Interests, Personal, Other, Employee: Genmab. I. Vergote: Financial Interests, Personal, Speaker, Consultant, Advisor: AbbVie, Agenus, Akesobio, AstraZeneca, Bristol Myers Squibb, Corcept, Daiichi Sankyo, Eisai, F. Hoffmann-La Roche, Genmab, GSK, Immunogen, ITM, Karyopharm, Kronos Bio, Mersana, MSD, Novartis, Novocure, Oncoinvent, OncXerna, Regeneron, Sanofi, Seagen, Verastem Oncology, Zentalis. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2025.08.1802

1167P Transcriptomic tumor microenvironment subtypes in cervical cancer reveal prognostic and therapeutic opportunities

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Background: Advanced cervical cancer persists despite HPV prevention. Patients often experience suboptimal outcomes due to limited treatment stratification and lack of predictive biomarkers. While the tumor microenvironment (TME) influences carcinogenesis and therapy response, it remains understudied in cervical cancer, especially in the context of HPV-driven oncogenesis. To address these gaps, we developed a TME-based transcriptomic classification to identify targetable features for each TME subtype.

Methods: RNA-seq data (n=949) from 6 open-source datasets were clustered using the Leiden algorithm based on ssGSEA-derived gene signatures scores (Bagaev et al., 2021). From these samples, whole-exome sequencing (n=377) and HPV16 gene expression (n=213) data were analyzed using the BostonGene pipeline. TCGA proteomics data (n=172) were also assessed for HPV-targeted protein activity. Signaling pathway activity was evaluated with PROGENy. Log-rank, Mann-Whitney U, and Chi-square tests were used to assess survival, quantitative values, and categorical associations between TME subtypes, respectively.

Results: We identified 5 distinct TME subtypes in cervical cancer, each characterized by specific molecular features that may serve as therapeutic targets (Table). IEF and IE were linked to better overall survival (P=0.01) and may benefit from immune checkpoint inhibitor (ICI) therapy. FH may respond to HPV E6/E7-targeted therapies, while FA may respond to emergent anti-fibrotic therapies. FA and FH were linked to poorer prognosis (P=0.01). Lastly, D may benefit from RAS/MAPK and PI3K-AKT-targeted therapies.

Table: 1167P Key features of cervical cancer TME subtypes

Subtype	TME features	Key molecular findings	P value
Immune-Enriched Fibrotic (IEF) (18%)	Immune and stromal-rich	Overexpression of *CTLA4*	<0.001
Immune-Enriched Non-Fibrotic (IE) (27%)	Immune-dominant	*CD274* amplification Overexpression of *CD274*	0.01 <0.001
Fibrotic Hypoxic (FH) (26%)	Hypoxic, moderately stromal	Overexpression of HPV16 E6/E7 Downregulation of E6/E7-targeted human proteins	<0.05 <0.001
Fibrotic Angiogenic (FA) (19%)	Highly fibrotic	Activation of TGFβ pathway	<0.001
Immune Desert (D) (10%)	Low TME, high tumor purity	*FBXW7* mutation *KRAS* mutation PI3K-AKT signaling alteration	0.02 0.005 0.009

Conclusions: Transcriptomic TME classification of cervical cancer yields new prognostic and therapeutic insights that underscore subtype-specific benefits of ICI, PI3K-, TGFβ-, and E6/E7-targeted therapies. Our findings support the use of precision treatment strategies that may improve patient outcomes.

Legal entity responsible for the study: BostonGene Corporation.

Funding: BostonGene Corporation.

Disclosure: V. Tomilova: Financial Interests, Personal, Full or part-time Employment: BostonGene Corporation; Financial Interests, Personal, Financially compensated role: BostonGene Corporation. A. Kravets: Financial Interests, Personal, Financially compensated role: BostonGene Corporation; Financial Interests, Personal, Full or part-time Employment: BostonGene Corporation; Financial Interests, Personal, Project Lead: BostonGene Corporation; Financial Interests, Personal, Stocks/Shares: BostonGene Corporation. S. Kurpe: Financial Interests, Personal, Financially compensated role: BostonGene Corporation; Financial Interests, Personal, Full or part-time Employment: BostonGene Corporation. A. Bagaev: Financial Interests, Personal, Financially compensated role: BostonGene Corporation; Financial Interests, Personal, Full or part-time Employment: BostonGene Corporation; Financial Interests, Personal, Leadership Role: BostonGene Corporation; Financial Interests, Personal, Stocks/Shares: BostonGene Corporation; Financial Interests, Personal, Project Lead: BostonGene Corporation. N. Kotlov: Financial Interests, Personal, Financially compensated role: BostonGene Corporation; Financial Interests, Personal, Full or part-time Employment: BostonGene Corporation; Financial Interests, Personal, Project Lead: BostonGene Corporation; Financial Interests, Personal, Stocks/Shares: BostonGene Corporation.

https://doi.org/10.1016/j.annonc.2025.08.1803

1168P Efficacy and safety of sacituzumab tirumotecan (Sac-TMT) monotherapy in advanced/metastatic cervical cancer: Results from a phase I/II study (MK-2870-001/KL264-01)

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Background: Treatment is limited for patients with advanced/metastatic cervical cancer who have progressed on prior therapy for advanced disease. Sac-TMT (MK-2870/SKB264) is a TROP2-directed ADC containing the cytotoxic topoisomerase I inhibitor payload KL610023. We report safety and efficacy from the cervical cancer cohort of the phase 1/2 study (NCT04152499).

Methods: Participants (pts) with locally advanced, unresectable or metastatic cervical cancer who progressed after ≥1 prior line of platinum-based chemotherapy in the advanced/metastatic setting and had ECOG PS 0 or 1 were included. Prior anti–PD-(L)1 therapy was required for pts with PD-L1 combined positive score ≥1. Previous bevacizumab was allowed. Sac-TMT 4 mg/kg Q2W was administered until PD, unacceptable toxicity, or withdrawal of consent. Primary endpoint was ORR per RECIST v1.1 by investigator. Secondary endpoints included DOR, PFS, and safety.

Results: As of data cutoff (Nov 18, 2024), 58 pts received at least 1 dose of sac-TMT 4 mg/kg, with a minimum of 25 wks follow-up. Median follow-up was 6.8 (range, 5.7–8.4) mo; median age was 55 y; all pts were Asian. 44 (76%) pts had high TROP2 expression (H-Score >200). Pts receiving 1, 2 or ≥3 prior lines of anti-cancer therapy were 22 (38%), 19 (33%) and 17 (29%), respectively; 31 (53%) received prior immunotherapy, and 36 (62%) received prior bevacizumab. At data cutoff, treatment was ongoing in 24 pts (41%). Confirmed ORR was 28% (95% CI, 17–41) (confirmed + unconfirmed ORR, 38% [95% CI, 26–52]); median DOR was not reached. Median PFS was 6.1 (95% CI, 3.9–NE) mo. Treatment-related AEs (TRAEs) occurred in 57 pts (98%). Grade 3–4 TRAEs occurred in 28 pts (48%); grade 3–4 TRAEs in ≥10% pts were anemia (26%), decreased neutrophil count (14%), and decreased white blood cell count (12%). No grade 5 TRAEs occurred, and TRAEs led to sac-TMT discontinuation in 1 pt (grade 3 anemia).

Conclusions: In pts with locally advanced, unresectable or metastatic cervical cancer, sac-TMT monotherapy showed promising antitumor activity and manageable safety. These data led to initiation of the ongoing phase 3 TroFuse-020 study of sac-TMT 4 mg/kg in advanced cervical cancer.

Clinical trial identification: NCT04152499.

Editorial acknowledgement: Medical writing assistance was provided by Lisa Denny, PhD, of ICON plc (Blue Bell, PA, USA). This assistance was funded by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Legal entity responsible for the study: Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd, Chengdu, China.

Funding: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Disclosure: J. Lee: Financial Interests, Personal, Invited Speaker: AstraZeneca, Takeda, MSD, Roche; Financial Interests, Personal, Advisory Board: Eisai, GI Innovation, Regeneron, Daiichi Sankyo, Genmab, Sutro, Merck, Seagen; Financial Interests, Institutional, Local PI: Alkermes, AstraZeneca, BerGenBio, Cellid, Clovis Oncology, Eisai, GI Innovation, ImmunoGen, Janssen, Merck, Mersana, MSD, Novartis, OncoQuest, Roche, Seagen, Synthon, Regeneron, Ascendis Pharma, Advenchen, BMS, Kelun, Sutro, GSK; Financial Interests, Personal and Institutional, Local PI: Beigene; Financial Interests, Personal, Steering Committee Member: AstraZeneca, OncoQuest, Seagen, ImmunoGen, MSD; Financial Interests, Institutional, Research Grant: Ono, Takeda, GSK; Financial Interests, Institutional, Other, Sub I: Corcept; Financial Interests, Institutional, Steering Committee Member: AbbVie; Financial Interests, Personal, Local PI: Zymeworks. M. Chen, Q. Chen, B. Akala: Financial Interests, Full or part-time Employment, may own stock in Merck & Co., Inc., Rahway, NJ, USA: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. X. Yu, D. Jing, J. Ge: Financial Interests, Full or part-time Employment: Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd., Chengdu, China. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2025.08.1804

1169P Non-cancer causes of death in survivors of cervical cancer

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Background: Research on non-cancer causes of death in patients with cervical cancer (CC) remains limited. This study aimed to evaluate and quantify the risks of mortality from non-cancer causes following a diagnosis of CC.

Methods: We performed a retrospective cohort study using data from the Surveillance, Epidemiology, and End Results (SEER) 17 registries in the U.S. (2000-2021) to assess causes of death for women diagnosed with CC stratified by demographics and tumor stage. Standardized mortality ratios (SMRs) for causes of death were calculated as observed-to-expected death ratios.

Results: A total of 67,145 patients diagnosed with cervical cancer were identified from the SEER database, of whom 24,830 (37.0%) died during the follow-up period. Over a period exceeding 10 years, 50% of patients died from non-cancer causes, although most deaths (87.7%) within the first 5 years following diagnosis were due to CC itself. Cardiovascular disease was identified as the leading non-cancer cause of death, accounting for 39% of deaths. Although rare, suicide, which accounted for 1% of deaths, should not be disregarded. Black patients had a higher likelihood of dying from non-cancer causes compared to other racial groups. Specifically, Black CC patients exhibited the highest risk of death from cardiovascular disease, with a subhazard ratio (sHR) of 3.01 (95% CI: 2.24–4.06).

Conclusions: For patients with a survival time exceeding 10 years, clinicians should shift their focus toward non-cancer causes of death, particularly cardiovascular diseases, which accounted for a substantial proportion of deaths among CC. These prompt clinicians to pay more attention to the risk of death caused by these non-cancer causes, which can provide relevant measures to intervene in advance.