

Oral Abstracts

Opening Ceremony and Plenary 1: Oral Abstract Presentations

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EMPOWER-CERVICAL 1/GOG-3016/ENGOT-CX9: RESULTS OF PHASE 3 TRIAL OF CEMIPIMAB VS INVESTIGATOR'S CHOICE CHEMOTHERAPY IN RECURRENT/METASTATIC CERVICAL CARCINOMA

¹K Tewari*, ²B Monk, ³I Vergote, ⁴A Miller, ⁵AC De Melo, ⁶HS Kim, ⁷YM Kim, ⁸A Lisyanskaya, ⁹V Samouelian, ¹⁰D Lorusso, ¹¹F Damian, ¹²C-L Chang, ¹³EA Gotovkin, ¹⁴S Takahashi, ¹⁵D Ramone, ¹⁶J Pikiel, ¹⁷J Li, ¹⁷M Mathias, ¹⁷MG Fury, ¹⁸A Oaknin.
¹University of California, Irvine, Division of Gynecologic Oncology, Orange, USA; ²Arizona Oncology (US Oncology Network) University of Arizona, Creighton University, Division of Gynecologic Oncology, Phoenix, USA; ³University Hospitals, Leuven, KU Leuven, Department of Obstetrics and Gynecology and Gynecologic Oncology, Leuven, Belgium; ⁴Roswell Park Comprehensive Cancer Center, Department of Biostatistics and Bioinformatics, Buffalo, USA; ⁵Brazilian National Cancer Institute, Division of Clinical Research, Rio de Janeiro, Brazil; ⁶Seoul National University Hospital, Department of Obstetrics and Gynecology, Seoul, Korea, Republic of; ⁷Asan Medical Center, University of Ulsan, Department of Obstetrics and Gynecology, Seoul, Korea, Republic of; ⁸St. Petersburg State Budgetary Institution of Healthcare, Department of Gynaecological Oncology, St. Petersburg, Russian Federation; ⁹CHUM, CRCHUM, Université de Montréal, Gynecology Oncology, Montreal, Canada; ¹⁰Fondazione Policlinico Universitario A Gemelli IRCCS and Catholic University of Sacred Heart, Gynaecology Oncology Unit, Rome, Italy; ¹¹Hospital Sao Lucas PUCRS, Gynaecology, Porto Alegre, Brazil; ¹²Mackay Memorial Hospital, Gynaecology, Taipei, Taiwan; ¹³State Budget Healthcare Institution Ivanovo Regional Oncology Dispensary, Gynaecology, Ivanovo, Russian Federation; ¹⁴The Cancer Institute Hospital of JFCR, Dep. of Medical Oncology, Tokyo, Japan; ¹⁵Barretos Cancer Hospital (Pio XII Foundation), Clinical Research Department, Barretos, Brazil; ¹⁶Szpital Pomorskie, Gynaecology, Gdynia, Poland; ¹⁷Regeneron Pharmaceuticals, Inc., Clinical Sciences Oncology, Tarrytown, USA; ¹⁸Vall d'Hebron Institute of Oncology (VHIO), Hospital Universitari Vall d'Hebron, Vall d'Hebron Barcelona Hospital Campus, Gynaecologic Cancer Programme, Barcelona, Spain

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Objectives EMPOWER-Cervical 1/GOG-3016/ENGOT-cx9 is an open-label, randomized (1:1), multi-center, Phase 3 trial of cemiplimab vs investigator's choice (IC) chemotherapy (chemo) in recurrent/metastatic (R/M) cervical cancer that has progressed after first-line (1L) platinum-based treatment (tx).

Methods Patients (pts) were enrolled regardless of PD-L1 expression; received cemiplimab 350 mg IV Q3W or IC chemo (pemetrexed, vinorelbine, gemcitabine, irinotecan, or topotecan), up to 96 weeks; and were stratified by histology (squamous cell carcinoma [SCC]/adenocarcinoma or adenocarcinoma [AC]). Primary endpoint was OS, analyzed hierarchically in pts with SCC followed by total population (SCC + AC). Additional endpoints included PFS, ORR, QoL, and safety. Interim analysis was scheduled when 85% events occurred among SCC pts.

Results 608 pts were randomized: median age, 51 years (range, 22–87); 477 SCC, 131 AC; ECOG performance status: 0 (46.5%), 1 (53.5%). Median cemiplimab exposure was

15 weeks (range, 1.4–100.7). At interim analysis, OS (table 1), PFS, ORR in overall and SCC populations, and mean change from baseline QoL in SCC, favored cemiplimab. Most common tx emergent AEs of any grade for cemiplimab vs IC chemo were anemia (25% vs 45%), nausea (18% vs 33%), and vomiting (16% vs 23%). Discontinuation due to AEs occurred in 8% (cemiplimab) and 5% (IC chemo).

Conclusions Cemiplimab significantly improves OS over single agent chemo for pts with R/M cervical cancer after 1L platinum-based tx regardless of histology and despite not having been selected by PD-L1 status. No new safety signals were observed.

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RANDOMIZED PHASE 3 STUDY OF LENVATINIB PLUS PEMBROLIZUMAB FOR ADVANCED ENDOMETRIAL CANCER (AEC): SUBGROUP ANALYSIS OF PATIENTS WITH DNA MISMATCH REPAIR DEFICIENT (dMMR) TUMORS

¹V Makker*, ²N Colombo, ³A Casado Herráez, ⁴A Santin, ⁵E Colomba, ⁶D Miller, ⁷K Fujiwara, ⁸S Pignata, ⁹S Banerjee, ¹⁰B Monk, ¹¹K Ushijima, ¹²R Penson, ¹³R Kristeleit, ¹⁴M Fabbro, ¹⁵M Orlando, ¹⁶H Mackay, ¹⁷M Ren, ¹⁸R Orlowski, ¹⁹L Dutta, ²⁰D Lorusso.
¹Memorial Sloan Kettering Cancer Center; Weill Cornell Medical Center, Department of Medicine, New York, USA; ²University of Milan-Bicocca, European Institute of Oncology IRCCS, Gynecologic Oncology Program, Milan, Italy; ³San Carlos University Teaching Hospital, Department of Medical Oncology, Madrid, Spain; ⁴Yale University School of Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences, New Haven, USA; ⁵Gustave Roussy Cancerology Institute, Department of Cancer Medicine, Villejuif, GINECO group, France; ⁶University of Texas Southwestern Medical Center, Gynecologic Oncology, Dallas, USA; ⁷Saitama Medical University International Medical Center, Department of Gynecologic Oncology, Hidaka, Japan; ⁸Instituto Nazionale Tumori IRCCS-Fondazione G. Pascale, Department of Urology and Gynecology, Naples, Italy; ⁹The Royal Marsden NHS Foundation Trust, Gynaecology Unit, London, UK; ¹⁰Arizona Oncology, Gynecologic Oncology, Obstetrics and Gynecology, Phoenix, USA; ¹¹Kurume University School of Medicine, Department of Obstetrics and Gynecology, Kurume, Japan; ¹²Harvard Medical School, Massachusetts General Hospital, Division of Hematology and Oncology, Boston, USA; ¹³Guy's and St Thomas' NHS Foundation Trust, Department of Oncology, London, UK; ¹⁴Institut Régional du Cancer de Montpellier, Service De Radiothérapie, Montpellier, France; ¹⁵Instituto Alexander Fleming, Oncologo Medico, Buenos Aires, Argentina; ¹⁶Odette Cancer Centre, Sunnybrook Health Sciences Centre, Medical Oncology, Toronto, Canada; ¹⁷Eisai Inc., Biostatistics, Oncology Business Group, Woodcliff Lake, USA; ¹⁸Merck and Co., Inc., Late Stage Clinical Development, Kenilworth, USA; ¹⁹Eisai Inc., Clinical Research, Woodcliff Lake, USA; ²⁰Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Division of Gynecologic Oncology, Rome, Italy

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Objectives In Study 309/KEYNOTE-775, lenvatinib + pembrolizumab (LEN+pembro) significantly improved PFS, OS, and ORR versus treatment of physician's choice (TPC) in aEC patients with DNA mismatch repair proficient tumors and all-comers following platinum-based therapy. We report results for dMMR aEC patients.

Methods Patients in Study 309/KEYNOTE-775 were randomized 1:1 to lenvatinib 20 mg orally daily + pembrolizumab 200 mg IV Q3W or TPC (doxorubicin 60 mg/m² IV Q3W or paclitaxel 80 mg/m² IV QW [3 weeks on/1 week off]). Patients had aEC with 1 prior platinum-based chemotherapy regimen (2 if one was given in the neoadjuvant/adjuvant setting). Prespecified efficacy (PFS, OS, and ORR) and safety analyses among dMMR patients are reported. P-values are nominal. Tumors were assessed by blinded independent central review per RECIST v1.1.

Results 130 Patients with dMMR aEC were randomized to LEN+pembro (n=65) or TPC (n=65). Median follow-up was 13.5 months for the LEN+pembro group and 8.8 months for

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	Cemiplimab median OS months (n)	IC chemo median OS months (n)	Hazard ratio for death (95% confidence interval)	P value
Total population	12.0 (n=304)	8.5 (n=304)	0.69 (0.56–0.84)	P<0.001
SCC population	11.1 (n=239)	8.8 (n=238)	0.73 (0.58–0.91)	P=0.003
AC population	13.3 (n=65)	7.0 (n=66)	0.56 (0.36–0.85)	P<0.005 (nominal P value, not adjusted for multiplicity)