

## Oral Abstracts

## Opening Ceremony and Plenary 1: Oral Abstract Presentations

O001/#331

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

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

10.1136/ijgc-2021-IGCS.1

**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.

O002/#43

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

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

10.1136/ijgc-2021-IGCS.2

**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/m<sup>2</sup> IV Q3W or paclitaxel 80 mg/m<sup>2</sup> 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

Abstract O001/#331 Table 1

	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)