#487 ARTISTRY-7: A PHASE 3, MULTICENTER STUDY OF NEMVALEUKIN ALFA IN COMBINATION WITH PEMBROLIZUMAB VERSUS CHEMOTHERAPY IN PATIENTS WITH PLATINUM-RESISTANT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER (GOG-3063; ENGOT-OV68)

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Introduction/Background ARTISTRY-7 will evaluate the novel engineered cytokine nemvaleukin alfa (nemvaleukin) in gynaecologic cancers. Nemvaleukin was designed to selectively bind to the intermediate-affinity interleukin-2 (IL-2) receptor, preferentially activating antitumour CD8+ T and NK cells with minimal regulatory T cell expansion, which may provide enhanced tumour killing and improved safety/tolerability versus high-dose IL-2. In preclinical studies, addition of a mouse nemvaleukin ortholog to anti-PD-1 treatment slowed tumour growth and increased survival in the EMT6 mouse tumour model. In ARTISTRY-1, responses were observed with nemvaleukin+pembrolizumab in 4 patients with platinum-resistant ovarian cancer (OC): 2 complete responses (1 in a patient with 5 prior lines of therapy), and 2 partial responses.

Methodology ARTISTRY-7 (NCT05092360) is an ongoing phase 3, multicentre, randomised study of nemvaleukin and/or pembrolizumab versus chemotherapy that is currently enrolling. Eligible patients are women (≥18 years) with histologically confirmed epithelial ovarian (high-grade serous, endometrioid, clear cell), fallopian tube, or primary peritoneal cancer. Patients must have had ≥1 prior line of platinum-based therapy, ≤5 prior lines of systemic anticancer therapy (platinum-resistant setting), and prior bevacizumab, with radiographic progression on most recent therapy. Patients with primary platinum-refractory disease (progression on first-line platinum therapy) or primary platinum resistance (progression <3 months after first-line platinum therapy completion) are excluded.

Approximately 376 patients will be randomised (3:1:1:3) to receive nemvaleukin 6 µg/kg IV (days 1–5)+pembrolizumab 200 mg IV (day 1) of each 21-day cycle, pembrolizumab or nemvaleukin monotherapy, or chemotherapy, and stratified by PD-L1 status, histologic subtype, and chemotherapy (paclitaxel vs others). Patients will continue treatment until disease progression or intolerable toxicity (maximum 35 pembrolizumab cycles; nemvaleukin can be continued). Primary endpoint: investigator-assessed progression-free survival (RECIST v1.1) with nemvaleukin+pembrolizumab vs chemotherapy. Secondary/exploratory endpoints include overall survival, other antitumor measures, safety, health-related quality of life, and pharmacokinetic/pharmacodynamic effects.

Results Trial in progress

Conclusion Pending data availability

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#703 HALIS: HABILITATION FOR LIFE STUDY. TELEMEDICINE-GUIDED PROMS: SIDE EFFECTS SCREENING AND EARLY INTERVENTION TO IMPACT QUALITY OF LIFE OF GYNECOLOGICAL CANCER PATIENTS

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Introduction/Background The number of women surviving gynaecological cancer is increasing due to improved cancer screening programmes and advances in cancer treatment. Patient Reported Outcomes Measures (PROMs) are a valid and reliable measurement tool to understand the patient's perception of her health-related quality of life (QoL). Lymphoedema, depression and anxiety, malnutrition and sarcopenia, and sexual dysfunction are conditions lowering QoL. Early detection with a mobile app could help to improve QoL in these patients.

Methodology Blinded randomised study (1:1 ratio), with two groups of patients. Via online app, patients will complete validated screening scales for lower-limb lymphoedema (GLCQ), anxiety-depression (HAD-14), sexual dysfunction (IFSFA-6) and sarcopenia-malnutrition (SARC-F and SNAQ) every two months after surgery along with self-perceived quality of life questionnaires (QLQ-C30, EN-24 or OV-28 or CX-24). In the experimental group the online app will alert in case of positive screening and the patient will be referred to the corresponding area for diagnosis and early treatment (Rehabilitation, Psycho-oncology, Sexual Health, and Nutrition). The control group will follow the standard usual care guidelines at the centre where patients will be opportunistically referred to specialized care.

Results Patients meeting all the inclusion criteria and none of the exclusion criteria will be recruited from the Gynaecology Oncology Unit of the University Hospital 12 de Octubre (extendable to other collaborating centres). Calculation of the sample size is made based on previous studies on quality of life that use the EORTC QLQ-C30 questionnaire as a measurement instrument. Sample size of 168 patients is calculated (alpha error 0.05 and beta error 0.2. Patients will be followed up for 20 months.

Conclusion Telemedicine systematic screening, diagnosis and early treatment of lower-limb lymphoedema, anxiety-depression, sexual dysfunction and sarcopenia-malnutrition all have a positive impact on the self-perceived quality of life by gynaecological cancer patients.

Disclosures Not applicable