AOU Città della Salute e della Scienza di Torino – PO S. Anna

Titolo:	A Phase 3 Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of Sacituzumab Tirumotecan (MK 2870) in Combination with Pembrolizumab Versus Pembrolizumab Alone as First-line Maintenance Treatment in Participants with Mismatch Repair Proficient Endometrial Cancer (**TroFuse-033 / MK-2870-033 /ENGOT en-29**).
Patologia:	Carcinoma endometriale
Tipo di Studio:	Interventistico con farmaco
Fase:	III
Principali criteri di inclusione:	1) The participant must have a histologically confirmed diagnosis of primary advanced or recurrent endometrial carcinoma that has been confirmed as pMMR by local pathology. Note: The local pMMR assay by immunohistochemistry should assess MSH6, PMS2, MSH2, and MLH1. pMMR is defined as all 4 proteins expressed. 2) Has radiographically evaluable disease, with measurable Stage III or either measurable or non-measurable Stage IV or recurrent disease per RECIST 1.1, as assessed by the investigator. Lesions situated in a previously irradiated area are considered measurable if progression has been shown in such lesions. Note: Participants with fluid-only disease (eg, pleural effusion or ascites, and no other radiographically apparent lesions) must have cytologic confirmation of malignancy. 3) Has received no prior systemic therapy for endometrial carcinoma except as noted below: * May have received 1 prior line of systemic platinum-based adjuvant and/or neoadjuvant chemotherapy in the setting of curative-intent. This prior chemotherapy may have been given as treatment involving chemotherapy alone, concurrent chemoradiation, or as part of a sequential approach such as in a regimen involving concurrent chemoradiation followed by chemotherapy. Instances in which both adjuvant and neoadjuvant systemic platinumbased chemotherapy are used will be counted as one line of chemotherapy.

	*May have received prior radiation with or without radiosensitizing chemotherapy if >2 weeks before the start of induction treatment. Participants must have recovered adequately from all radiation-related toxicities (as determined by the investigator), not require systemic corticosteroids, and not have had radiation pneumonitis. A 1- week washout is permitted for palliative radiation (<=2 weeks of radiotherapy) to non-CNS disease. * May have received prior hormonal therapy for treatment of endometrial carcinoma, provided that it was discontinued >1 week before the start of induction treatment. 4) Available tissue for TROP2, MMR, p53. Archival tissue or new biopsy (not RT-treated).
Principali criteri di esclusione:	1) POLE or MMRd 2) Carcinosarcoma, neuroendocrine tumors, endometrial sarcoma, sarcoma 3) Candidate for curative surgery or RT 4) Prior ADCs or ICIs 5) Synchronous tumors in the prior 3 years 6) CNS metastases
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