Titolo:	Studio di Fase 3, randomizzato, in aperto, multicentrico per valutare l'efficacia e la sicurezza di sacituzumab tirumotecan in combinazione con pembrolizumab rispetto a pembrolizumab in monoterapia come trattamento di mantenimento di prima linea in partecipanti con tumore endometriale mismatch repair proficient (pMMR) (TroFuse-033/GOG-3119/ENGOT-en29)
Patologia:	Tumore endometriale
Tipo di Studio:	interventistico
Tipologia	profit
Fase:	3
Principali criteri di inclusione:	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. Prior Therapy 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 platinum-based 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 (see also Section 5.2). 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.
Principali criteri di esclusione:	Has carcinosarcoma, neuroendocrine tumors or endometrial sarcoma, including stromal sarcoma, leiomyosarcoma, adenosarcoma, or other types of sarcomas. 2. Is known to have a POLE mutation. 3.Has carcinosarcoma, neuroendocrine tumors or endometrial sarcoma, including stromal sarcoma, leiomyosarcoma, adenosarcoma, or other types of sarcomas. 4. Is known to have a POLE mutation.
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