A.O. Ordine Mauriziano di Torino

Titolo:	Sperimentazione multicentrica di Fase 3, randomizzata, controllata con placebo, in doppio cieco, di selinexor nella terapia di mantenimento dopo terapia sistemica per pazienti con carcinoma endometriale p53 wild-type avanzato o ricorrente
Patologia:	Carcinoma endometriale
Tipo di Studio:	nterventistico con farmaco
Tipologia	profit
Fase:	3
Principali criteri di inclusione:	Histologically confirmed EC including endometrioid, serous, undifferentiated, and carcinosarcoma. 3. TP53 wt assessed by NGS, evaluated by a central vendor. 4. Completed at least 12 weeks of platinum-based therapy with or without ICI for Primary Stage IV or at first relapse and achieved confirmed partial or complete response (PR or CR) by imaging, according to RECIST version 1.1. Treatment for Primary Stage IV disease is defined as: a. had first-line platinum-based therapy along with primary or later debulking surgery and achieving an R0 resection (R0 resection indicates a macroscopic complete resection of all visible tumor), and achieved CR after at least 12 weeks platinum-based therapy, and/or continue to have no evidence of disease after at least 12 weeks of chemotherapy and surgery OR b. had first-line platinum-based therapy along with primary or later debulking surgery and achieving R1 or R2 resection (incomplete removal of all macroscopic disease) and achieved PR or CR after at least 12 weeks platinum-based chemotherapy, OR c. had no surgery and achieved PR or CR after at least 12 weeks platinum-based chemotherapy. OR At first relapse (ie, relapse after the first primary therapy regimen including surgery, chemotherapy, radiotherapy, endocrine therapy, and/or ICI for Stage I-IV disease), defined as: a. had Stage I – III disease at diagnosis and received, therapy with surgery and/or radiotherapy and adjuvant therapy (eg, chemotherapy and/or ICI and/or endocrine therapy) with subsequent relapse. Upon relapse, patients must have received at least 12 weeks of platinumbased chemotherapy, and achieved a PR or CR upon completion of this therapy, OR b. had Stage IV disease at diagnosis and received primary therapy with or without surgery with subsequent relapse. Upon relapse patients must have received at least 12 weeks of platinum-based chemotherapy (eg, chemotherapy and/or ICI and/or endocrine therapy) and achieved a PR or CR upon completion of therapy.
Principali criteri di esclusione:	Has any uterine sarcomas (carcinosarcomas – not excluded), clear cell or small cell carcinoma with neuroendocrine differentiation. 2. Has received a blood or platelet transfusion during the 2 weeks prior to C1D1. Patients' hemoglobin must be assessed within 2 weeks of screening and at least 1 week post transfusion.
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