

Study Title	MITO26: Phase II Trial On Trabectedin In The Treatment Of Advanced Uterine And Ovarian Carcinosarcoma (Cs)
Primary Objective	To determine the activity in terms of objective response rate by RECIST version 1.1 (Complete and Partial Response [CR + PR]) with trabectedin in patients advanced uterine and ovarian carcinosarcoma
Secondary Objectives	<ul style="list-style-type: none"> • Progression-free survival [the diagnosis of progression will be assessed by radiological criteria; CA 125 increases alone (GCIG criteria of progression) will not be considered as progression of disease without a radiological confirmation of progression]. • Overall survival • Duration of response • Toxicity profile of trabectedin in this patient population.
Inclusion Criteria	<ul style="list-style-type: none"> • Histologically documented Stage I-IV or recurrent uterine or ovarian carcinosarcoma not amenable to surgery or radiotherapy • No more than 2 previous chemotherapy lines • PS 0-2 (ECOG) • Age > 18 • Measurable disease • Life expectancy of at least 3 months • Adequate organ functions: • Hematopoietic; Absolute neutrophil count $\geq 1,500/\text{mm}^3$; Platelet count $\geq 100,000/\text{mm}^3$; Hemoglobin ≥ 9 g/dL • Hepatic; AST and ALT ≤ 1.5 times upper limit of normal (ULN)* ; Alkaline phosphatase ≤ 2.5 times ULN* ; Bilirubin ≤ 1.5 times ULN NOTE: * ≤ 3 times ULN if liver metastases are present • Renal; Creatinine Clearance ≥ 45 mL/min or Serum Creatinine $\leq 1.5 \times$ ULN • Serum Albumin >3.0 g/dL • Previous Brachytherapy treatment for uterine carcinosarcoma is allowed • No other invasive malignancy within the past 3 years except non-melanoma skin cancer • Written Informed Consent
Exclusion Criteria	<ul style="list-style-type: none"> • More than 2 previous chemotherapy lines • Single tumor lesion inside a previous irradiated field • Pregnant (potentially fertile patients must be not in pregnancy during and for at least 3 months after study participation and must have a negative serum pregnancy test) • Active infection requiring antibiotics • Symptomatic peripheral neuropathy > grade 2 according to the NCI Common Toxicity Criteria. • Congestive heart failure or angina pectoris even if it is medically controlled. Previous history of myocardial infarction within 1 year

	<p>from study entry, uncontrolled high risk hypertension or arrhythmia.</p> <ul style="list-style-type: none"> • Unstable or severe intercurrent medical condition that, in the opinion of the investigator, might interfere with achievement of study objectives • Psychological or sociological conditions, addictive disorders, or family problems, which would preclude compliance with the protocol
Number of Patients to enroll	16/43 enrolled patients (al 31.05.2018)

For Information

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