withdraw from the study. The primary endpoint is progression-free survival (PFS) as assessed by the investigator in the all-comers population and the dMMR population per RECIST version 1.1. Secondary efficacy endpoints are PFS assessed by blinded independent central review per RECIST version 1.1, overall survival, objective response rate, duration of response, disease control rate, safety and tolerability, and patient-reported outcomes.

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PHASE 3 TRIAL OF TUMOR TREATING FIELDS CONCOMITANT WITH WEEKLY PACLITAXEL FOR PLATINUM-RESISTANT OVARIAN CANCER: ENGOT-OV50/GOG-329/INNOVATE-3

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Introduction/Background Tumor Treating Fields (TTFields) are a non-invasive, antimitotic cancer therapy. The Phase 2 INNOVATE study demonstrated safety of TTFields/weekly paclitaxel in 31 PROC (platinum-resistant ovarian cancer) patients (Vergote Gyn Onc 2018); efficacy: median PFS 8.9 months, 25% partial response, 71% clinical benefit and 61% 1-year survival rate. This phase 3 ENGOT-ov50/GOG-329/INNOVATE-3 study [NCT03940196] investigates TTFields plus weekly paclitaxel in PROC patients.

Methodology Patients (N=540) will have PROC (RECIST V1.1) within 6 months of last platinum therapy with maximum of 2–5 prior lines of systemic therapy, ECOG 0–1 and no peripheral neuropathy >grade1. Patients with primary refractory disease will be excluded. Patients will be randomized 1:1 to weekly paclitaxel alone or weekly paclitaxel (starting of dose 80 mg/m² weekly for 8 weeks, and then on Days 1, 8, and 15 for subsequent 28-day cycle) plus TTFields (200 kHz for 18 hours/day and continued if no progression in the abdominal or pelvic regions ('in-field region') per RECIST V1.1. Clinical follow-up will be performed q4w, with radiological follow-up (CT or MRI scans of the abdomen and chest) q8w. The primary endpoint is overall survival. Secondary endpoints: PFS, objective response rate, AEs, and quality of life (EORTC QLQ-C30 with QLQ-OV28). Sample size (n=540) will detect an increase in median OS from 12 to 16 months (HR 0.75). Data Monitoring Committee (DMC) meeting (March 2020) concluded that data to-date showed no safety issues and recommended trial continuation.

Results TiP N/A

Conclusion TiP N/A

Disclosures

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BIOPSAR STUDY: ULTRASOUND-GUIDED PREOPERATIVE BIOPSY TO ASSESS HISTOLOGY OF SARCOMA-SUSPICIOUS UTERINE TUMORS. A NEW STUDY PROTOCOL

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Topic: Trials in progress abstract

Introduction/Background The preoperative differential diagnosis between a uterine fibroma and a sarcoma is a challenge. Available diagnostic tools are rather inconclusive to distinguish between two pathologies. However, potential accurate diagnostic methods would be of great clinical impact in order to optimize surgical treatment.

Methodology A prospective multi-center interventional study will be performed. Ten tertiary French centers will participate in the present study. The overall inclusion study period will be 2 years, overall study duration will be 5 years. Patients greater than 35 years old, diagnosed with suspicious uterine tumor and needing surgical intervention will be included. Uterine tumors will be considered as suspicious in case of rapid tumor growth ($\geq 30\%$ of the maximum diameter in 1-year interval), symptomatic tumors in postmenopausal women, tumors characterized by certain suspicious ultrasound criteria history of treatment with tamoxifen and genetical predisposal to cancer syndromes. Included patients will undergo preoperatively a Vaginal Ultrasound-Guided Biopsy (VUGB). There will be two histopathological diagnoses for each patient, the first based on the biopsy specimen received preoperatively (Index test) and the second based on the surgical specimen of uterus resected 'en block'. These diagnoses will be compared in order to assess diagnostic performance of VUGB. Histological criteria used for both diagnoses will be that of Bell et al which were revised by OMS 2014 classification.