Abstracts

Exclusion Criteria

- Pelvic Mass >8 cm
- open surgical approach considered necessary following MDT review.
- Women lacking capacity to the extent they are unable to understand or complete trial documentation/questionnaires will be excluded from the trial.

MIRRORS inclusion criteria are intentionally wide, not restricting by Body Mass Index (BMI), patient comorbidity or Ca125 values.

Surgery will commence with an initial laparoscopic assessment followed by a decision to proceed to robotic or open interval debulking surgery. The aim of surgery is to remove all visible disease safely by whichever route. If conversion to open surgery is required to complete this, then it will be done.

Results All women recruited to MIRRORS, whether eventually undergoing robotic or open surgery, will be followed up to assess recovery, complication rate, pain and quality of life.

If the following Success Criteria are met, we will progress to MIRRORS-RCT:

- $\geq 20\%$ of women eligible for the study accept inclusion in MIRRORS.
- Robotic IDS Complication rate is not higher than for open interval debulking surgery

MIRRORS
Minimally Invasive Robotic Surgery, Role in Optimal Debulking Ovarian Cancer, Recovery & Survival

Abstract 255 Figure 1

- Conversion to open surgery rate not greater than 50% in patient group deemed suitable for Robotic IDS following initial diagnostic laparoscopy.

Conclusion Robotic surgery is unlikely to be suitable in all cases of ovarian cancer, particularly those with large pelvic masses or extensive disease around the upper part of the abdomen, however, it has the potential to provide significant recovery and quality of life benefits. Ultimately we would like to determine whether, in selected women, robotic surgery offers improved quality of life and recovery with equivalent overall and progression free survival.

Disclosures Anil Tailor: Proctor for Intuitive Surgical

Jayanta Chatterjee: paid-lectures on behalf of pharmaceutical companies

Agnieszka Michael: Educational-grants: Clovis, GSK, Ipsen, Novartis, Pfizer, and Tesaro

Simon Butler-Manuel: Proctor for Intuitive Surgical, Plasma Surgical & Ethicon

387

ENGOT-EN6/GOG-3031/NSGO-RUBY: A PHASE 3, RANDOMISED, DOUBLE-BLIND, MULTICENTER STUDY OF DOSTARLIMAB + CARBOPLATIN-PACLITAXEL VERSUS PLACEBO + CARBOPLATIN-PACLITAXEL IN RECURRENT OR PRIMARY ADVANCED ENDOMETRIAL CANCER (EC)

¹Mansoor R Mirza, ²Robert L Coleman, ³Lars Harker, ⁴Brian Slomovitz, ⁵Giorgio Valabrega, ⁶Ellie Im, ⁷Monica Walker, ⁸Matthew Powell. ¹Nordic Society of Gynaecological Oncology – Clinical Trial Unit (Nsgo-Ctu); Rigshospitalet, Copenhagen University Hospital; Department of Oncology; ²University of Texas MD Anderson Cancer Center; ³Arbeitsgemeinschaft Gynäkologische Onkologie (AGO); University Hospital Schleswig-Holstein, Campus Lübeck; ⁴Sylvester Comprehensive Cancer Center, University of Miami Health Center; ⁵Multicenter Italian Trials in Ovarian Cancer (Mito), Università Di Torino, Candiolo Cancer Institute, Istituto Di Ricovero e Cura A Carattere Scientifico (Ircs), Fondazione del Piemonte Per L'oncologia (Fpo); ⁶Glaxosmithkline; ⁷Washington University School of Medicine in St. Louis, St. Louis

10.1136/ijgc-2020-ESGO.197

Background Carboplatin-paclitaxel is standard systemic anti-cancer therapy for recurrent or advanced EC for which surgery and/or radiation are not curative. Dostarlimab (TSR-042) is an anti-programmed cell death (PD)-1 humanised monoclonal antibody that has demonstrated antitumour activity and an acceptable safety profile in patients (pts) with recurrent or advanced EC in the GARNET trial. The RUBY trial will evaluate the efficacy and safety of dostarlimab in combination with carboplatin-paclitaxel in recurrent or primary advanced EC compared with carboplatin-paclitaxel alone.

Trial Design This is a global, randomised, double-blind, multicenter, placebo-controlled study. Eligible pts must have first recurrent or primary stage III or stage IV EC with a low potential for cure by radiation therapy or surgery alone or in combination. Pts with carcinosarcoma are eligible for enrolment. 470 pts will be enrolled from approximately 160 sites in the ENGOT countries, United States, and Canada. Stratification factors are DNA mismatch repair status (proficient [p], or deficient [d] MMR), prior external pelvic radiotherapy (yes or no), and disease status (recurrent, primary stage III or primary stage IV). Pts will be randomised 1:1 to receive combination dostarlimab 500 mg or placebo + carboplatin AUC 5 + paclitaxel 175 mg/m² every 3 weeks for 6 cycles followed by dostarlimab 1000 mg or placebo monotherapy every 6 weeks for up to 3 years in the absence of progressive disease, death, unacceptable toxicity, or patient/physician decision to

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.

Disclosures Sponsor: GlaxoSmithKline, Waltham, MA, USA

NCT number: NCT03981796

Encore statement: This data is presented on behalf of the original authors with their permission. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, May 29–31, 2020, Virtual.

Dr. Mirza reports personal fees and other from Karyopharm Therapeutics; Personal fees and other from Sera Prognostics and Roche; Grants and Personal fees from AstraZeneca, Clovis Oncology, Pfizer, GSK, Genmab, BioCad, Sotio, Boehringer Ingelheim, Geneos Therapeutics, Merck, Oncology Venture, Seattle Genetics, Sera Prognostics, Takeda Pharmaceutical Company Ltd, and Zailab.

Dr. Coleman reports consulting fees from Merck, Roche/Genentech, AstraZeneca, Oncomed/Mateo, Novocure, Oncosec, Janssen, Clovis, Tesaro/GSK, Abbvie, Eisai, Arrivive, and Oncoquest; grants from Merck, Roche/Genentech, V-Foundation, AstraZeneca, Janssen, Clovis, Genmab and Abbvie; and honoraria/reimbursement from Merck, Roche/Genentech, AstraZeneca, Oncomed/Mateo, Novocure, Oncosec, Janssen, Clovis, Tesaro/GSK, Eisai, Arrivive and OncoQuest.

Dr. Slomovitz reports consulting/advisory fees from GlaxoSmithKline.

Dr. Powell reports consulting/advisory fees from Roche/Genentech, AstraZeneca, Tesaro, and Clovis Oncology; and speakers' bureau at Genentech/Roche, AstraZeneca, Tesaro and Clovis Oncology.

Drs. Harker and Valabrega have nothing to disclose.

Drs. Im, Walker, and Guo are employees of GlaxoSmithKline.

403

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

¹Ignace B Vergote, ²Jalid Sehoul, ³Roldano Fossati, ⁴Robert Coleman, ⁵Bradley Monk, ⁶Larry Copeland, ⁷David O'malley. ¹Leuven Cancer Institute, Leuven, Belgium; ²Leuven Cancer Institute, Leuven, Belgium; ³Gynaecological Oncology, ²Charité Universitätsmedizin Berlin; ⁴Klinik für Gynäkologie; ³Ircs-Istituto Di Ricerche Farmacologiche, Milan; ⁴MD Anderson Cancer Center University of Texas; ⁵Arizona Oncology US Oncology Network; ⁶The James Cancer Hospital; ⁷Ohio State University Comprehensive Cancer Center; ⁷Ohio State University Comprehensive Cancer Center

10.1136/ijgc-2020-ESGO.198

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

554

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

¹Stamatios Petousis, ²Sabrina Croce, ²Michel Kind, ²Caroline Lalet, ²Guillaume Babin, ³Chrysoula Margioulas-Siarkou, ²Dennis Querleu, ²Anne Floquet, ²Marina Pulido, ²Frederic Guyon. ¹2nd Department of Obstetrics and Gynaecology, Aristotle University of Thessaloniki; ²Institut Bergonie, Bordeaux, France; ³Institut Bergonie, Bordeaux, France; ²2nd Department of Obstetrics and Gynaecology, Aristotle University of Thessaloniki, Greece

10.1136/ijgc-2020-ESGO.199

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.