Selection of Sites & Feasibility Questionnaire
Ovarian Front-Line Study

"An Adaptive Randomized Phase 3 Comparison of Standard Platinum Based Therapy versus Platinum Therapy and TSR-042 Followed by Niraparib and TSR-042 Maintenance Therapy in Patients with Stage III or IV Cancer of the Ovary, Fallopian Tube, or Peritoneum"

Protocol Number: 3000-03-005 / ENGOT-ov44

Scientific coordinator: ***Pr Eric PUJADE-LAURAINE***
Coordinating investigator: ***Dr Anne-Claire Hardy-Bessard***

Dear Madam/Sir,

ENGOT (European Network for Gynaecological Oncological Trial, the GINECO group and TESARO are planning to conduct an international phase III trial comparing standard platinum based therapy versus platinum therapy and TSR-042 followed by niraparib and TSR-042 maintenance therapy in patients with stage III or IV cancer of the ovary, fallopian tube, or peritoneum.

The GINECO will be the leading group of this study, working in partnership with TESARO.
We look forward to hearing about your interest on this exciting study.

This study will take place in many European countries as well in the US and Canada.

This will be an adaptive study design to ensure patients are receiving standard of care.

- During the course of the study, results of several studies in ovarian cancer treatment are anticipated which have the potential to impact the standard of care. Study sites will be notified as these events occur and the study design will utilize prospective adaptive design techniques to ensure that patients are receiving the current ovarian treatment paradigm.

For more information, you will find attached the protocol synopsis.

Current milestone dates
First patient in: Q2 2018
Last patient in: Q2 2020
Last Follow-up: Q3 2023

The following document is divided in two parts:

- The first part corresponds to the listing of the items that you will have to check for the selection of your sites.
- The second part is a questionnaire we would like you to answer and return by fax or email to:

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Before completing the feasibility questionnaire, you will find below a listing of the **items that you have to take into account for the selection of your sites.** All these items are mandatory for the sites.

Previous site experience	
☐	Each center must have already participated in a randomized study in gynecology within the last 3 years.
Potential recruitment	
☐	Each site must be able to randomize at least 6 patients during the 24 months period recruitment.
☐	If there are competitive trials within the center, you must ensure that it will not be a restriction for patient recruitment in the study.
Specific study procedures	
☐	Each site must be able to utilize platinum-based chemotherapy in combination with paclitaxel (administered every 3 weeks) as front-line therapy for ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.
☐	All patients will be required to provide an archival tumor sample at screening for HRD testing. If an archival tumor sample is not available, the site will need to obtain a tumor biopsy at screening prior to treatment.
☐	Each site must be able to perform: - Collection and shipment of blocks from an archival tumor sample to the central laboratory. - Blood sample collection, handling (centrifugation) and storage at -20 °C
☐	Each site must be able to send blood samples within 1 day of collection to the central laboratory to get the ctDNA HRR status for stratification.
☐	Each site must be able to perform tumor assessment (CT/MRI scan) with the same technique/machine and preferably with the same radiologist during the study.
☐	Each site must be able to perform CT/MRI scan (chest, abdomen, and pelvis) systematically at the date as noted in the attached synopsis.
☐	Each site must be able to assign a study coordinator dedicated to the study.

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Cooperative Group:	
Number of sites proposed for study participation:	
Number of subjects estimated to be contributed by the group:	

	Collaborative group Lead Investigator for the Study
Name	
Address	
Country	
Phone	
Fax	
E-mail	

Operational Contact	Other Important Contact (please specify)
Name	
Address	(if different)
Country	
Phone	
Fax	
E-mail	

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Questions	
1	Are there any inclusion/exclusion criteria, or any other aspect of the trial design, that limits acceptability and/or ability or willingness to recruit? ☐ Yes ☐ No; **If Yes**, please specify why
2	What is the maximum acceptable time for biomarker results before initiation of front-line treatment? ☐ ≤2 Weeks ☐ >2 to ≤ 4 Weeks ☐ >4 to ≤6 Weeks
3	How many centers of your group could participate in this study? _____ centers How many patients could your group randomize in 24 months? _____ patients * *Each site should recruit at least 6 patients during the 24 months recruitment period*.
4	Do you expect any unusually long lead times involved for protocol approval or site start up in your country? ☐ Yes ☐ No; **If Yes**, please specify why
5	How long after receiving the final protocol would you be able to recruit your first patient? _____ months
6	Are the mandatory CT/MRI scan exams and their frequency acceptable as a part of the study? ☐ Yes ☐ No; **If No**, please specify why
7	Are there any of sites selection criteria challenging for your group? ☐ Yes ☐ No; **If Yes**, please indicate which one and comment

8	Patient Reported Outcomes (PROs) will be collected at screening and throughout the duration of the study as noted in the attached schedule of events. The PROs being collected are: • EQ-5D-5L = European Quality of Life 5-Dimension 5-Level Scale • EORTC-QLQ-C30 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 • EORTC-QLQ-OV28 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Ovarian Cancer Module OV28 Do you foresee any challenges with the completion of these questionnaires? ☐ Yes ☐ No **If yes**, please explain the challenges
9	Other Comments:

Thank you for your collaboration!