NSGO-OV-UMB1
ENGOT-OV30 / NSGO
UMBRELLA

A phase II umbrella trial in patients with relapsed ovarian cancer
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ENGOT-OV30 / NSGO

EudraCT number: 2017-002805-36

Sponsor: NSGO

Study Chair: Mansoor Raza Mirza

Participating groups & Lead PIs:

NSGO:	MR Mirza
SGCTG UK:	C Gourley
PMHC Canada:	A Oza
BGOG Belgium:	I Vergote
ANZGOG Australia:	M Friedlander
COGI US:	J Barek
GOTIC Japan:	K Fujiwara
KGOG S Korea	SY Ryu
NOGGO Germany:	Jalid Sehouli

Study Status

- Cohort A submitted (DKMA, EC) in DK
- Submission in NOR, FIN, SWE in Q4 17
- Expected FPI: Jan 18

- Cohort B (SGCTG UK), submission end Q1 18
- Cohort C (PMHC Canada), submission Q3 18

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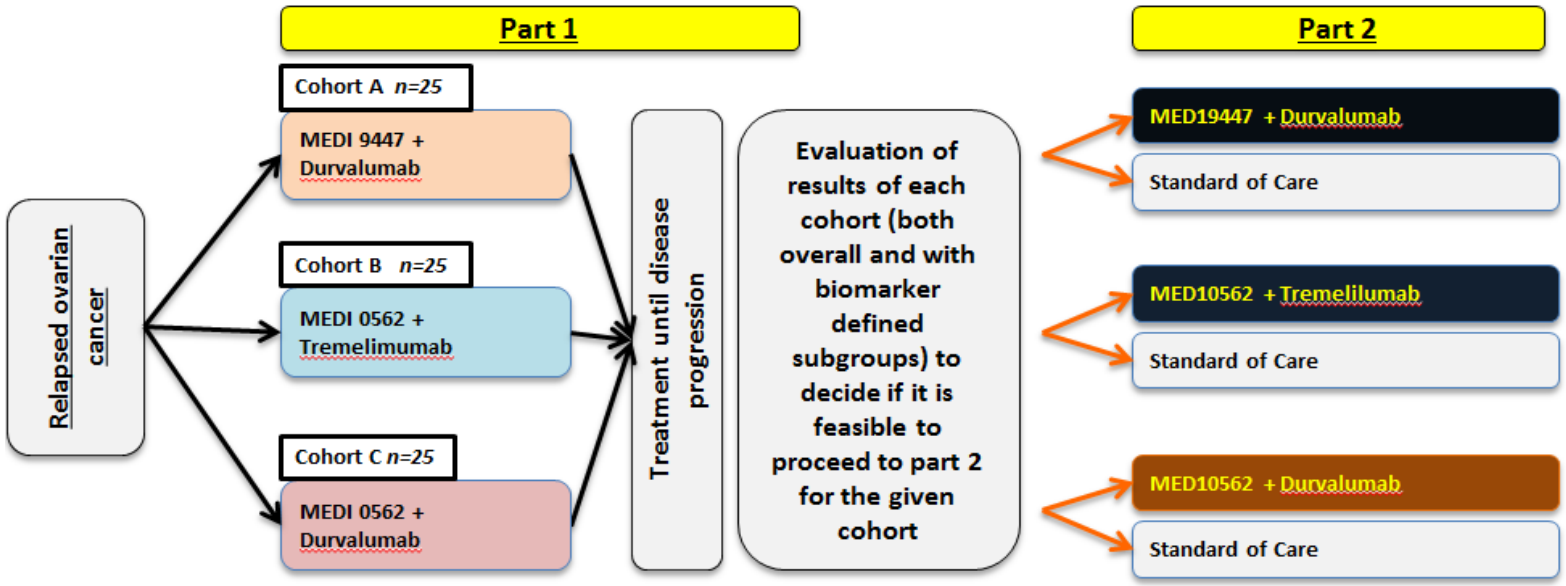

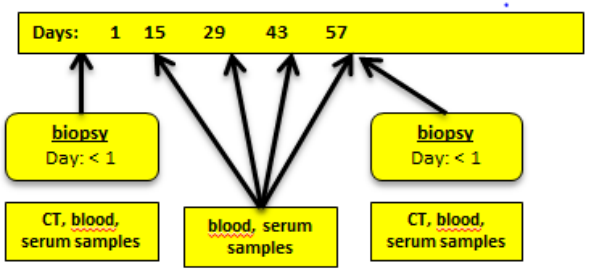

2:1 randomization

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Primary endpoint:

- Disease control rate (DCR) (CR+PR+SD) at 16 weeks.

Secondary endpoints:

- Progression-Free Survival (PFS) by RECIST v1.1: at 6 & 12 months and median PFS
- PFS by Immune-RECIST at 6 & 12 months and median PFS
- Overall survival (OS)
- Objective response rate according to RECIST v1.1 (ORR)
- Duration of (Overall) Response (DoR)
- Safety and tolerability.

Translational research objectives:

- Compare any changes in expression of baseline biomarkers compared to biopsy at day 56 and biopsy upon progression of disease.
- Evaluate any correlation of baseline tumor PD-L1 expression to response
- Evaluate any correlation of CD4 (T helper & Tregs) & CD8 expression to response.
- Evaluate pharmacodynamics responses in blood
- Evaluate effect of treatment on circulating myeloid-derived suppressor cells (MDSC)

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Dosages & schedule:

For Cohort A:

- MEDI9447: 3000 mg, IV, Q2W
- Durvalumab: 1500 mg, IV, Q4W

Duration of treatment:

Until progression of disease or intolerable toxicity

Response assesments:

Before day 0, and then every 8 weeks.

Tumour biopsies (mandatory):

Before day 0; at day 56

Tumour biopsy at progression of disease is optional

Blood/Serum Samples (mandatory):

Before day 0 and at days 14, 28, 56. Then every 56 days and at progression of disease

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Inclusion criteria Cohort A

- Platinum-sensitive disease: defined as disease progression ≥ 6 months following the last administered dose of platinum-based therapy. Patients must have received atleast one line of chemotherapy for platinum-sensitive disease. **OR** Platinum-resistant disease: defined as disease progression < 6 months following the last administered dose of platinum-based therapy. **OR** Platinum-refractory disease: defined as lack of response or disease progression while receiving the most recent therapy.
- Histological confirmed ovarian, fallopian tube or peritoneal cancers.
- Histological types: high-grade serious, high-grade endometriod, undifferentiated, carcinosarcoma or mixed histology.
- Subjects must have at least 1 measurable lesion as defined by RECIST guidelines. This should not be the same lesion used for biopsy.
- Archival tumour tissue must be screened for CD73 and only CD73 positive patients will enter this trial.
- Patient agrees to undergo all analysis (blood, serum, tissue); radiological examinations according to protocol.
- Mandatory tumour biopsy before treatment (before day 0) and at day 56 of treatment.