

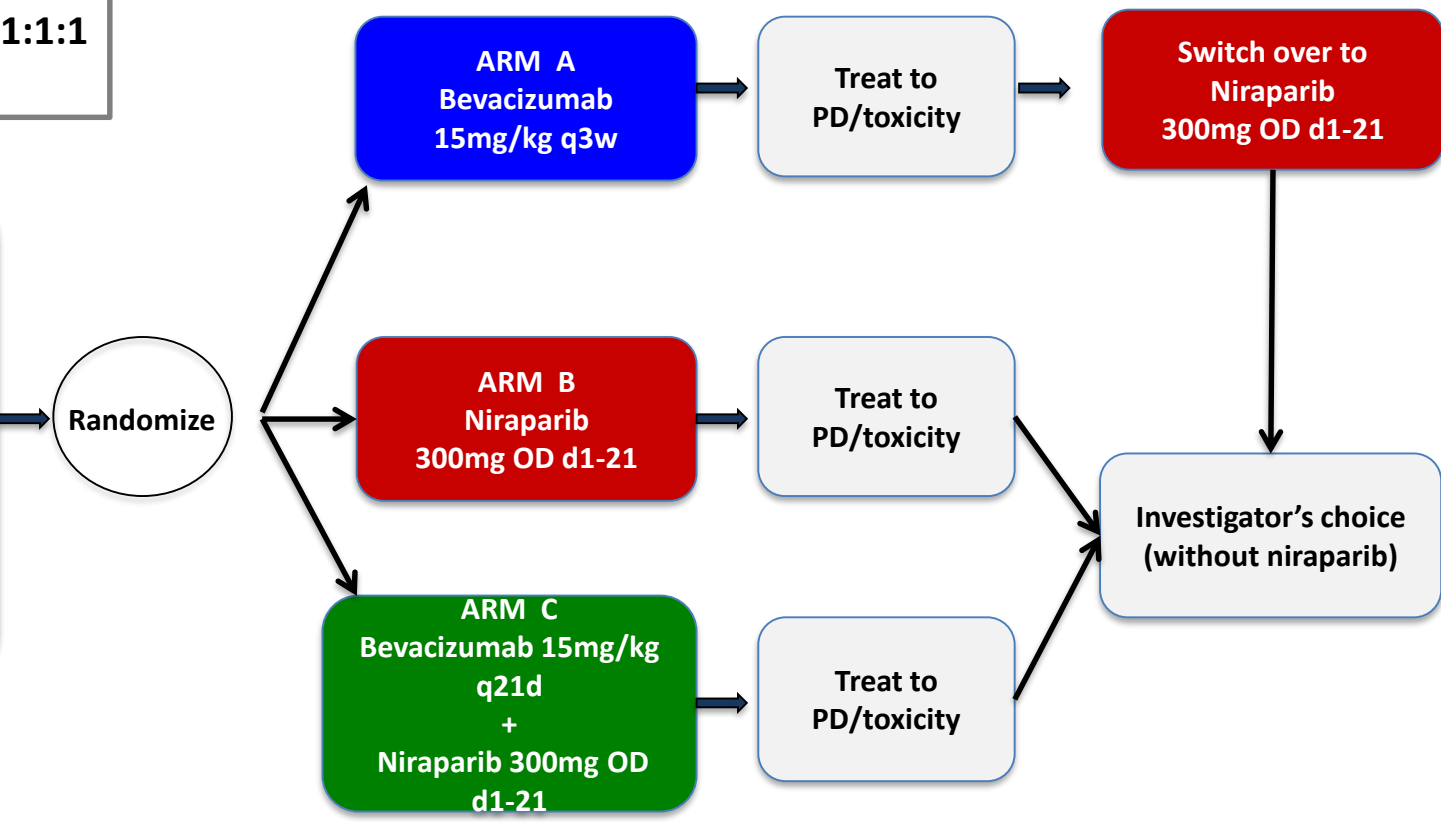


ENGOT-OV24-NSGO/AVANOVA Phase 2

Randomization: 1:1:1
n=132

Platinum-sensitive Ovarian Cancer

Homologous Recombination Deficiency (HRD) positive score



Sponsor: NSGO
Project Manager: Louisa Boufercha
Statistician: DePont Christensen
PI: Mirza

Stratifications

- BRCA status: BRCA mutated vs. non-carrier
- Prior receipt of anti-angiogenic therapy (yes/no)
- Prior lines of therapy: 1-3 vs > 3 lines

ENGOT-OV24-NSGO/AVANOVA (Phase 2) - Trial Status

| Country | Sites | PI | Submission status | SIV | Randomized |
|--------------|---------------------------|------------------------------|---|---|------------|
| DK | Rigshospitalet | Mansoor R. Mirza (NC) | <ul style="list-style-type: none"> CA: Approved: 18.12.2015 EC: Approved: 01.03.2016 | 03.12.2015 | 3 |
| | Herlev | Trine Juhler-Nøttrup | | 30.03.2015 | 2 |
| | Odense | Jørn Herrstedt | | 08.03.2016 | - |
| | Aarhus | Ranva Hassel | | 19.08.2016 | - |
| | Aalborg | Bente Lund | | 16.12.2015 | 3 |
| FI | Tampere | Johanna Mäenpää (NC) | <ul style="list-style-type: none"> CA: Approved: 19.07.2016 EC: Approved: 06.06.2016 | 30.09.2016 | - |
| | Kuopio | Maarit Anttila | | TBD | - |
| | Turku | Sakari Hietanen | | TBD | - |
| NO | Haukeland | Line Bjørge (NC) | <ul style="list-style-type: none"> CA: Approved: 29.09.2016 EC: Approved: Oct 2016 | TBD | - |
| | Stavanger | Bent Fiane | | TBD | - |
| SE | Lund | Susanne Malander (NC) | <ul style="list-style-type: none"> CA: Approved 22.04.2016 EC: Approved: 22.03.2016 | 16.09.2016 | - |
| | Linköping | Per Rosenberg | | 26.09.2016 | - |
| | Sahlgrenska | Maria Dimoula | | 16.09.2016 (web-based) On site monitoring visit pending | - |
| | Uppsala | Hanna Dahlstrand | | 16.09.2016 (web-based) On-site monitoring visit: 11.11.2016 (Planned) | - |
| US | MGH | Michael Birrer (NC) | <ul style="list-style-type: none"> Hard copies were submitted by GSO to FDA and were received the 09.09.2016. Re-submission to FDA done 20.09.2016. The 16.09.2016 Myriad submitted the risk determination letter and the acknowledgement letter to FDA. It was received on 19.09.2016. Reply with comments received from FDA on 05.10.2016. The IND was clinically reviewed and following a response were send to FDA to answer their criticisms. Currently waiting for a response from FDA. | TBD | - |
| | Huntsman Cancer Institute | Theresa Werner | | TBD | - |
| Total | | | | | 8 |



NSGO-OV-UMB1: A Phase 2 Umbrella Trial in Recurrent Ovarian Cancer

Simon 2-stage design for each cohort

Relapsed ovarian cancer

Cohort A

OX40
(days: 0 – 28)

OX40 + Durvalumab
(days: 29 – PD) **Coordinating Group SGCTG**

Cohort B

OX40
(days: 0 – 28)

OX40 + CTLA4
(days: 29 – PD) **Coordinating Group PMHC**

Cohort C

CD73
(days: 0 – 28)

CD73 + Durvalumab
(days: 29 – PD) **Coordinating Group NSGO**

Treatment until disease progression

Days: 0 28 56 140

biopsy
Day: < 0

biopsy
Day: 28

biopsy
Day: 56

CT, blood, serum samples

CT, blood, serum samples

CT, blood, serum samples

