ESGO 20
INTERNATIONAL MEETING OF THE EUROPEAN SOCIETY OF GYNAECOLOGICAL ONCOLOGY (ESGO)
NOVEMBER 04-07, 2017 I VIENNA, AUSTRIA
European Gynaecological Oncology Congress 2017

NSGO

REGION H Rigshospitalet

New Treatment Options in Ovarian Cancer

Mansoor Raza Mirza

NSGO: Nordic Society of Gynaecological Oncology
&
Rigshospitalet: Copenhagen University Hospital, Denmark

Mansoor Raza Mirza

Disclosures *(last 24 months)*

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Study Grants:

AstraZeneca
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Pfizer
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Tesaro

ENGOT
European Network of
Gynaecological Oncological Trial groups

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GYNECOLOGIC
CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

GCIG
Gynecologic Cancer InterGroup

Need for Level 1 Evidence

Phase II Trial in Ovarian Cancer with Gemcitabine

Results: 100% response rate

Ovarian Cancer

RANDOMIZE

Carboplatin + Paclitaxel

→ **Carboplatin + Paclitaxel**
+ Gemcitabine

Hansen et al. Ann Oncol 1999

Three Phase III Trials in Ovarian Cancer with Gemcitabine

Ovarian Cancer

RANDOMIZE

→ **Carboplatin + Paclitaxel**

→ **Carboplatin + Paclitaxel**
+ Gemcitabine

Bookman et al. J Clin Oncol 2006
DuBois et al. J Clin Oncol 2009

Three Phase III Trials in Ovarian Cancer with Gemcitabine

Ovarian Cancer

axel

NEGATIVE

axel

E

Bookman et al. J Clin Oncol 2006
DuBois et al. J Clin Oncol 2009

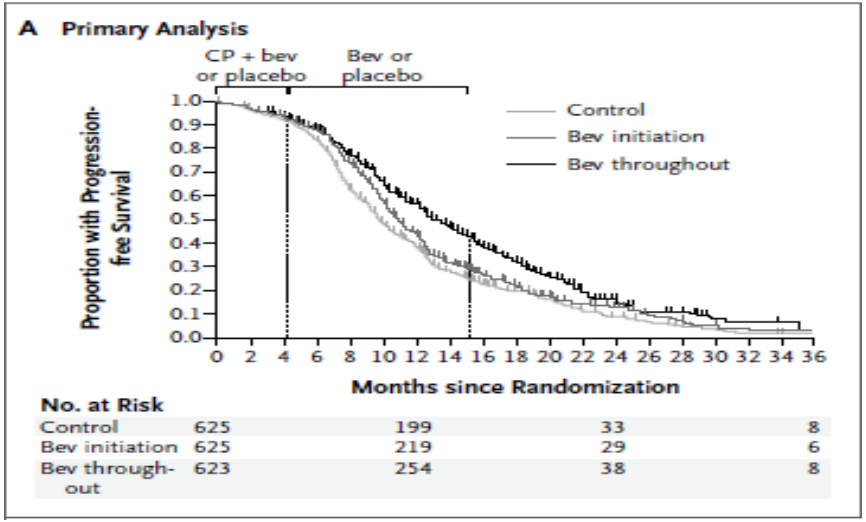
Clinical Progress in Novel Therapies

- **Anti-angiogenic therapy**
- **PARP inhibition**
- **Immunotherapy**

Antiangiogenic therapy
Bevacizumab in primary Ovarian Cancer

2 positive trials

Improved PFS by adding bevacizumab to carboplatin/paclitaxel and subsequent maintenance therapy



GOG 218: Bev throughout vs placebo
HR 0.717; 95% CI 0.625-0.824, p<0.001

Burger RA et al. New Eng J Med 2011

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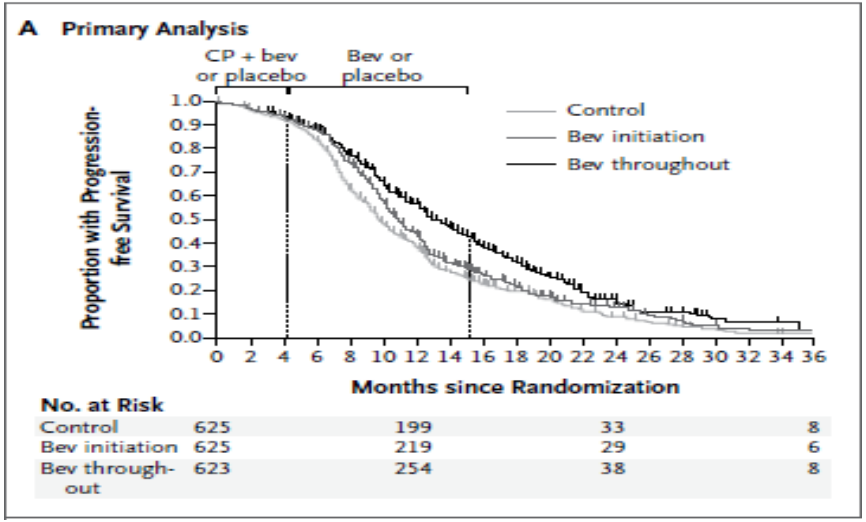
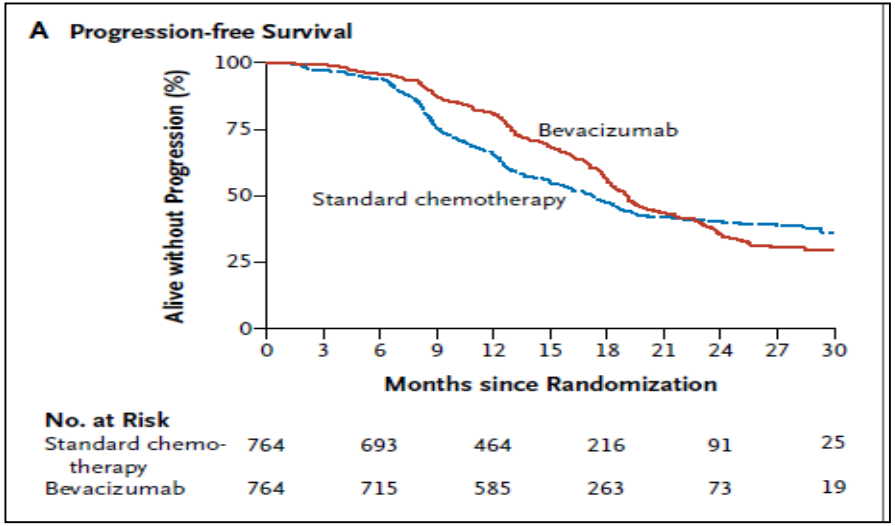




GOG 218: Bev throughout vs placebo
HR 0.717; 95% CI 0.625-0.824, p<0.001

Burger RA et al. New Eng J Med 2011

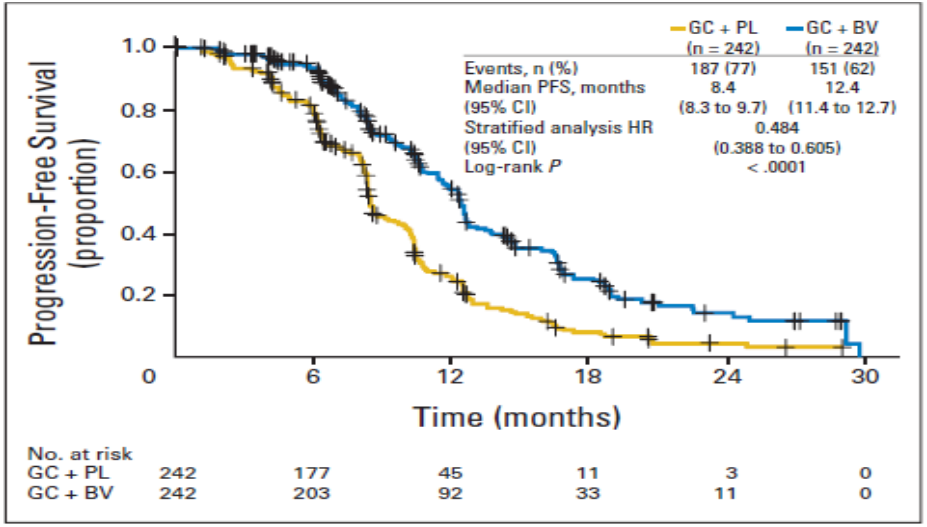
ICON 7: Bev vs control
HR 0.77; 95% CI 0.77-0.99; p=0.04

Perren TJ.... Mirza MR et al. New Eng J Med 2011

Antiangiogenic therapy
Bevacizumab in Recurrent Ovarian Cancer: *Platinum-Sensitive Relapse*

2 positive trials

Improved PFS by adding bevacizumab to platinum based chemo and subsequent maintenance therapy



OCEANS: PFS CG+/-Bev
HR 0.484; 95% CI 0.388-0.605, p<0.001

Aghajanian C et al. J Clin Oncol 2012

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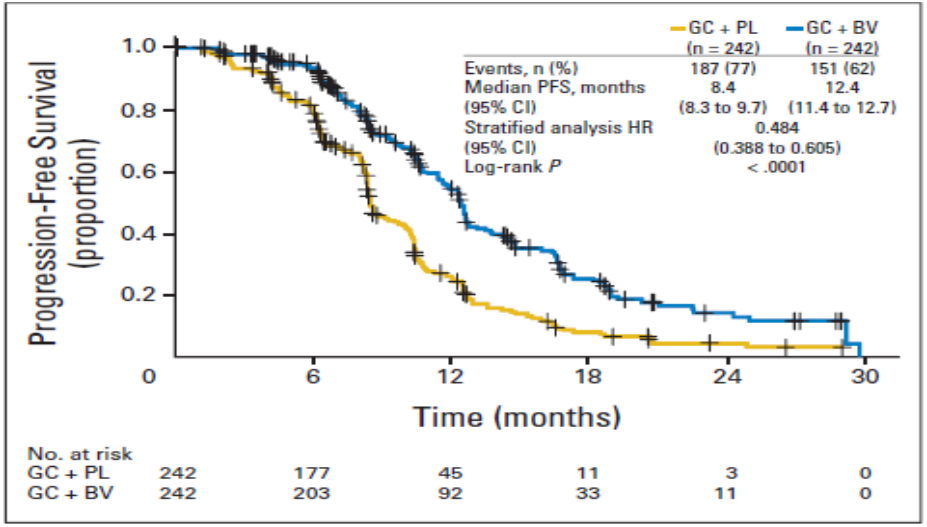
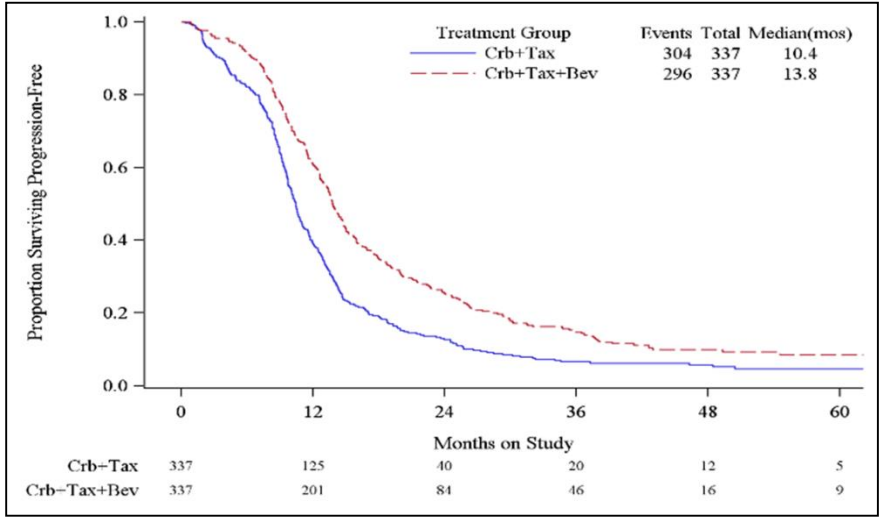




OCEANS: PFS CG+/-Bev
HR 0.484; 95% CI 0.388-0.605, p<0.001

Aghajanian C et al. J Clin Oncol 2012

GOG 213: TC +/- Bev
HR 0.61; 95%CI 0.52-0.72, p<0.0001

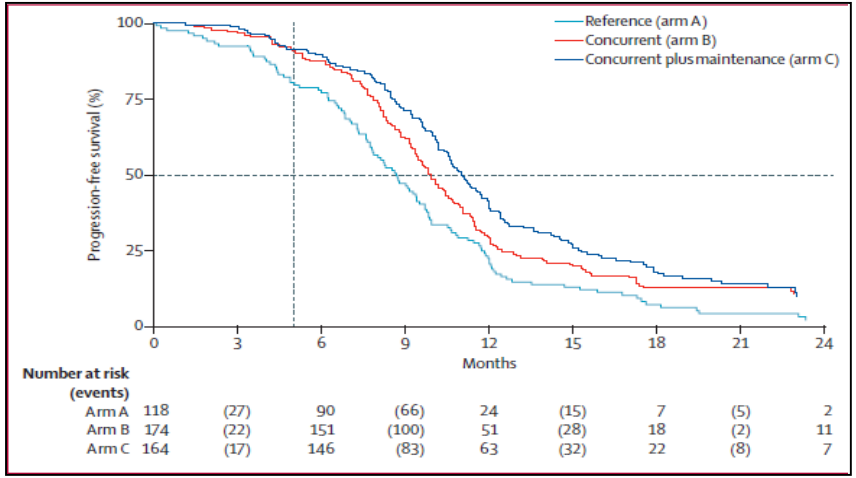
Coleman RA et al. SGO 2015

Antiangiogenic therapy
Tyrosine Kinase Inhibitors in Recurrent Ovarian Cancer

1 positive trial

Improved PFS or PFS & OS by adding a TKI standard chemotherapy

Cediranib



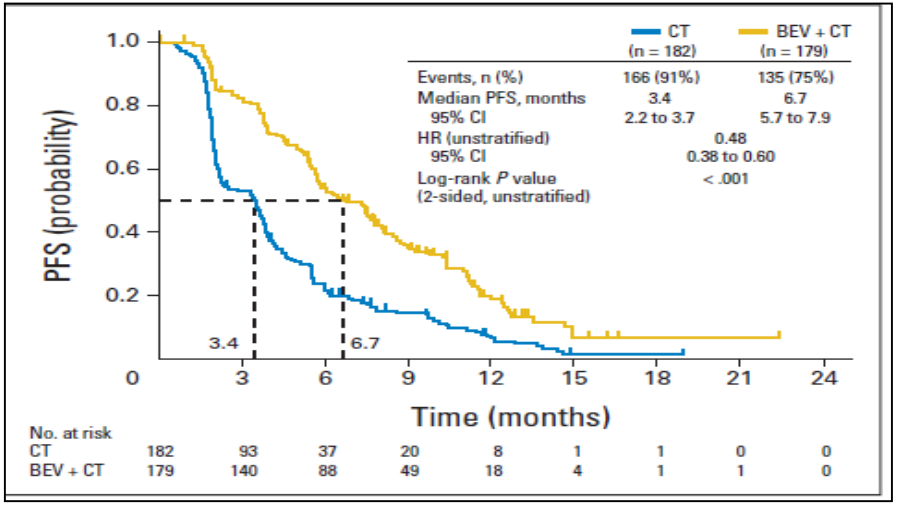
ICON 6: Platinum +/- Cediranib
HR 0.56; 95%CI 0.44-0.72, p<0.001

Ledermann J et al. Lancet 2016

Antiangiogenic therapy
Bevacizumab in Recurrent Ovarian Cancer: *Platinum-Resistant Relapse*

1 positive trial

Improved PFS by adding bevacizumab to non-platinum based chemo + QoL benefit in symptomatic pts.



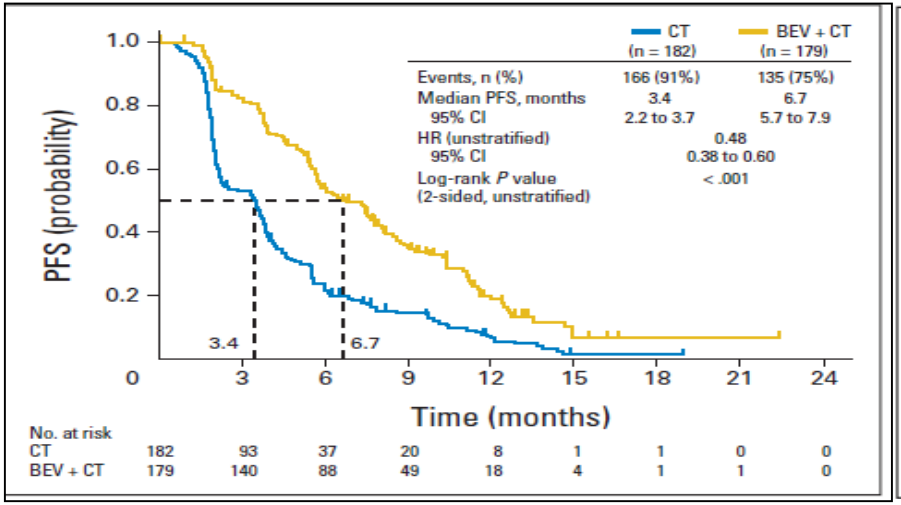
AURELIA: PFS NonPlat +/- Bev
HR 0.48; 95% CI 0.38-0.60, p< 0.001

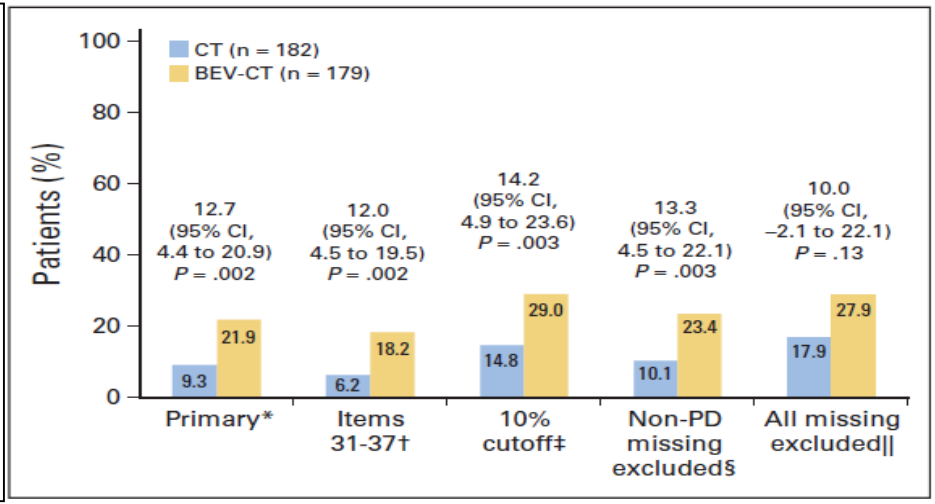
Pujade-Lauraine E.... Mirza MR et al. J Clin Oncol 2014

Antiangiogenic therapy
Bevacizumab in Recurrent Ovarian Cancer: *Platinum-Resistant Relapse*

1 positive trial

Improved PFS by adding bevacizumab to non-platinum based chemo + QoL benefit in symptomatic pts.





AURELIA: PFS NonPlat +/- Bev
HR 0.48; 95% CI 0.38-0.60, p< 0.001

AURELIA: Primary and sensitivity analysis of the primary hypothesis (≥ 15% improvement in symptomatic pts)

Pujade-Lauraine E.... Mirza MR et al. J Clin Oncol 2014

Stockler MR.... Mirza MR et al. J Clin Oncol 2014

Antiangiogenic therapy
Facts & Clinical Considerations

But do we have any biomarkers to select the right population?

Antiangiogenic therapy
Facts & Clinical Considerations

But do we have any biomarkers to select the right population?

If not: what are the selection criteria?

So far, only Bevacizumab is approved in ovarian cancer
Bevacizumab is only allowed once in the course of disease
The benefit of adding bevacizumab is given in primary, early and late relapse

What are the risks of bevacizumab

Pulmonary embolism
Hypertension
Bowel perforation and fistula

Antiangiogenic therapy
Facts & Clinical Considerations

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Pulmonary embolism
Hypertension
Bowel perforation and fistula

Every ovarian cancer patient should receive bevacizumab during the course of disease

PARP Inhibitors

- Inhibiting base excision repair
- Trapping PARP on damaged DNA, thus interfering with the catalytic cycle of PARP, hindering DNA repair & promoting double-strand breaks
- Disrupting BRCA1 recruitment to damaged DNA
- Activating non-homologous end-joining, which is more prone to errors.

Audeh MW et al. Lancet 2010; 376:245-51
Murai J et al. Cancer Res 2012;72:5588–5599
Konecny et al. 2016

Status of phase III PARP inhibitors trials

	Reported	Awaited
Niraparib	**ENGOT-OV16 / NOVA**	*PRIMA*
Olaparib	**ENGOT-OV30 / SOLO2**	*SOLO1* *PAOLA1*
Rucaparib	**ARIEL3**	
Veliparib	**-**	*GOG3005*
Talazoparib	**-**	*Ovarian Cancer Strategy Unclear*

Status of FDA & EMA approvals

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Maintenance Therapy

	FDA	EMA
Niraparib	**All patients** ***regardless of histology, BRCA & HRD status***	**All patients** ***regardless of BRCA & HRD status*** ***Positive CHMP opinion***
Olaparib	**All patients** ***regardless of BRCA status***	**BRCAmut only**
Rucaparib	*Awaited*	*Awaited*

Post Multiple-Lines of Therapy

	FDA	EMA
Rucaparib	**BRCAmut** only	-
Olaparib	**BRCAmut** only	-

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Results from Randomized Trials in Ovarian Cancer

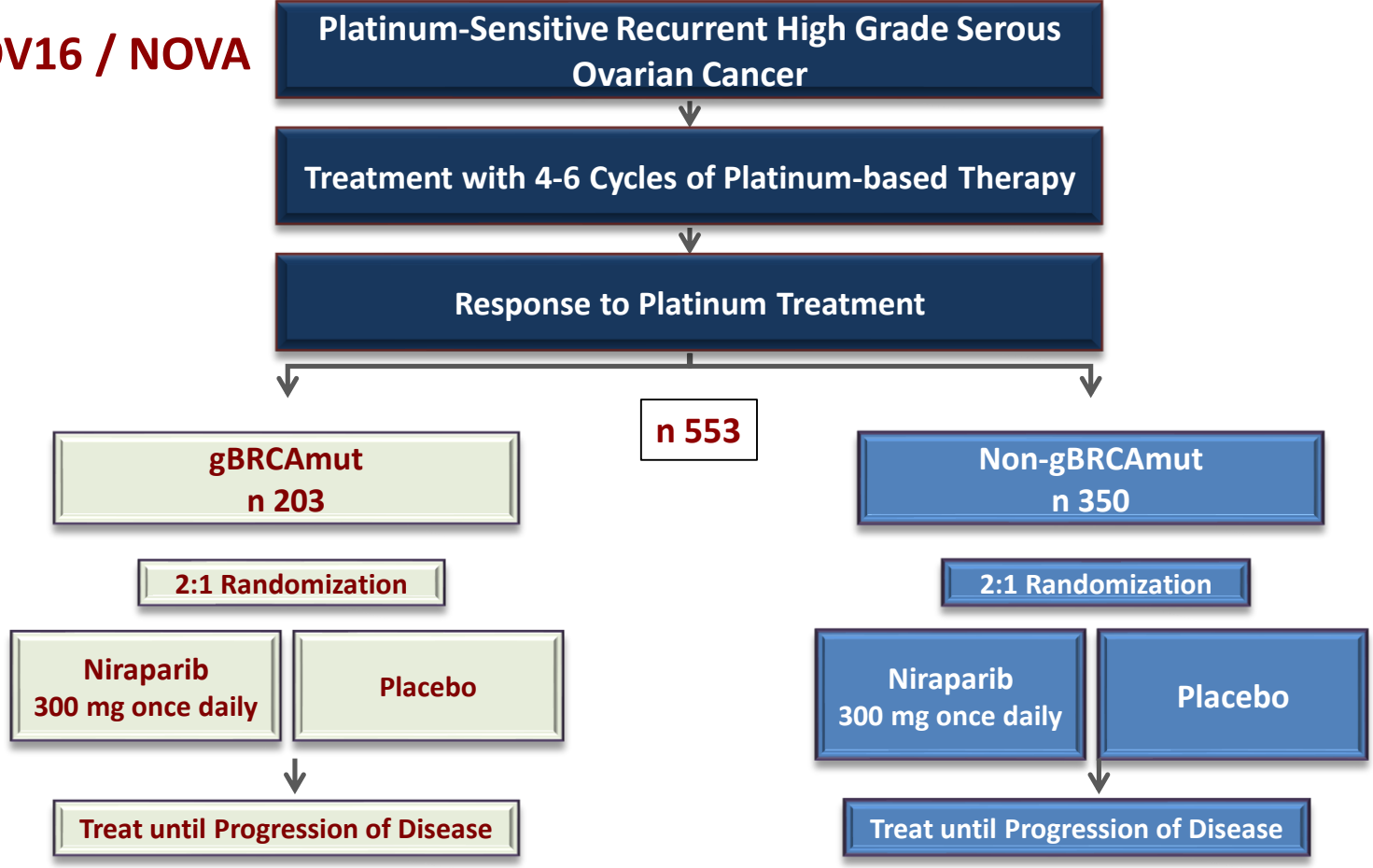
Niraparib:	**ENGOT-OV16 / NOVA**	**phase 3**	**randomized**
Olaparib:	**Study 19**	**phase 2**	**randomized**
	ENGOT-OV21 / SOLO2	**phase 3**	**randomized**
Rucaparib:	**ARIEL3**	**phase 3**	**randomized**

ENGOT-OV16 / NOVA
Study Hypothesis

Niraparib, as a selective PARP1/2 inhibitor, will provide a clinical benefit to all patients who have platinum-sensitive recurrent ovarian cancer who are in response to platinum, regardless of *gBRCA* mutation status

Mirza MR et al. N Engl J Med 2016;375:2154-64

ENGOT-OV16 / NOVA



Mirza MR et al. N Engl J Med 2016;375:2154-64

ENGOT-OV16 / NOVA

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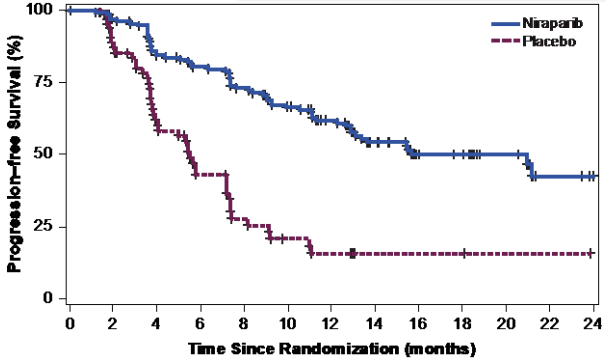
Recurrent ovarian cancer following a complete or partial response to platinum-based therapy£

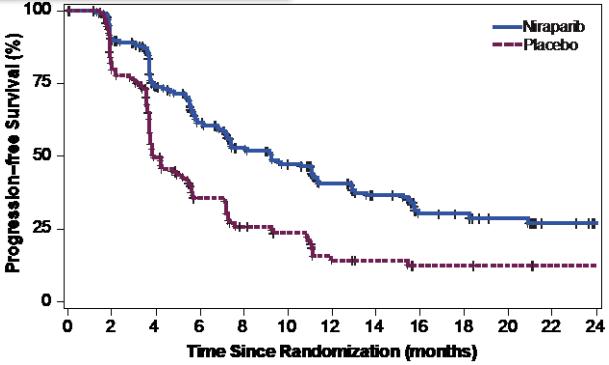
Evaluate g*BRCA* mutation status*

g*BRCA*mut



Treatment	PFS Median (95% CI) (Months)	Hazard Ratio (95% CI) p-value	% of Patients without Progression or Death	
			12 mo	18 mo
Niraparib (N=138)	**21.0** (12.9, NR)	**0.27** (0.173, 0.410) p<0.0001	62%	**50%**
Placebo (N=65)	**5.5** (3.8, 7.2)		16%	16%

non-g*BRCA*mut†



Treatment	PFS Median (95% CI) (Months)	Hazard Ratio (95% CI) p-value	% of Patients without Progression or Death	
			12 mo	18 mo
Niraparib (N=234)	**9.3** (7.2, 11.2)	**0.45** (0.338, 0.607) p<0.0001	41%	**30%**
Placebo (N=116)	**3.9** (3.7, 5.5)		14%	12%

Mirza MR et al. N Engl J Med 2016;375:2154-64

The Study 19

Phase 2 randomised trial of maintenance olaparib in platinum-sensitive high-grade serous relapse OC

randomized, double-blind, placebo-controlled phase II maintenance study

n 265 patients

Patients:

- **Platinum-sensitive high-grade serous ovarian cancer**
- ≥2 previous platinum regimens
- Last chemotherapy was platinum-based, to which they had a maintained PR or CR prior to enrolment
- Stable CA-125

Olaparib
400 mg po bid

Randomised 1:1

Placebo
po bid

Treatment until disease progression

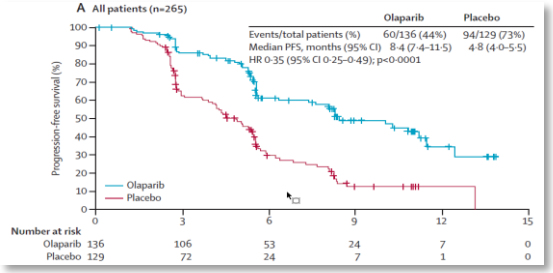
Primary end point:
PFS

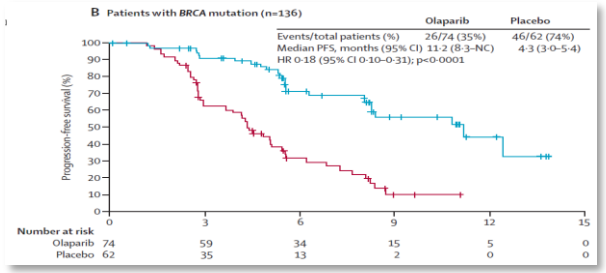
bid, twice daily; CA-125, Cancer Antigen 125;
CR, complete response; po, orally; PR, partial response.

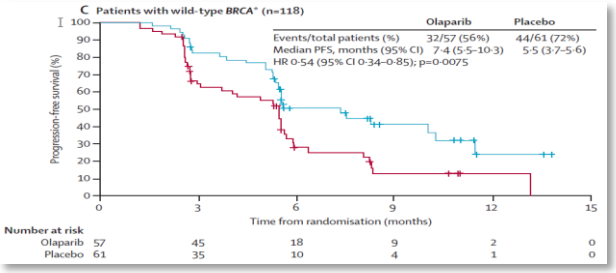
Ledermann J et al. N Engl J Med 2012;366:1382–1392

The Study 19

Phase 2 randomised trial of maintenance olaparib in platinum-sensitive high-grade serous relapse OC







Whole population with HGSOC

BRCA^{mut}

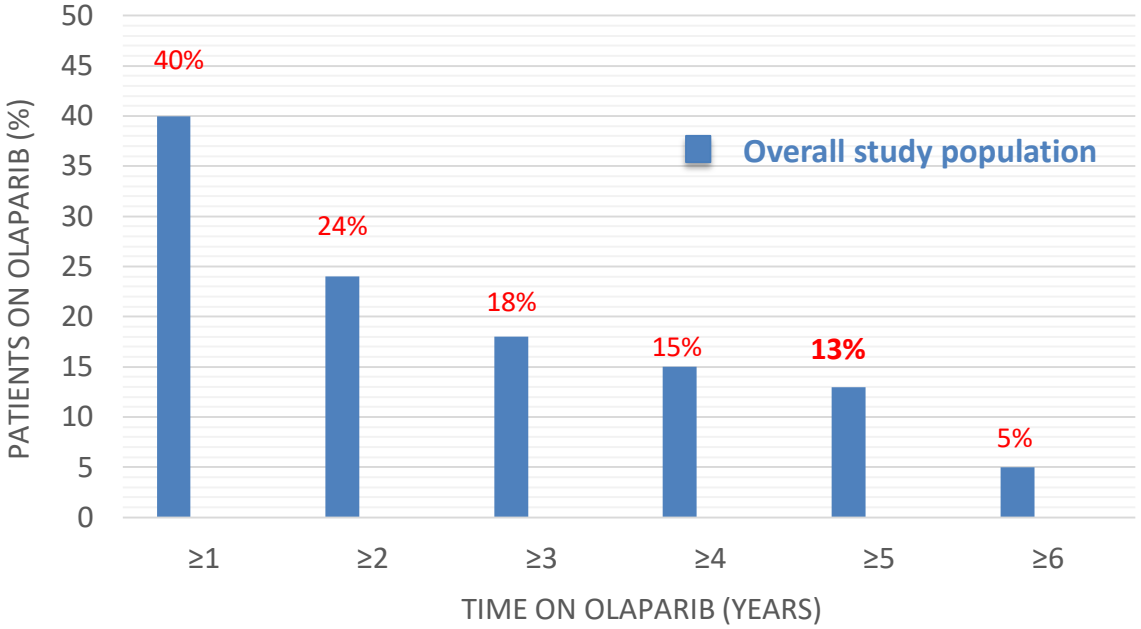
BRCA^{wt}

Ledermann J et al. N Engl J Med 2012

Ledermann J et al. Lancet Oncol 2014

Long-term exposure to olaparib in 'study 19' in BRCAm and BRCA^{wt}

Median follow-up of 5.9 years: **15 patients (11%)** still receiving olaparib

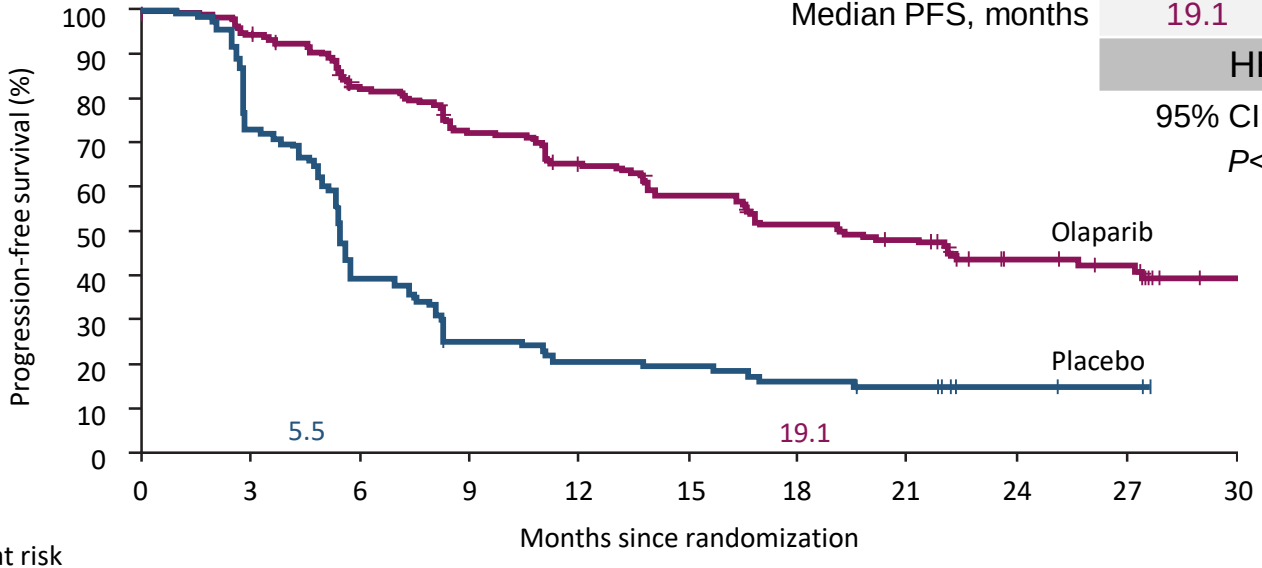


Ledermann J et al. ASCO 2016

ENGOT-OV21 / SOLO2

Progression-Free Survival

	Olaparib (n=196)	Placebo (n=99)
Events (%)	107 (54.6)	80 (80.8)
Median PFS, months	19.1	5.5
HR 0.30		
95% CI 0.22 to 0.41		
P<0.0001		



No. at risk

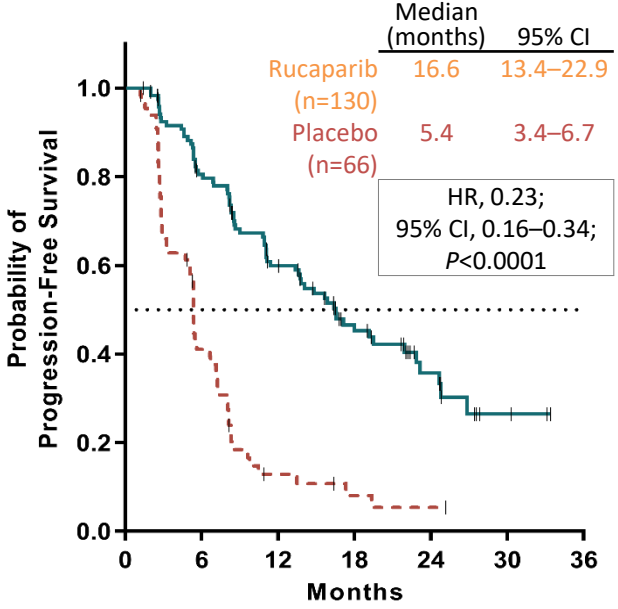
Olaparib	196	182	156	134	118	104	89	82	32	29	3
Placebo	99	70	37	22	18	17	14	12	7	6	0

Median follow-up was 22.1 months in the olaparib group and 22.2 months for placebo

Pujade-Lauraine E et al. Lancet Oncol 2017

ARIEL3: Progression-Free Survival

BRCA mutant

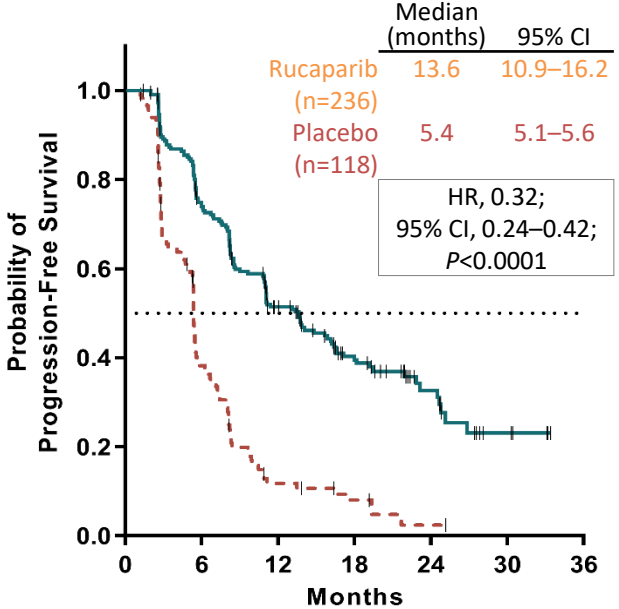


At risk (events)

Rucaparib	130 (0)	93 (23)	63 (46)	35 (58)	15 (64)	3 (67)	0 (67)
Placebo	66 (0)	24 (37)	6 (53)	3 (55)	1 (56)	0 (56)	

Rucaparib, 48% censored Placebo, 15% censored

HRD

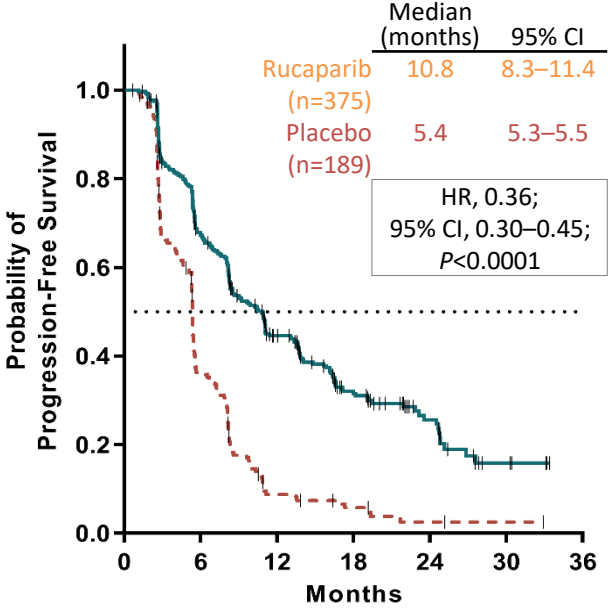


At risk (events)

Rucaparib	236 (0)	161 (55)	96 (104)	54 (122)	21 (129)	5 (134)	0 (134)
Placebo	118 (0)	40 (68)	11 (95)	6 (98)	1 (101)	0 (101)	

Rucaparib, 43% censored Placebo, 14% censored

ITT



At risk (events)

Rucaparib	375 (0)	228 (111)	128 (186)	65 (217)	26 (226)	5 (234)	0 (234)
Placebo	189 (0)	63 (114)	13 (160)	7 (164)	2 (167)	1 (167)	0 (167)

Rucaparib, 38% censored Placebo, 12% censored

Coleman RL et al. Lancet 2017

Adverse Events (any grade; PARP / placebo)

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	Rucaparib	Olaparib	Niraparib
Fatigue	69 / 44	66 / 39	59 / 41
Nausea	75 / 37	76 / 33	74 / 45
Vomiting	37 / 15	37 / 19	34 / 16
Constipation	37 / 24	20 / 23	40 / 20
Diarrhea	**32 / 22**	**33 / 20**	19 / 21
Dysgeusia	**39 / 7**	**27 / 7**	10 / 4
Decreased appitite	23 / 14	22 / 11	25 / 14
Anemia	37 / 6	44 / 8	50 / 7
Thrombocytopenia	28 / 3	8 / 3	**61 / 6**
Hypertension	-	**-**	**19 / 4**
Photosensitivity reaction	**17 / 1**	**-**	**-**
Increased Creatinine	**15 / 2**	-	-
Increased ALT/AST	**34 / 4**	-	-

Rucaparib: ***Coleman RL et al.*** ***Lancet 2017***

Olaparib: ***Pujade-Lauraine E et al.*** ***Lancet Oncol. 2017***

Niraparib: ***Mirza MR et al.*** ***N Engl J Med 2016***

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Adverse Events

Treatment Related Dose Discontinuations

Rucaparib	Olaparib	Niraparib
13.4%	11%	14.7%

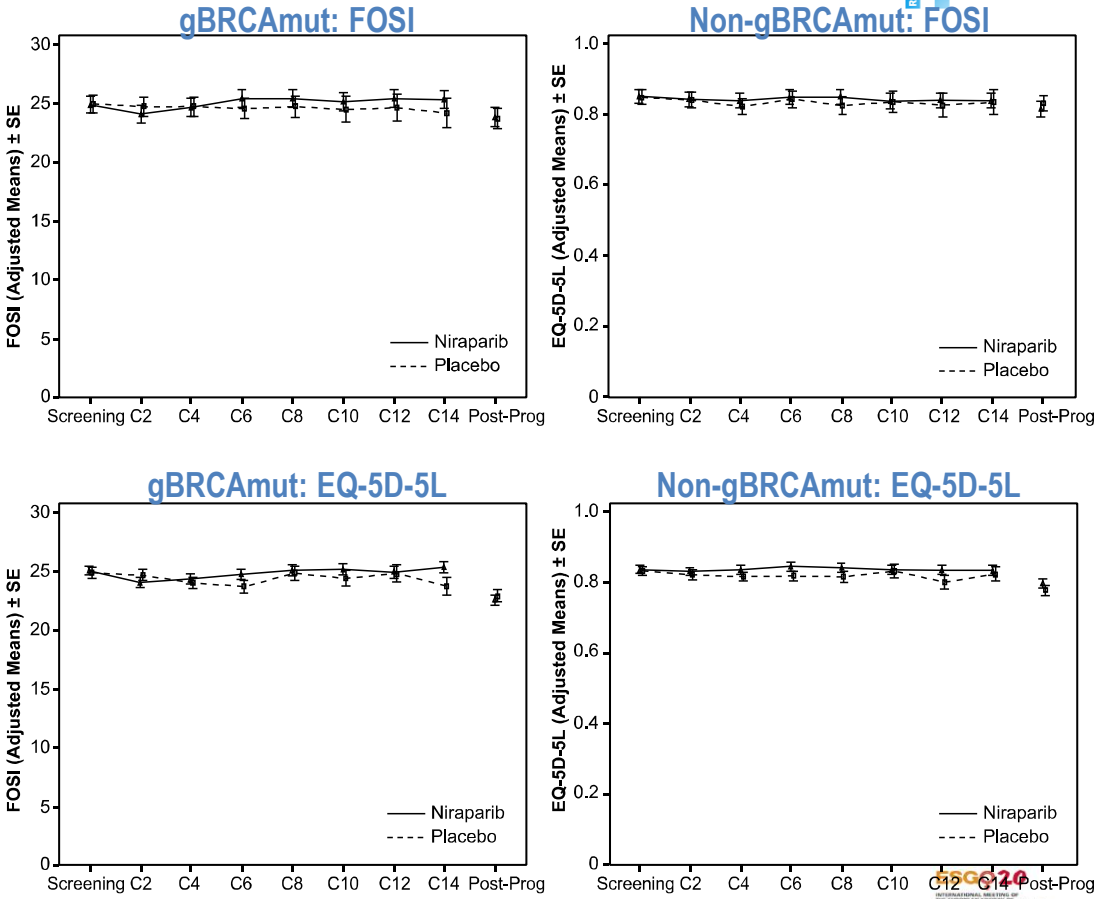
Rucaparib: *Coleman RL et al.* *Lancet 2017*

Olaparib: *Pujade-Lauraine E et al.* *Lancet Oncol. 2017*

Niraparib: *Mirza MR et al.* *N Engl J Med 2016*

NOVA: Patient-Reposted Outcomes

- **Measured using the Functional Assessment of Cancer Therapy – Ovarian Symptom Index (FOSI) and the EQ-5D-5L**
- **PRO surveys were collected at:**
  - Screening visit
  - Every other cycle through cycle 14
  - Post progression
- **Compliance rates were high, and similar between the two treatment arms**
  - Niraparib: FOSI completion rate ranged from 75.0% to 97.1%
  - Placebo: FOSI completion rate ranged from 77.6% to 97.4%
- **PROs were similar for niraparib compared with placebo**



Mirza MR et al. N Engl J Med 2016;375:2154-64

Conclusions: PARPi

- **PARP significantly improved PFS in patients with platinum-sensitive recurrent ovarian cancer.**

- **Efficacy is highest in BRCAmut population**

- **Beyond BRCA, platinum-sensitivity remains the best “biomarker” for response to PARP inhibitors**

PARPi Combination Therapies

Increased DNA damage:

DNA repair inhibitors:

Radiation: complex DNA damage

DNA damage primes the immune system:

Immunotherapies: harnessing the genomic instability/genomic load

Stromal Inhibition: switch to C1 phenotype / block immune response

Create / re-create HRD:

Induce hypoxia: Anti-angiogenics

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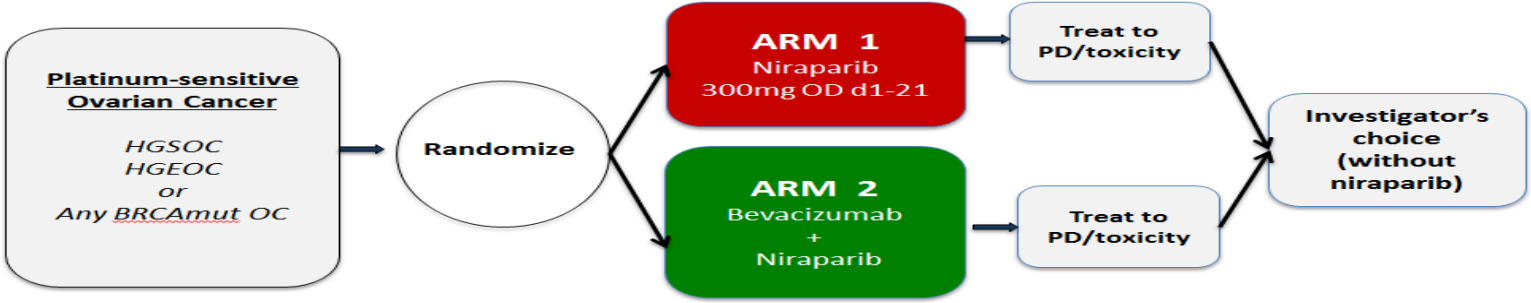
OV24/AVANOVA

A two-arm, open-label, phase II randomized study to evaluate the efficacy of niraparib versus niraparib-bevacizumab combination in Women with platinum-sensitive epithelial ovarian, fallopian tube, or peritoneal cancer.



Stratification factors:
HRD positive/negative
TFI: 6-12 mo vs. >12 mo

Randomization: 1:1
n=94

Arm 1: niraparib median PFS 8mdr
Arm2: Nir + Bev median PFS 14mdr
inclusion 18 months
Drop outs: 10%

HR 0.57
Power 80%
alpha 0.1

No. of already recruited patients: 73 (part 2)

Planned No. of patients: 94 (part 2)

Status: recruiting

Sponsor: NSGO
PI: Mansoor Raza Mirza
Project Manager: Louisa Boufercha
Statistics: René DePont Christensen

CAN IMMUNO-ONCOLOGY BECOME A NEW TREATMENT OPTION IN OVARIAN CANCER?

Ongoing Phase III Immuno-Oncology Studies in ovarian cancer

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First-line

JAVELIN OVARIAN 100[1]
Stage 3-4 HGSOC;
n=951

R

- Paclitaxel + carboplatin followed by observation
- Paclitaxel + carboplatin followed by avelumab maintenance
- Paclitaxel + carboplatin + avelumab followed by avelumab maintenance

PFS

Late relapse

ATALANTE[2]
Ovarian cancer with late relapse;
n=405

R

- Placebo (until PD) + bevacizumab + platinum-based chemotherapy
- PD-L1 (until PD) + bevacizumab + platinum-based chemotherapy

PFS

Platinum resistant

JAVELIN Ovarian 200[3]
Stage 3-4 HGSOC;
n=550

R

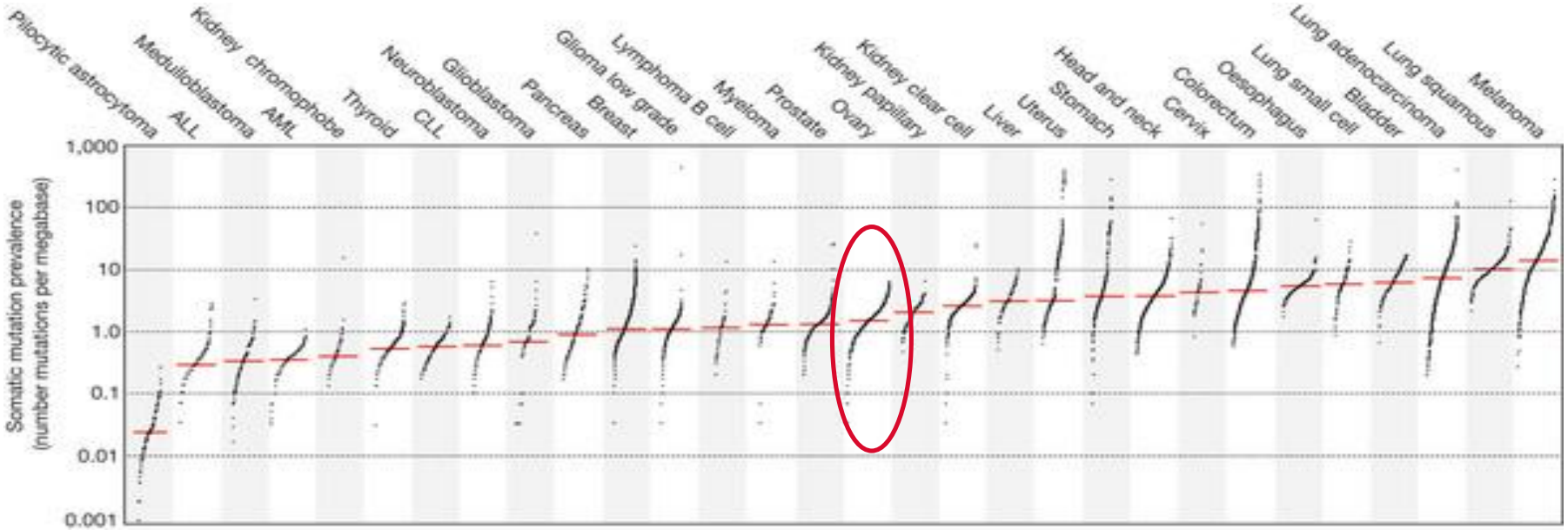
- Avelumab
- Avelumab + Pegylated Liposomal Doxorubicin
- Pegylated Liposomal Doxorubicin

OS

1. NCT02718417 (Sponsor: Pfizer; PI: Monk & Ledermann). Available at: https://clinicaltrials.gov/ct2/show/NCT02718417?term=NCT02718417&rank=1;
2. NCT02891824 (Sponsor: GINECO; PI: Kurtz). Available at: https://clinicaltrials.gov/ct2/show/NCT02891824?term=NCT02891824&rank=1;
3. NCT02580058 (Sponsor: Pfizer; PI: Monk & Pujade-Lauraine). Available at: https://clinicaltrials.gov/ct2/show/NCT02580058?term=NCT02580058&rank=1

ESGO 2.0 VIENNA, AUSTRIA 2017

PD-1/PD-L1 monotherapy in ovarian cancer



Alexandrov et al., Nature 2013

Immune Checkpoint Inhibitors in OC: Overview

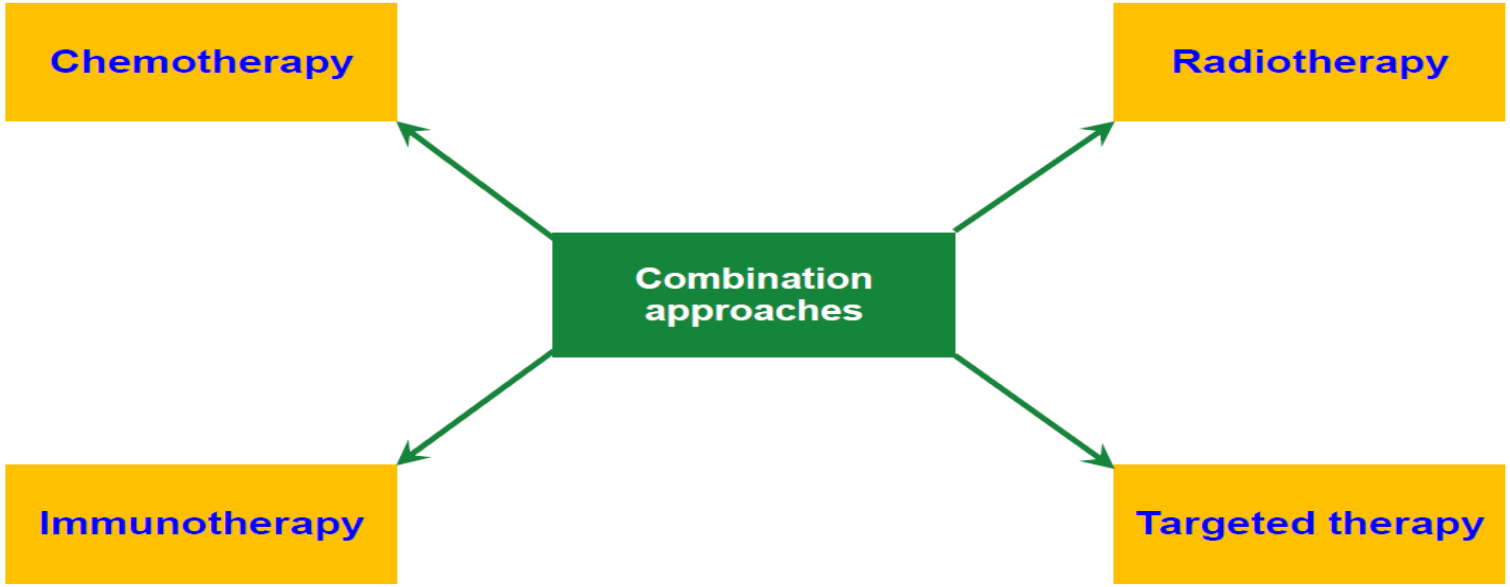
	Ipilimumab[1]	Nivolumab[2]	Pembrolizumab[3]	Avelumab[4]	PD-L1[5]	Durvalumab[6]
N	9	20	26	124	12	20*
Prior therapies	Not reported	≥4: 55%	≥5: 38.5%	≥3: 65.3%	≥6: 58%	Median: 4*
PD-L1+ prevalence	Not reported	80% (IC 2/3)	100% (≥1% TC)	77% (≥1% TC)	83% (IC 2/3)	>5% TC: 73% (11/15)*
ORR	Not reported	15%	11.5%	9.7%	25%	Not reported

* Includes ovarian cancer (n=15), triple-negative breast cancer (n=2), cervical cancer (n=2), and uterine leiomyosarcoma patients (n=1).

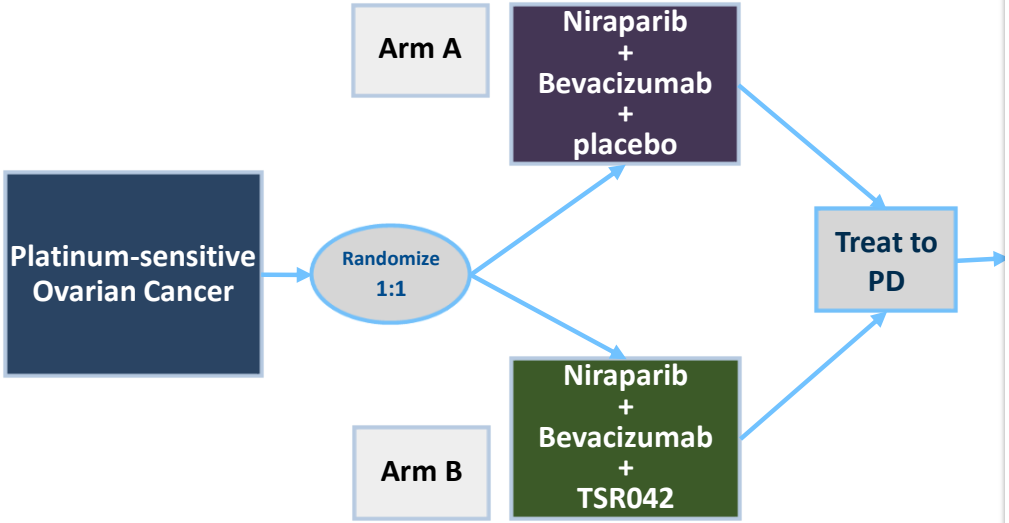
CI, confidence interval'; DCR, disease control rate; IC, immune cell; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; TC, tumor cell; TRAE, treatment-related adverse event, Tx, treatment.

1. Hodi FS et al. *Proc Natl Acad Sci U S A*. 2008;105:3005-3010. 2. Hamanishi J et al. *J Clin Oncol*. 2015;33:4015-4022. Abstract 5510. 3. Varga A et al. Presented at ASCO 2015. 4. Disis ML et al. Presented at ASCO 2016. Abstract 5533. 5. Infante JR et al. Presented at ESMO 2016. Abstract 871. 6. Lee JM et al. Presented at

Raising the bar with combinations



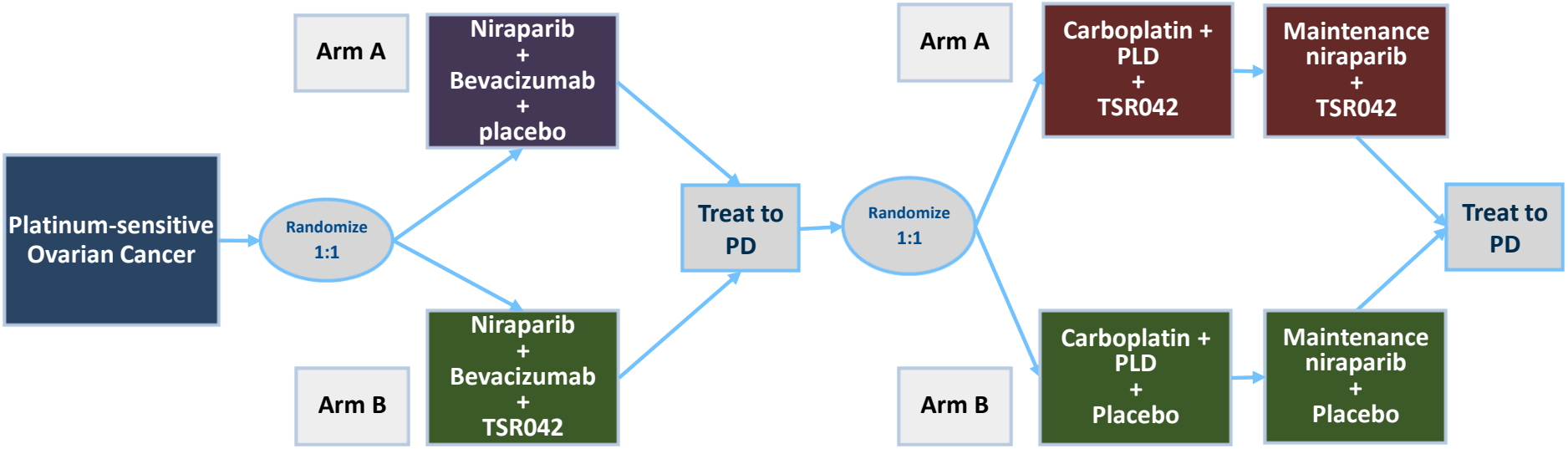
ENGOT-OV42-NSGO / AVANOVA-Imune1
Multicenter, Double-blind, Phase 2 Randomized Trial
n=338



Stratification factors Part 1

- BRCAmut vs BRCAwt
- Chemotherapy-Free Interval: 6-12mo vs >12 mo

ENGOT-OV42-NSGO / AVANOVA-Imune1
Multicenter, Double-blind, Phase 2 Randomized Trial
n=223



Stratification factors Part 2

- BRCA status
- Duration of treatment in part 1: 6-12mo vs >12 mo

A phase II umbrella trial in patients with relapsed ovarian cancer

NSGO-OV-UMB1

ENGOT-OV30 / NSGO

EudraCT number: 2017-002805-36

Sponsor: NSGO

Study Chair: Mansoor Raza Mirza

Participating groups & Lead PIs:

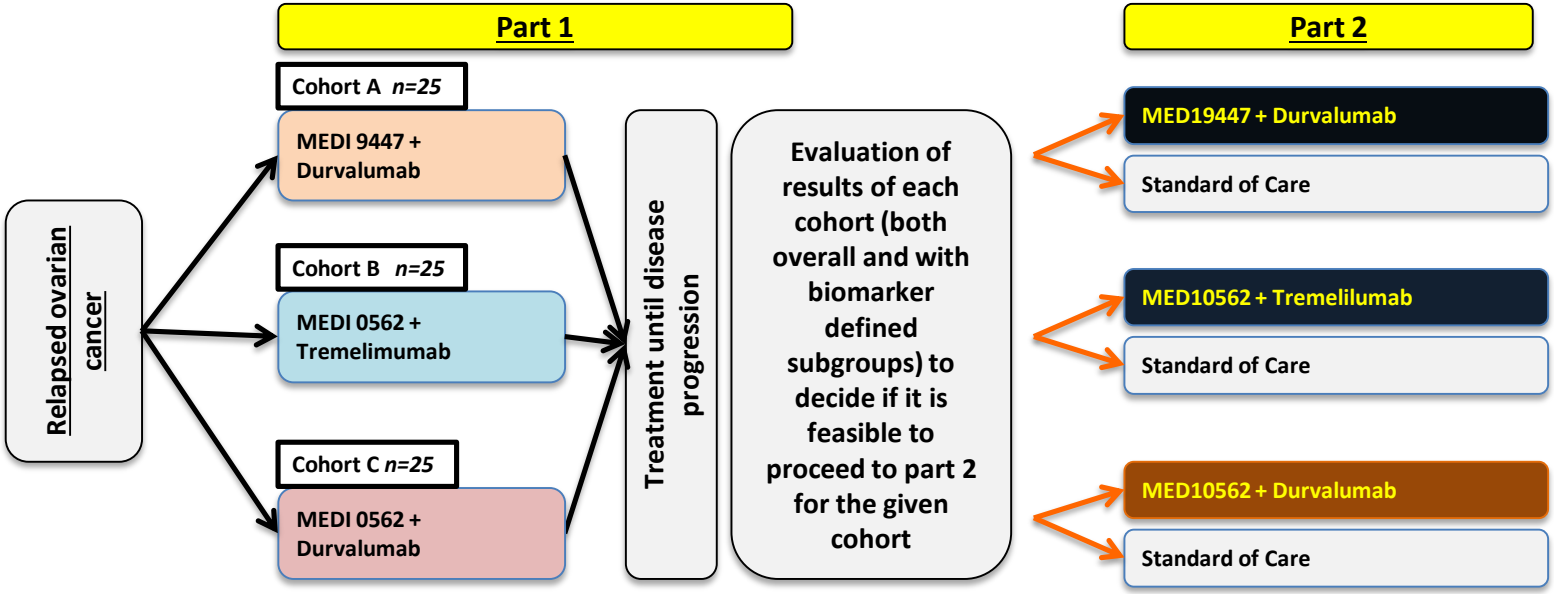
- NSGO: MR Mirza
- SGCTG UK: C Gourley
- PMHC Canada: A Oza
- BGOG Belgium: I Vergote
- ANZGOG Australia: M Friedlander
- COGI US: J Barek
- GOTIC Japan: K Fujiwara
- KGOG S Korea SY Ryu
- NOGGO Germany: Jalid Sehouli

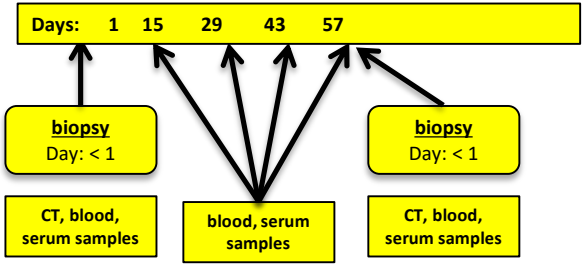
Study Status

- Cohort A accepted (DHMA, 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

A phase II umbrella trial in patients with relapsed ovarian cancer





2:1 randomization

NSGO-OV-UMB1
ENGOT-OV30

OVATIL for Cure

Sponsor: NSGO
Chair: G Coukos
Co-Chair: M R Mirza

NSGO
Rigshospitalet

Relapsed ovarian cancer

Each Cohort *n=12*

- Cohort 1: Carboplatin-Pegylated Lyposomal Doxorubicin (PLD) x2 followed by High-Dose CT & TIL
- Cohort 2: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid
- Cohort 3: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab
- Cohort 4: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab + IDOi
- Cohort 5: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab + A2aRi
- Cohort 6: Carboplatin-PLD x2 followed by High-Dose CT & TIL followed by acetylsalicylic acid in combination with Durvalumab +MEDI9447

Treatment until disease progression

Evaluation of results of each cohort (both overall and with biomarker defined subgroups) to decide if it is feasible to proceed to part 2 for the given cohort

Days: 1 | day -7of TIL | day -1 of TILL | day 21 of TIL

biopsy
Day: < 1

CT, blood, serum samples

blood, serum samples

Biopsy

CT, blood, serum samples

LUDWIG CANCER RESEARCH
NSGO
S↑2C STAND UP TO CANCER
OVA CURE

Ovarian Cancer Targeted Therapy Landscape *Overview*

NSGO

Rigshospitalet

	PARPi	PDL1/L1i	VEGFi	PARPi + VEGFi	PARPi + PD1/L1i	VEGFi + PD1/L1i
First-line Treatment	Veliparib + chemo VELIA	Avelumab + chemo JAVELIN 100	Bev + chemo GOG-218 Bev + chemo ICON7			PD-L1 + Bev + chemo; IMagyn50
First-line Maintenance	Olaparib, SOLO-1 (gBRCA) Niraparib PRIMA			Olaparib + Bev PAOLA-1 Rucaparib + Bev, MITO25 (tBRCA, HRD+)		
Recurrent, PS Treatment	Olaparib, SOLO-3 (gBRCA) Rucaparib; ARIEL4 (tBRCA) Niraparib QUADRA		Bev + chemo; OCEANS Bev + chemo; GOG-213	Olaparib + Cediranib, GY-004 Niraparib + Bev AVANOVA	Ola.+ Durva. MEDIOLA (gBRCA) Ruca. + PD-1 (Part 2)	PD-L1 + Bev + chemo; ATLANTE
Recurrent, PS Maintenance	Rucaparib; ARIEL3 Olaparib, SOLO-2 (gBRCA) Olaparib; OReO Niraparib, NOVA					
Recurrent, PROC Treatment		Avelumab + chemo; JAVELIN 200	Bev + chemo; AURELIA	Ola. + Cediranib, CONCERTO Olaparib + Cediranib, GY-005	Niraparib + Pembro TOPACIO	OVAR 2.29 PD-L1 + Bev + chemo

*Includes PARPs (niraparib, olaparib, rucaparib, veliparib) and PD1/L1s (PD-L1, avelumab).

Key: Olaparib; Veliparib; Rucaparib; Avelumab; PD-1; Bevacizumab; Niraparib

ESGO 2.0 INTERNATIONAL MEETING OF THE EUROPEAN SOCIETY OF GYNAECOLOGICAL ONCOLOGY (ESGO) VIENNA, AUSTRIA 2017