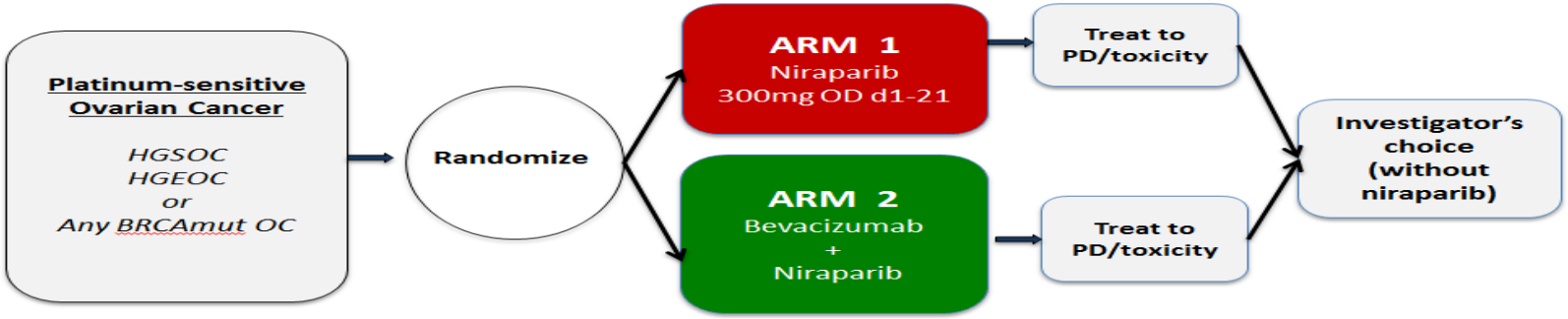
Ongoing Trials – status update

ENGOT-OVAR24/AVANOVA

Trial setting: 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.

Study Design:



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

Sponsor(s): NSGO

Planned No. of patients: 94 (part 2)

Current accrual: 73 (part 2)

Other important information: Status - recruiting

Ongoing Trials – status update

ENGOT-OVAR24/AVANOVA

Country	Sites	PI	Submission status	SIV	CTA	Pts. Randomized
DK	Rigshospitalet	Mansoor R. Mirza (NC)	**Version 3.0** CA: Approved: 20.01.2017 EC: Approved: 25.01.2017	03.12.2015	Yes	**16**
	Herlev	Ulla Peen		30.03.2016	Yes	**5**
	Odense	Gitte-Bettina Nyvang		08.03.2016	Yes	**9**
	Aarhus	Ranva Hassel		19.08.2016	Yes	**3**
	Aalborg	Bente Lund		16.12.2015	Yes	**9**
FI	Tampere	Johanna Mäenpää (NC)	**Version 3.0** CA: Approved: 03.03.2017 EC: Approved: 07.03.2017	30.09.2016	Yes	**5**
	Kuopio	Maarit Anttila		08.11.2016	Yes	**8**
	Turku	Sakari Hietanen		27.01.2017	Yes	**6**
NO	Haukeland	Line Bjørge (NC)	**Version 3.0** CA: Approved EC: Approved: 21.03.2017	TBD	Yes	-
	Stavanger	Bent Fiane		TBD	Yes	-
SE	Lund	Susanne Malander (NC)	**Version 3.0** CA: Approved: 29.05.2017 EC: Approved: 02.05.2017	16.09.2016	Yes	**6**
	Linköping	Gabriel Lindahl		26.09.2016	Yes	**4**
	Sahlgrenska	Maria Dimoula		16.09.2016: Web-based 29.11.2016: On-site MV	Yes	**4**
	Uppsala	Hanna Dahlstrand		16.09.2016 Web-based 11.11.2016: On-site MV	Yes	**3**
US	MGH	Richard Penson	• IND approved the 07.10.2016. • Protocol version 3.0 submitted to FDA on 24.02.2017 by email, CD sent on 02.03.2017. • Non-Significant Risk Determination letter from the FDA received 28.03.2017. • Submission package send to FDA on 29.08.2017 (new site: UAB, change PI at MGH and change of Monitor in the US). • Silent approval received from FDA the 30.09.2017.	26.04.2017 Web-based	Yes	-
	Huntsman Cancer Institute	Theresa Werner		25.04.2017 Web-based	Yes	**4**
	UAB	Michael Birrer (NC)		TBD	Pending	-
Total						**82**