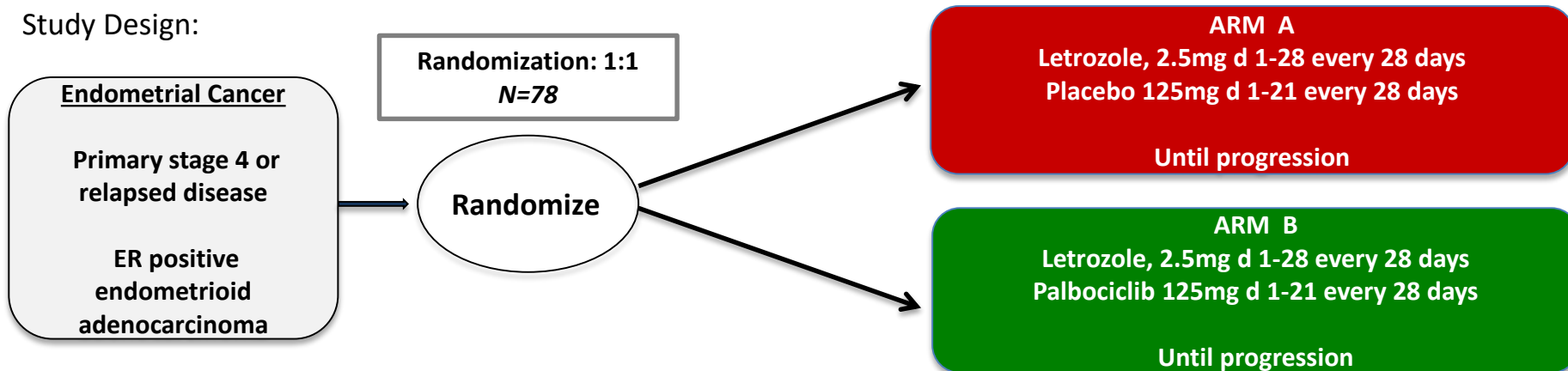


## EN3-NSGO/PALEO

Trial setting: A randomized, double-blind, placebo-controlled, phase II trial of Palbociclib in combination with Letrozole versus Placebo in combination with Letrozole for patients with Estrogen Receptor Positive advanced or recurrent Endometrial cancer.

Study Design:



Sponsor(s): NSGO

Planned No. of patients: 78

Current accrual: 9

**Stratification:**

- Number of prior lines (primary adv disease vs. 1<sup>st</sup> relapse vs. ≥2 relapses)
- Measurable vs. evaluable disease
- Prior use of MPA/Megace

Other important information: *Very slow recruitment in the PALEO study, due to late initiation of sites. MITO still pending regarding approvals from CA and EC, all other groups have received approvals and are in the process of initiating sites, and hopefully soon more patients will be included.*

Country	Sites	PI	Planned SIV	Site activated	Submission status	Pts. Randomized
Denmark	Rigshospitalet	<b>Mansoor R. Mirza (NC)</b>	26/02-17	15/02-17	CA: 13/10: Approved EC: 13/10: Approved	9
	Odense	Gitte-Betina Nyvang	26/02-17	15/02-17		
	Aalborg	Bente Lund	15/9-17	18/9-17		
Norway	Haukeland (Bergen)	<b>Line Bjørge (NC)</b>			CA: 02/01: Approved	
	Radium Hospitalet	Kristina Lindemann	30/6-17	30/8-17	EC: 03/01: Approved	
Finland	Tampere	<b>Annika Auranen (NC)</b>	21/8-17	4/9-17	CA: 17/03: Approved	
	Kuopio	Maarit Anttila			EC: 13/03: Approved	
NOGGO		<b>Jalid Sehouli (NC)</b>			CA: 28/6-17: Approved EC: 21/6-17: Approved	
	Charité Universitätsmedizin Berlin	Dr. Radoslav Chekerov				
	Kliniken Essen Mitte	PD Dr. Beyhan Ataseven	20/9-17	27/9-17		
	Klinikum der Universität München	PD Dr. Julia Gallwas				
	Universitätsklinikum Halle (Saale)	Dr. Hans-Georg Strauss				
Klinikum der Friedrich-Schiller-Universität Jena	Prof. Dr. Ingo Runnebaum					
Universitäts-Frauenklinik Heidelberg	Prof. Dr. Frederic Marmé	9/11-17				
GEICO	HU 12 de Octubre	<b>Dr. Cesar Mendiola (NC)</b>			CA: 27/6-17: Approved EC: 17/5-17: Approved	
	ICO Hospitalet	Dra. Marta Gil	18/9-17	10/9-17		
	ICO Girona	Dra. Pilar Barretina				
	HU Reina Sofía	Dra. María Jesús Rubio				
HU La Paz	Dr. Andrés Redondo					
MITO	Torino	Giorgio Valabrega			CA and EC: Submission in June 2017	Status September – awaiting AIFA approval, following EC will approve
	Rome	<b>Giovanni Scambia (NC)</b>				
	Napoli	Sandro Pignata				
	Milano	Domenica Lorusso				
	Lecce	Graziana Ronzino				
Bologna	Claudio Zamagni					
<b>Total</b>			<b>8</b>	<b>7</b>		<b>9</b>