

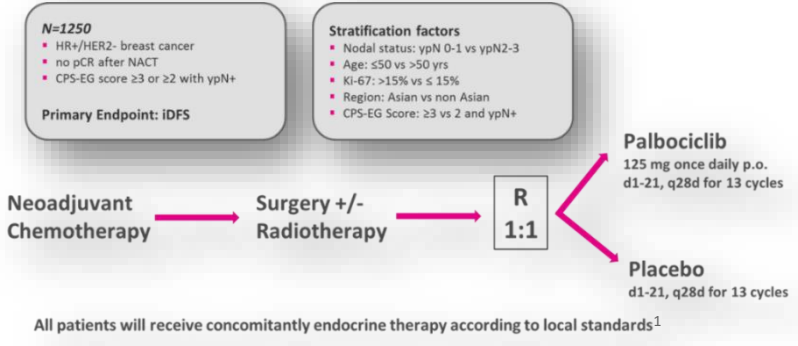
# Ovarian Function in Young Patients Treated with Postneoadjuvant Palbociclib and Endocrine Therapy for HR-positive, HER2-negative Early Breast Cancer: Explorative Analysis in Penelope-B

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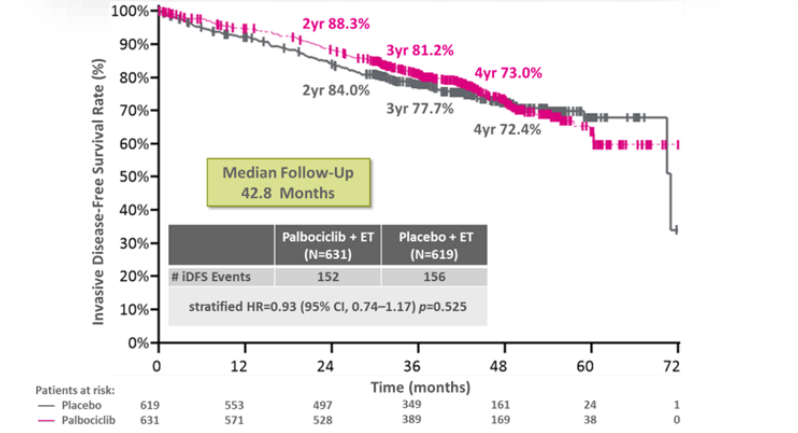
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# Introduction



- Background
- About 50% of the patients in the Penelope-B study were premenopausal at baseline<sup>2</sup>
  - Estradiol (E2), follicle-stimulating hormone (FSH), anti-Müllerian hormone (AMH) values might be influenced by post-neoadjuvant palbociclib
  - Changes in hormones for patients treated with CDK4/6 inhibitors + ET are not well explored

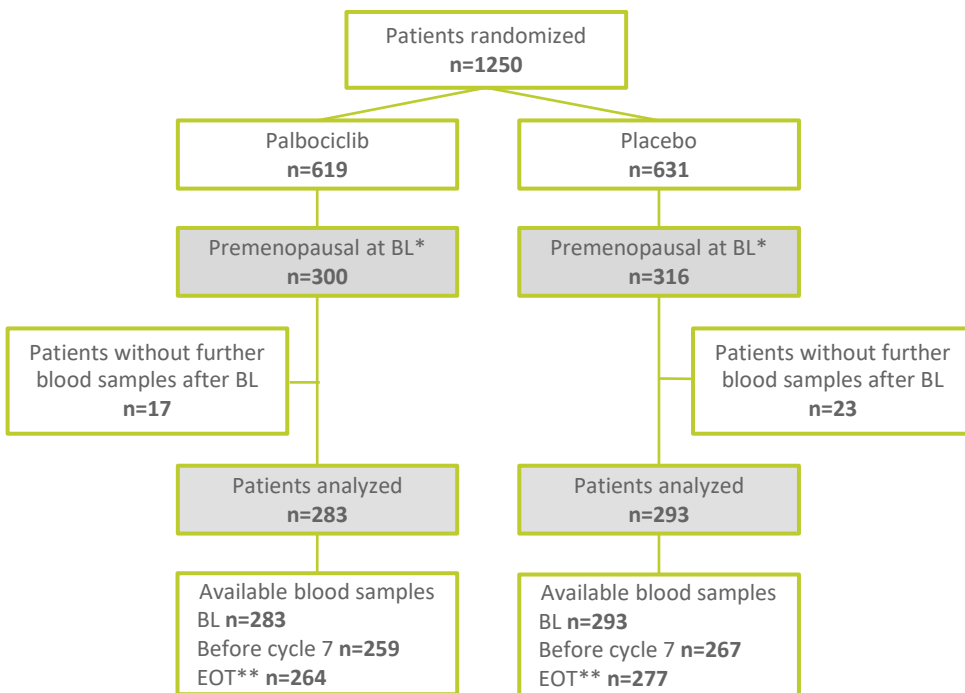
- Objectives
- To assess and to compare between arms:
    - Hormone levels (FSH and E2)
    - AMH values (fertile vs non-fertile)
  - Subgroups:
    - Menopausal status (pre- vs postmenopausal), as defined by levels of E2 and FSH at baseline
    - GnRH analogue use (yes vs no)
    - Age ( $\leq 40$  vs  $>40$  years)



1. Loibl S et al. J Clin Oncol 2021; 2. Marmé ASCO 2021

# Patients' Flow and Baseline Characteristics

## Patients' Flow



\*as reported by the investigator at baseline (BL), anamnestic

\*\*End of treatment (EOT), samples collected 4 weeks after last therapy

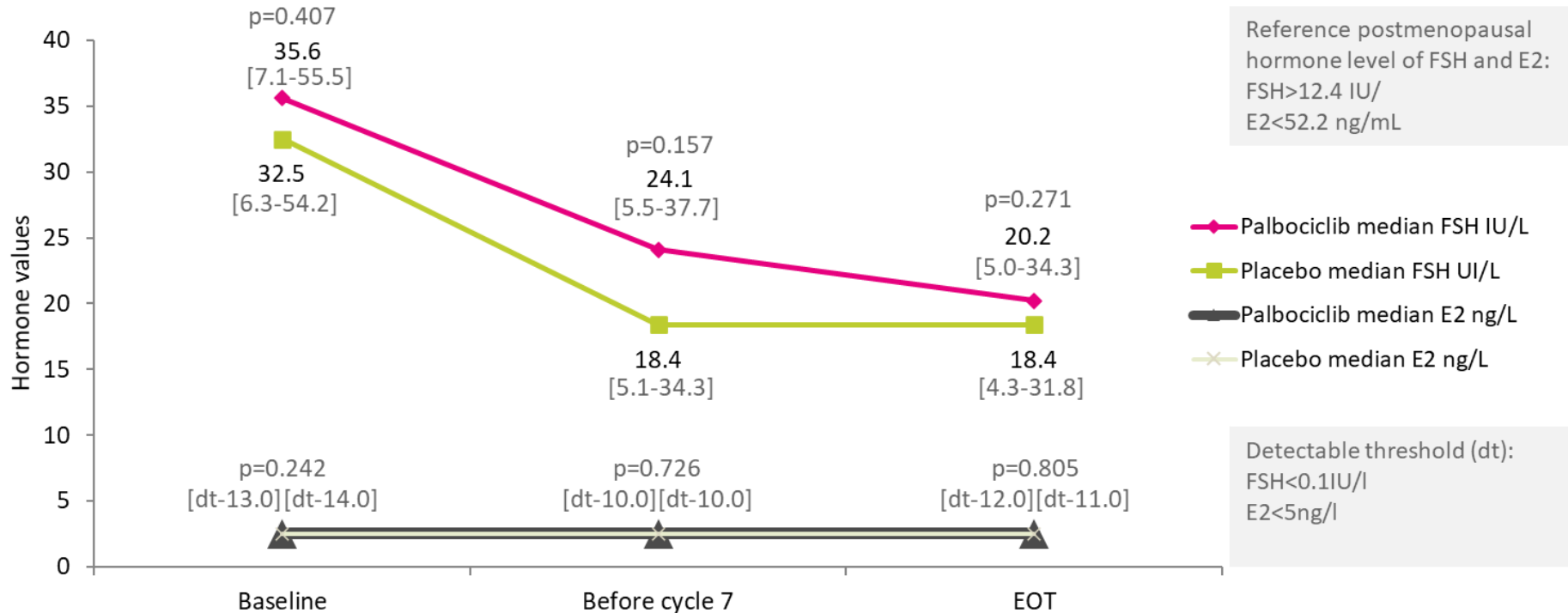
## Baseline Characteristics

Characteristics		Palbociclib n=283		Placebo n=293	
		N	%	N	%
Age	(median [range])	43	[22-55]	43	[19-56]
	≤40 years	105	37.1	106	36.2
	>40 years	178	62.9	187	63.8
Race/Ethnicity	Caucasian/White	204	72.1	217	74.1
	Black	5	1.8	1	0.3
	Asian	41	14.5	34	11.6
	Hispanic	1	0.4	5	1.7
	Other	32	11.3	36	12.3
BMI	<25	133	47.0	137	46.8
	≥25	150	53.0	156	53.2
ECOG Performance Status	0	244	86.2	254	86.7
	1	39	13.8	39	13.3
GnRH analogue use*	No	189	66.8	192	65.5
	Yes	94	33.2	101	34.5

Abbreviations: BMI, Body-Mass-Index; GnRH, Gonadotropin-Releasing-Hormone.

\*GnRH analogue use during NACT was not captured.

# Level of Estradiol and FSH During the Study

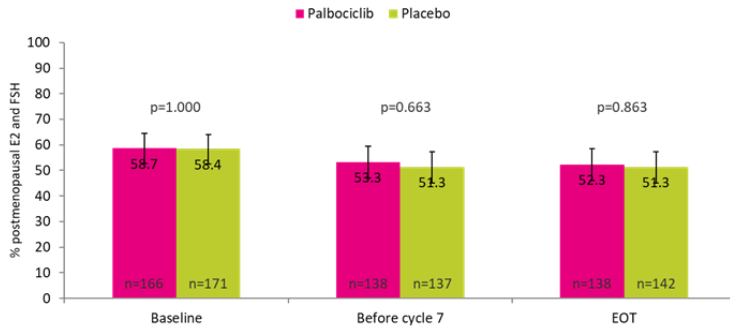


- Median estradiol values were below dt at all time points
- A similar trend was observed in all predefined subgroups

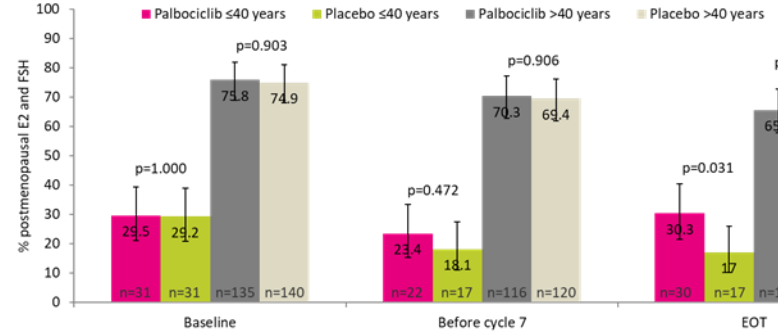
Median and interquartile range are reported

# Rates of Postmenopausal Levels of Estradiol and FSH

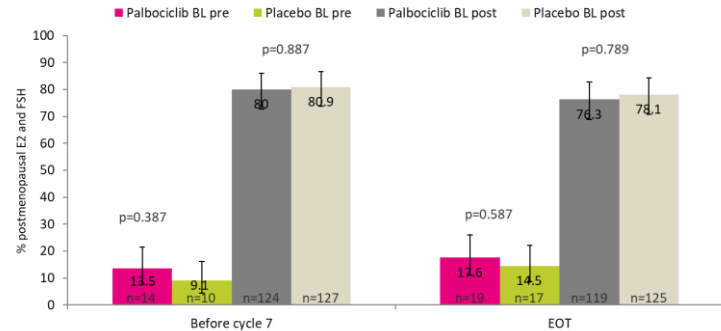
## Overall



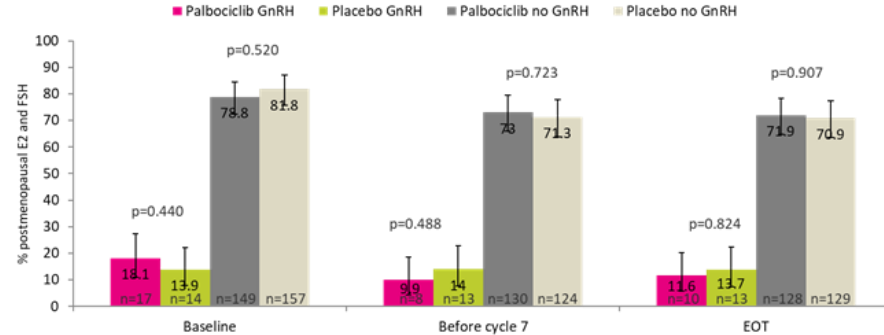
## Age



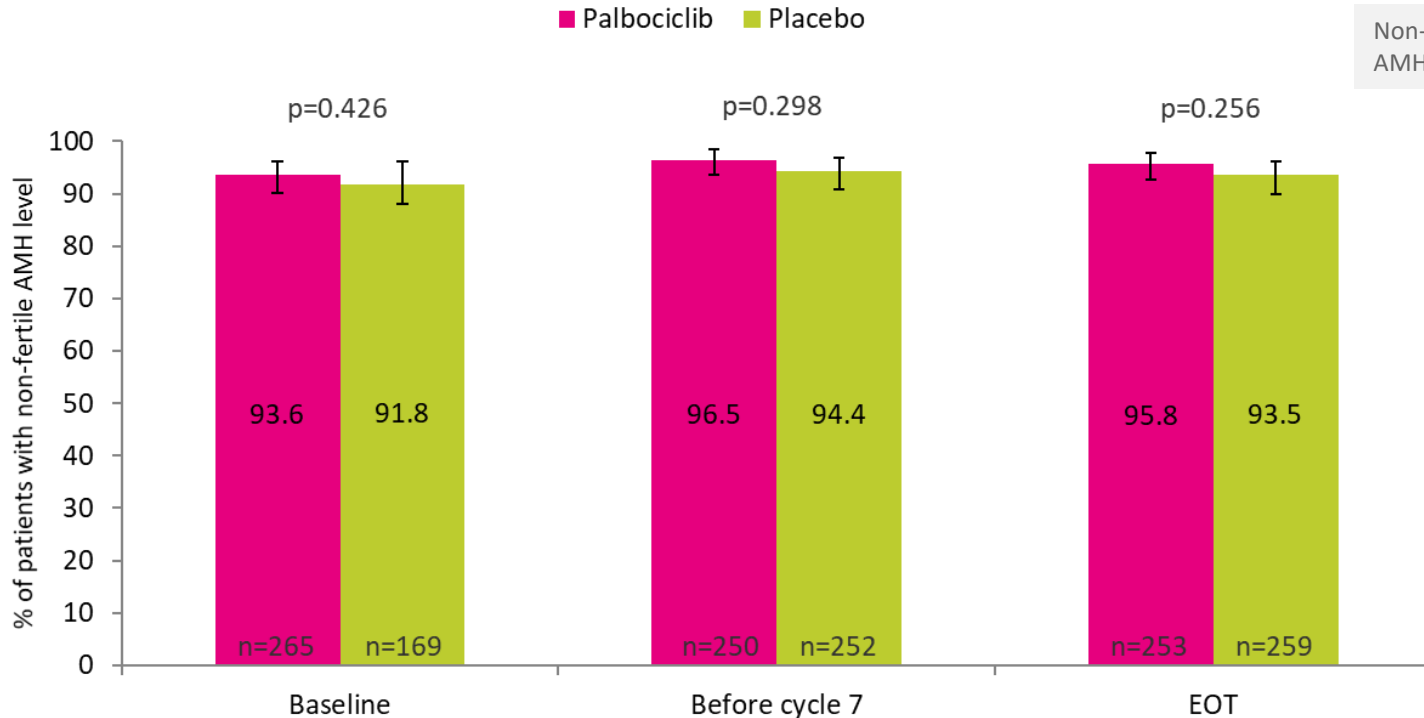
## Hormone-defined Menopausal Status



## GnRH Analogue use



# Rates of Patients with Non-fertile Level of AMH



- Median AMH was below the detection limit (0.03 ng/mL) at all time points
- No difference was observed in subgroups

# Summary and Conclusions

- **Palbociclib did not influence estradiol and FSH levels significantly when added to the endocrine therapy after NACT in women who are premenopausal at study entry<sup>1,2</sup>**
- **At study start, even if patients were defined as premenopausal by the investigators (anamnestic), the majority had postmenopausal hormone levels**
- **Palbociclib does not seem to impact the ovarian reserve as defined by AMH levels overall and in subgroups**
- **Studies on new drugs should incorporate prospective data collection of fertility parameters and hormones analysis in order to adequately counsel young patients**



# Acknowledgement

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## Cooperating partners

## GBG

### Collaborating study groups



### Members of the Subboard GBG and AGO-B

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