



# Quality of life from the Penelope-B study on high-risk HR+/HER2- early breast cancer patients treated with endocrine therapy with or without palbociclib

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# Penelope-B Results

**N=1250**

- HR+/HER2- breast cancer
- no pCR after NACT
- CPS-EG score  $\geq 3$  or  $\geq 2$  with ypN+

**Primary Endpoint: IDFS**

**Stratification factors**

- Nodal status: ypN 0-1 vs ypN2-3
- Age:  $\leq 50$  vs  $> 50$  yrs
- KI-67:  $> 15\%$  vs  $\leq 15\%$
- Region: Asian vs non Asian
- CPS-EG Score:  $\geq 3$  vs 2 and ypN+

Neoadjuvant  
Chemotherapy

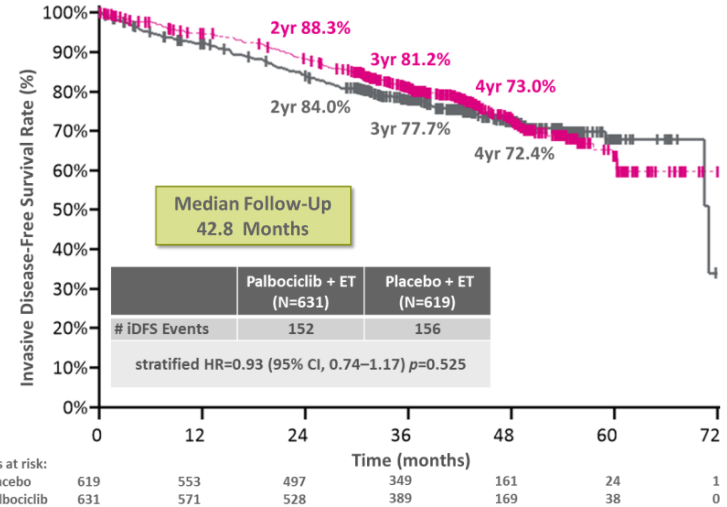
Surgery +/-  
Radiotherapy

**R**  
**1:1**

**Palbociclib**  
125 mg once daily p.o.  
d1-21, q28d for 13 cycles

**Placebo**  
d1-21, q28d for 13 cycles

All patients will receive concomitantly endocrine therapy according to local standards



■ **Secondary objective:**

– Assessment of Quality of Life and comparison between treatment arms.

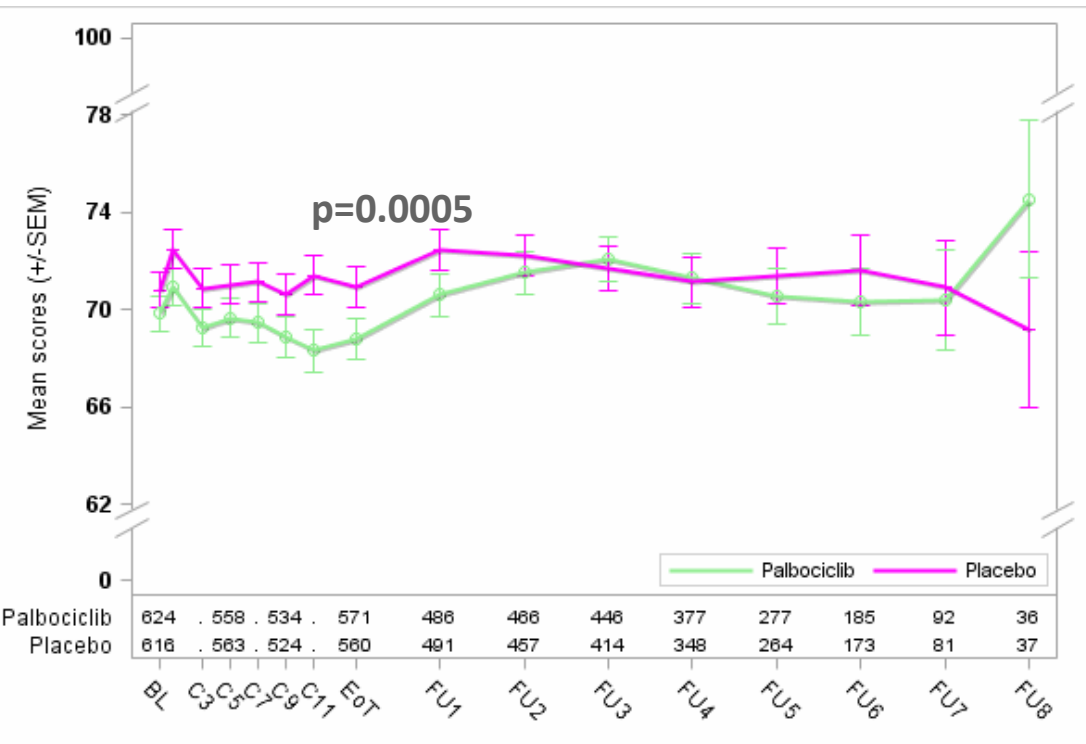
# Penelope-B Quality of Life (QoL)

## Health related Quality of Life (HRQoL) methodology

- QoL was evaluated using a general (**EORTC QLQ-C30**), a breast cancer-specific (**EORTC QLQ-BR23**) and a fatigue symptom (**EORTC QLQ-FA13**) questionnaires (scores range from 0 to 100).
- Higher scores of **C30** and **FA13** indicate better functioning and a better General Health Score (GHS/QoL) or worse symptom severity, respectively.
- Patient-reported outcome (PROs) was assessed during screening, on cycles 1, 3, 5, 7, 9, 11, then, every 6 months after end of treatment visit.
- Overall, 924 of 1250 patients (73.9%) completed the baseline and at least one post baseline questionnaire of all PRO instruments.

# HRQoL Results

## EORTC QLQ-C30 Global Health Status (GHS)

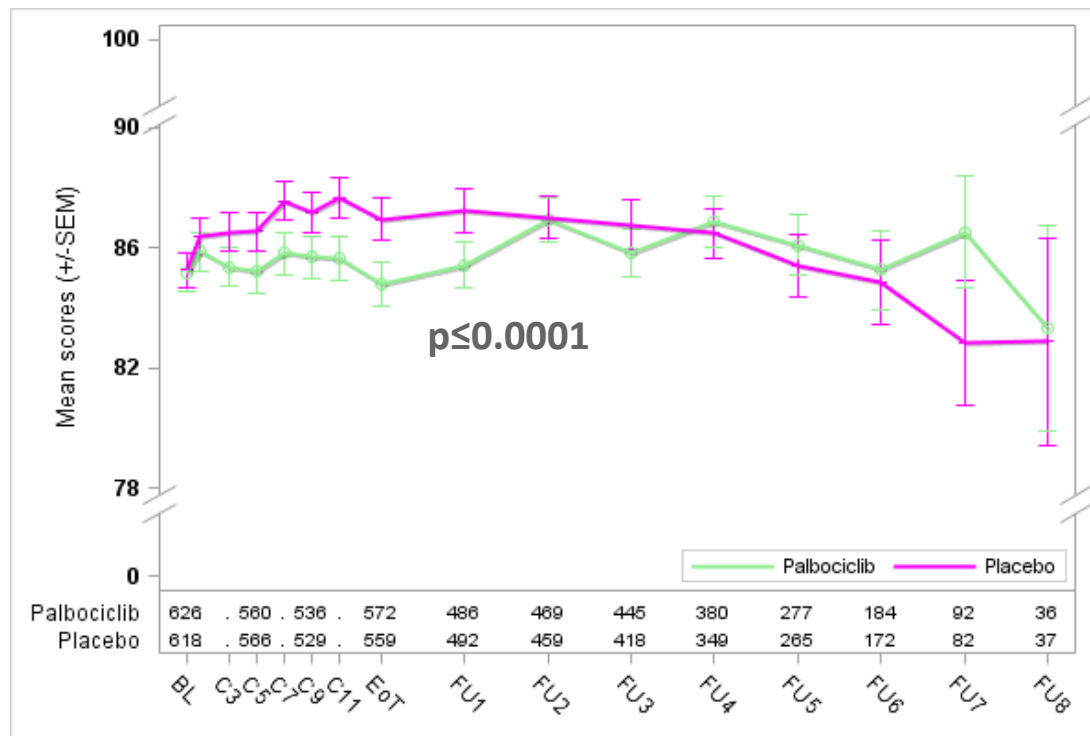


- GHS by the EORTC QLQ-C30 was generally high in both treatment arms: mean [SD]: palbociclib 70.1 [19.3], placebo 71.4 [18.8]
- Slightly lower GHS in the palbociclib arm (LeastSquare mean difference: 0.82, p<0.001), especially during the active treatment phase of the study.

# HRQoL Results

## Physical functioning (EORTC QLQ-C30)

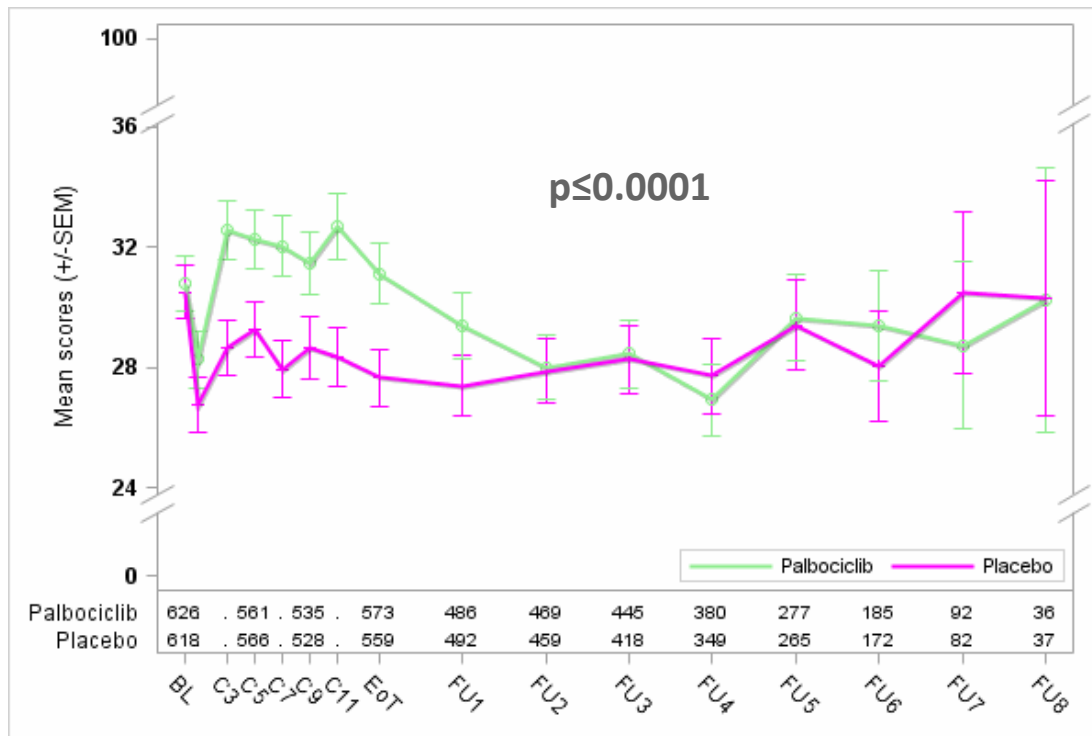
- Slightly better **Physical Functioning** was reported in the placebo arm: mean [SD]: palbociclib 85.8 [16.3], placebo 86.7 [15.6], until approximately one year after end of treatment.
- No statistically significant differences were observed for **FA13 Physical Functioning Score**.



# HRQoL Results

## Fatigue (EORTC QLQ-C30)

- Less **Fatigue** was reported in the placebo arm: mean [SD]: palbociclib 30.3 [23.8], placebo 28.2 [22.7] during the active phase of the study.
- Other QLQ-C30 Scores were comparable between arms
- No relevant differences in BR23 and FA13 questionnaires were documented.





- Patient-reported global QoL was generally maintained during the study in both treatment arms.
- Slight differences, in terms of Global Health Status, Physical Functioning and Fatigue, statistically favored placebo arm but none met published clinically meaningful thresholds<sup>1</sup>.



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