STUDY DESIGN

Primary objectives

1. To demonstrate that the combination of palbociclib, trastuzumab and endocrine therapy is superior to TPC in prolonging PFS in HER2+/HR+ and PAM50 luminal intrinsic subtype mBC.

Secondary objectives

1. To evaluate disease control rate (DCR), overall response rate (ORR) and overall survival in both treatment arms.

2. To evaluate the safety profile in both treatment arms.

3. To assess patient reported BC specific health status (QoL) and general health status in both treatment arms.

4. To investigate tumor and blood biomarkers (TMB, C2D1 and EoT) as predictors of response or resistance to the study treatment.

 OBJECTIVES

STUDY DESIGN

Palbociclib 125 mg QD 3W + Trastuzumab* + Endocrine therapy**

Physician's treatment choice***

1:1

1-4 prior therapies

(Trastuzumab and/or TDM-1)

PAM50 Luminal subtype

HER2+/HR+ metastatic BC

Palbociclib 125 mg QD 3W + Trastuzumab and/or TDM-1

Physician's treatment choice***

- Visceral disease: Yes vs No

- Number of previous regimens: 1-4

- HR+/HER2+, PAM50 Luminal A or B tumors

- At least 1 (maximum 4) previous lines of anti-HER2 regimens for locally advanced or metastatic BC, with at least one prior trastuzumab-based regimen.

- 18 years.

- Pre and postmenopausal women, age ≥ 18 years.

- Histologically confirmed HER2+/HR+ and PAM50 Luminal A or B tumors in primary or metastatic sample.

- An estimated total of 516 patients will be screened to include 232 patients with HER2+/HR+ Luminal A or B tumors.

- The recruitment is ongoing in 20 sites in Spain included in SOLTI and GEICAM networks.

- To date, 125 patients have been screened and 34 enrolled.

- This study has an 80% power with two-sided alpha=0.05 to detect a hazard ratio of 0.62 in favor of the palbociclib arm.

- Inclusion criteria:

  - Pre and postmenopausal women, age ≥ 18 years.

  - Histologically confirmed HER2+/HR+ and PAM50 Luminal A or B tumors in primary or metastatic sample.

  - At least 1 (maximum 4) previous lines of anti-HER2 regimens for locally advanced or metastatic BC, with at least one prior trastuzumab-based regimen.

- Exclusion criteria:

  - Previous treatment with a cyclin-dependent kinase inhibitor.

REFERENCES


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DISCLOSURE STATEMENT OF FIRST AUTHOR

Ciruelos reports personal fees from Pfizer and non-financial support from Pfizer during the conduct of the study; personal fees from Roche, personal fees from Lilly, personal fees from Astra Zeneca, personal fees from Novartis, and personal fees from MSD outside the submitted work.

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BACKGROUND

PATRICIA is a prospective, open-label, multicenter phase II trial that aims to assess palbociclib in combination with trastuzumab with or without endocrine therapy in patients with HER2- positive advanced BC.

The trial, initially, comprised 3 cohorts: A (ER-; palbociclib and trastuzumab), B1 (ER+; palbociclib and trastuzumab) and B2 (ER+; palbociclib, trastuzumab and letrozole).

The results showed that the progression-free survival (PFS) rate at 6 months in cohorts A, B1, and B2 were 33.3% (5/15), 42.8% (12/28), and 46.4% (13/28), respectively.

Luminal disease defined by PAM50 was found independently associated with longer PFS compared with non-luminal disease (10.6 vs. 4.2 months median PFS; adjusted hazard ratio = 0.40; P = 0.003).

The study has an 80% power with two-sided alpha=0.05 to detect a hazard ratio of 0.62 in favor of the palbociclib arm.

The recruitment is ongoing in 20 sites in Spain included in SOLTI and GEICAM networks. To date, 125 patients have been screened and 34 enrolled.

STUDY DESIGN

Chief investigator: Eva Ciruelos. We thank Pfizer for their provision of palbociclib and their financial contribution.