

Clinical trials of cyclin inhibitors for advanced breast cancer (metastatic) in all type of patients

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1 CDK4/6 inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|---|
| palbociclib + exemestane vs capecitabine | | | |
| PEARL <i>ongoing</i> [NCT02028507] n=NA follow-up: | Palbociclib, 125 mg, orally once daily on Day 1 to Day 21 followed by 7 days off treatment given as every 28 days cycles in combination with Exemestane, 25 mg, orally once daily (continuously). versus Capecitabine, 1,250 mg/m ² twice daily for 2 weeks followed by a 1 week rest period, given as 3 weeks cycles. Capecitabine can be administered at a dose of 1,000 mg/m ² twice daily for 2 weeks followed by a 1 week of rest period, given as 3 weeks cycles, in | Hormonal Receptor (HR) Positive/HER2 Negative Metastatic Breast Cancer (MBC) Patients With Resistance to Non-steroidal Aromatase Inhibitors | open label HUNGary |
| palbociclib + fulvestrant vs fulvestrant alone | | | |
| PALOMA 3 , 2015 [NCT01942135] n=347/174 follow-up: | palbociclib (125 mg per day orally for 3 weeks, followed by 1 week off) and fulvestrant (500 mg intramuscularly per standard of care every 14 days for the first three injections and then every 28 days) versus placebo and fulvestrant | women with HR+, HER2 negative metastatic breast cancer whose disease has progressed after prior endocrine therapy | Parallel groups double-blind 17 countries |
| ribociclib (LEE011)+ fulvestrant vs fulvestrant alone | | | |
| MONALEESA-3 <i>ongoing</i> [NCT02422615] n=NA follow-up: | Riblociclib 600mg daily oral (days 1 to 21 in a 28-day Cycle) in combination with fulvestrant 500mg i.m. injections every 28 days (Cycle n Day 1) with 1 additional dose on Day 15 of Cycle 1 versus placebo + fulvestrant 500mg i.m. injections every 28 days (Cycle n Day 1) with 1 additional dose on Day 15 of Cycle 1 | post-menopausal women with advanced breast cancer | double-blind |
| palbociclib + letrozole vs letrozole alone | | | |

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| Trial | Treatments | Patients | Trials design and methods |
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| PALOMA-4 <i>ongoing</i> [NCT02297438] n=NA follow-up: | Palbociclib, 125mg, orally once daily on Day 1 to Day 21 of every 28-day cycle followed by 7 days off treatment in combination with Letrozole, 2.5mg, orally once daily (continuously) versus Placebo, 125mg, orally once daily on Day 1 to Day 21 of every 28-day cycle followed by 7 days off treatment in combination with Letrozole, 2.5mg, orally once daily (continuously). | Asian Postmenopausal Women With ER+/HER2- Advanced Breast Cancer | china |
| palbociclib + letrozole vs letrozole alone | | | |
| PALOMA 1/TRIO-18 , 2015 [NCT00721409] n=84/81 follow-up: | continuous oral letrozole 2.5 mg daily plus oral palbociclib 125 mg, given once daily for 3 weeks followed by 1 week off over 28-day cycles versus continuous oral letrozole 2.5 mg daily | postmenopausal women with advanced oestrogen receptor-positive and HER2-negative breast cancer who had not received any systemic treatment for their advanced disease | Parallel groups open-label |
| PALOMA-2 <i>ongoing</i> [NCT01740427] n=650 follow-up: | PD-0332991, 125mg, orally once daily on Day 1 to Day 21 of every 28-day cycle followed by 7 days off treatment in combination with Letrozole, 2.5mg, orally once daily (continuously). versus Placebo, 125mg, orally once daily on Day 1 to Day 21 of every 28-day cycle followed by 7 days off treatment in combination with Letrozole, 2.5mg, orally once daily (continuously) | postmenopausal women with ER(+)/HER2(-) advanced breast cancer who have not received prior systemic anti cancer therapies for their advanced/metastatic disease | double-blind USA |
| ribociclib (LEE011) + letrozole vs letrozole alone | | | |
| MONALEESA-2 , 2016 [NCT01958021] n=334/334 follow-up: 18 months | ribociclib (600 mg per day on a 3-weeks-on, 1-week-off schedule) plus letrozole (2.5 mg per day) versus placebo + letrozole | postmenopausal women with HR-positive, HER2-negative recurrent or metastatic breast cancer who had not received previous systemic therapy for advanced disease | Parallel groups double-blind 29 countries |
| Abemaciclib +nsAI vs nsAI | | | |
| Monarch3 <i>ongoing</i> [NCT02246621] n=450 follow-up: | Abemaciclib (LY2835219) + nonsteroidal aromatase inhibitors (nSAI) versus Placebo + NSAI | Postmenopausal Women With Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer With No Prior Systemic Therapy in This Disease Setting | double-blind |
| ribociclib (LEE011) + nsAI/TAM gos vs nsAI/TAM + gos | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|---------------------------|
| MONALEESA-7 <i>ongoing</i> [NCT02278120] n=NA follow-up: | LEE011 600 mg daily oral (3 weeks on/ 1 week off) in Combination With Tamoxifen and Goserelin or a Non-steroidal Aromatase Inhibitor (NSAI) and Goserelin versus placebo in Combination With Tamoxifen and Goserelin or a Non-steroidal Aromatase Inhibitor (NSAI) and Goserelin | premenopausal women with HR positive, HER2 negative advanced breast cancer | |
| palbociclib vs placebo | | | |
| PENELOPE-B <i>ongoing</i> [NCT01864746] n=NA follow-up: | - | Hormone Receptor Positive Her2 Normal Patients With Residual Disease After Neoadjuvant Chemotherapy and Surgery | |

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PALOMA 3, 2015:

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MONALEESA-7, :

PENELOPE-B, 0:

2 About TrialResults-center.org

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