Clinical trials of CDK (cyclin-dependent kinase) inhibitor for advanced breast cancer (metastatic) in HR+ HER2-

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1 CDK4/6 inhibitor

Trial	Treatments	Patients	Trials design and methods
palbociclib + exemestane vs capecitabine			
PEARL *ongoing* [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/m2 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/m2 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 *ongoing* [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	Parallel groups double-blind
palbociclib + letrozole vs letrozole alone			

continued...

Trial	Treatments	Patients	Trials design and methods
PALOMA-4 *ongoing* [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	Parallel groups double-blind china
palbociclib + letrozole vs letrozole alone			
PALOMA-2 , 2016 [NCT01740427] n=666 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	Parallel groups double-blind USA
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
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			
MONARCH 3 , 2017 [NCT02246621] n=493 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	Parallel groups double-blind
ribociclib (LEE011) + nsAI/TAM gos vs nsAI/TAM + gos			

continued...

Trial	Treatments	Patients	Trials design and methods
MONALEESA-7 *ongoing* [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	Parallel groups double-blind

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2 About TrialResults-center.org

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