# Alliance A171601: A Phase II Trial Assessing the Tolerability of Palbociclib in Combination with Letrozole or Fulvestrant in Patients Aged 70 and Older with Estrogen Receptor-positive, HER2-Negative Metastatic Breast Cancer

Mina S. Sedrak, MD

City of Hospital National Medical Center

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## Rationale

This study addresses a key research priority of the Cancer and Aging Research Group, National Cancer Institute, National Institute on Aging, and the Institute of Medicine: the assessment of cancer therapy in older adults.[1,2] Palbociclib is a novel drug with the potential to change the treatment of metastatic breast cancer- a disease of aging. The combination of palbociclib and endocrine therapy (letrozole or fulvestrant) is associated with an improvement in progression-free survival (PFS) compared to endocrine therapy alone.[3,4] However, a small proportion of patients enrolled in these studies were age 75 and older. The pivotal trial of palbociclib reported in the package insert notes that only 37 patients (44%) were ≥65 years of age and 8 patients (10%) were ≥75 years of age.

The goal of this study is to fill this gap in knowledge by utilizing a phase II design to examine the tolerability of palbociclib and endocrine therapy among older adults age 70 and older with estrogen receptor positive, HER2 negative breast tumors. A comprehensive cancer-specific geriatric assessment which includes an evaluation of functional status, other medical conditions, cognitive function, nutritional status, social support, psychological state, and a review of medications will be included, as well as an assessment of adherence.

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## Objective

**Primary**

- To estimate the safety and tolerability (adverse event rate) of the combination of palbociclib and letrozole or fulvestrant in adults age 70 or older with ER-positive, HER2-negative metastatic breast cancer.

**Secondary**

- To describe the full toxicity profile including all grade $\geq$ 2 adverse events (per CTCAE version [v.] 5.0)
- To describe rates of dose reductions, dose holds, and hospitalizations.
- To estimate median time to treatment failure, including PFS and OS.
- To estimate the rate of adherence to palbociclib, letrozole and fulvestrant.

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## Study Schema

1 cycle = 28 days

**Registration** →

**TREATMENT**

**Palbociclib**
125 mg a day
(Once daily orally on days 1-21 of each 28 day cycle)

**and**

**Letrozole or Fulvestrant**
(Per treating investigator discretion)
Dosing per packet insert in each 28 day cycle

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Continue protocol treatment until unacceptable toxicity, disease progression, or patient withdrawal

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## Treatment Plan

| Palbociclib plus Letrozole | | | | | |
|---|---|---|---|---|---|
| | **Week 1** | **Week 2** | **Week 3** | **Week 4** | **Week 5+** |
| Palbociclib | 1 capsule every day | 1 capsule every day | 1 capsule every day | No capsule | 1 capsule every day for 21 days, then 7 days no capsules |
| Letrozole | 1 pill every day | 1 pill every day | 1 pill every day | 1 pill every day | 1 pill every day for 28 days |

| Palbociclib plus Fulvestrant | | | | | |
|---|---|---|---|---|---|
| | **Week 1** | **Week 2** | **Week 3** | **Week 4** | **Week 5+** |
| Palbociclib | 1 capsule every day | 1 capsule every day | 1 capsule every day | No capsule | 1 capsule every day for 21 days, then 7 days no capsules |
| Fulvestrant | Injection on Day 1 | No injection | Injection on Day 15 | No injection | Injection on Day 1 of every 28-day cycle |

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## Key Eligibility Criteria

- ER-positive, HER2-negative metastatic breast cancer. Histologic confirmation is required.
- Measurable disease or non-measurable disease
- Planning to begin endocrine therapy for metastatic disease. One prior line of endocrine therapy or chemotherapy for metastatic disease is allowed.
- No prior therapy with a CDK inhibitor
- Resolution of all acute toxic effects of prior therapy or surgical procedures to CTCAE Grade ≤ 1 (except alopecia)
- No untreated brain metastases. Patients with treated brain metastases must have completed treatment with steroids.
- No second malignancies other than non-melanoma skin cancers or cervical carcinoma in situ
- No active infection requiring treatment with antibiotics
- Must be able to swallow and retain oral medication
- Patient Age: ≥ 70 years
- Patients must be able to read and comprehend English or Spanish.
- Chronic concomitant treatment with strong inhibitors or inducers of CYP3A is strongly discouraged on this study.

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## Contact Us

Study Chair: Mina S. Sedrak, MD
City of Hope National Medical Center
E-mail: msedrak@coh.org
Phone: 800-826-4673

Protocol Coordinator: Niveditha Subbiah
E-mail: niveditha@uchicago.edu
Phone: 773-702-9934