Protocol Title: 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

Target Population: Stage IV Breast Cancer that is ER Positive and HER2/neu Negative

Summary: 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.

Key Eligibility Criteria:

- Documentation of disease:
  - Estrogen Receptor (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.
  - 1 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) prior to registration.
- No untreated brain metastases.
  - Patients with treated brain metastases must have completed treatment with steroids to be eligible.
- No second malignancies other than:
  - Non-melanoma skin cancers or
  - Cervical carcinoma in situ
- No active infection requiring treatment with antibiotics.
- Patients must be able to swallow and retain oral medication.
- Adequate baseline organ function:
  - Absolute Neutrophil Count (ANC) ≥ 1500/mm³ (1.5 x 10⁹/L).
  - Platelet Count ≥ 100,000/mm³ (100 x 10⁹/L).
  - Creatinine Clearance ≥ 30 ml/min calculated using the Cockcroft-Gault formula.
  - Total Serum Bilirubin ≤ 1.5 upper limit of normal (ULN)
    - < 3 ULN if Gilbert’s Disease
  - Aspartate Aminotransferase (AST) and/or Alanine Aminotransferase (ALT) ≤ 3 x ULN
    - ≤ 5.0 x ULN if liver metastases present
  - Alkaline Phosphatase ≤ 2.5 x ULN
    - ≤ 5 x ULN if bone or liver metastases present

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03633331