For Patients with Metastatic Breast Cancer

EAI142 Available Through ECOG-ACRIN Cancer Research Group

[18F] Fluoroestradiol (FES) PET as a Predictive Measure for Endocrine Therapy in Patients with Newly Diagnosed Metastatic Breast Cancer

**Patient Population**

See Section 4.0 for Complete Eligibility Details

- Age ≥18 years with life expectancy > 6 months
- Must not be pregnant or breast-feeding
- Patient is a premenopausal/postmenopausal woman, or man for whom endocrine therapy with/without a CDK4/6 inhibitor is planned post FES-PET/CT completion
- ECOG PS 0-3 (restricted to PS 0-2 if age > 70 years)
- No history of allergic reaction to compounds of similar chemical/biologic composition to 18F-FES
- Must not be in liver failure; must be medically stable
- Must have ER+ breast cancer histologically confirmed either from a metastatic biopsy or from a primary breast tumor. If biopsy is NOT available, then metastatic disease must be documented by 2 imaging methods (patients with effusion only disease/disease only in the liver are not eligible)
- The pathology report AND either tumor tissue [blocks or unstained slides] OR a photomicrograph of the ER IHC slides from at least 1 site of metastatic disease and/or from primary breast cancer must be available
- Must not have HER2+ metastatic disease
- Must NOT be planning to receive everolimus nor HER2 directed therapy in addition to endocrine therapy
- Must not have received prior endocrine therapy for metastatic disease (i.e., must be first-line)
- May receive/have received adjuvant endocrine therapy as long as the criteria per protocol are met
- Must not have a history of > 1 line of chemotherapy for metastatic disease and must be off chemotherapy for ≥ 2 weeks; prior chemo in the adjuvant setting is allowed
- Disease must be measurable (RECIST 1.1.) and be ≥ 1.5cm in longest dimension, OR non-measurable ≥ 1.5cm in longest dimension
- Institution must meet ECOG-ACRIN approval per protocol

**Treatment Plan**

See Section 6.0 for Complete Study Design Details

- The experimental FES-PET/CT is required to be completed 0 to 30 days prior to initiation of first-line endocrine therapy for metastatic ER+ breast cancer
- Qualified institutions may manufacture their own FES in coordination with/after approval from NCI’s CIP
- Correlative radiology studies are required within 6 weeks prior to FES-PET/CT
- FDG-PET/CT is strongly encouraged, but optional within 6 weeks before the FES-PET/CT
- See protocol for imaging schedule: 1-2 screening visits, submission of pathology materials, optional FDG-PET, visit on the day of FES-PET/CT, visit 4 is the optional day of reproducibility FES-PET/CT, visit 5 occurs week 1-4 post first FES-PET/CT, follow-up will continue until 2 years after the last patient is enrolled (standard of care; every 6 months post start of endocrine therapy for 2 years then annually/until disease progression; +/- 1 month for the 1st visit and subsequent visits have a window of +/- 2 months)
- If a patient progresses, they will only be followed for vital status
- The injected dose of FES will be 6 mCi +/- 20%; there will be no dose modifications for FES administration
- Treatment will be administered on an outpatient basis
  - Patients will be treated using tamoxifen, an aromatase inhibitor; fulvestrant, or a combination of these agents
  - For premenopausal patients, ovarian suppression is allowed/expected for those undergoing therapy with an aromatase inhibitor
  - Endocrine therapy in combination with CDK 4/6 inhibitors is allowed
  - Investigational therapeutic agents and cytotoxic chemotherapy is not allowed

**Patient Enrollment**

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

**Protocol Information**


Please Enroll Your Eligible Patients!
EAI142 Available Through ECOG-ACRIN Cancer Research Group

[^{18}F] Fluoroestradiol (FES) PET as a Predictive Measure for Endocrine Therapy in Patients with Newly Diagnosed Metastatic Breast Cancer

**Schema**

1. Newly diagnosed ER+ metastatic breast cancer patients scheduled for endocrine therapy

2. Correlative radiology (CT, MRI, or bone scan) within 6 weeks before FES-PET/CT

3. OPTIONAL: FDG-PET/CT scan within 6 weeks before FES-PET/CT scan

4. FES-PET/CT and serum hormone level 0-30 days prior to endocrine therapy

5. OPTIONAL: 2nd FES-PET/CT for least re-test substudy (at least 24 hours and no more than 10 days after the first FES-PET/CT)

6. Endocrine therapy +/- palbociclib initiated 0-30 days after completion of FES-PET/CT

7. Follow-up completed for up to two years after the last patient is enrolled.