For Patients with Oligometastatic HER2– EGA

EA2183 Available Through ECOG-ACRIN Cancer Research Group
A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)

### Patient Population
See Section 3.0 for Complete Eligibility Details

**Registration to Step 1:**
- ≥ 18 years of age, ECOG PS 0-1, and adequate lab values
- Must have histologically confirmed HER2– metastatic esophageal/gastric adenocarcinoma (AJCC 8th ed.)
- Must have oligometastatic disease (see protocol):
  - At most 3 radiologically visible metastatic lesions (not sites), in addition to the primary site
  - Anatomically defined lymphadenopathy will be considered as 1 site of metastatic disease
  - No patients with radiologically evident peritoneal metastasis
- No contraindications to 5-FU/capecitabine/oxaliplatin, or radiation therapy (consultation with radiation oncologist)
- HIV-infected patients must meet criteria per protocol
- Patients with a prior/concurrent malignancy whose natural history/treatment does not have the potential to interfere with the safety/efficacy of the investigational regimen are eligible
- Patients who had prior definitive treatment for early stage EGA with surgery/chemoradiation are eligible as long as recurrent disease developed at least 6 months after prior therapy completion
- No prior treatment with 5-FU/capecitabine/oxaliplatin containing systemic therapy (exceptions per protocol)
- Major surgery must be completed ≥ 4 weeks of registration; no live vaccines within 30 days of registration
- No patients with CNS metastasis; no uncontrolled intercurrent illness

**Registration to Step 2:**
- Must have histologically confirmed HER2- metastatic esophageal/gastric adenocarcinoma (AJCC 8th ed.) with stable disease after 4 cycles of FOLFOX or 6 cycles of CAPOX (Step 1 treatment)
- Must have no evidence of disease progression (RECIST) since Step 1 registration; patients with complete radiologic response are eligible for Step 2

### Treatment Plan
See Section 5.0 for Complete Treatment Details

**Step 1 – Induction Chemotherapy (2 chemotherapy backbones allowed at the preference of the treating physician):**
- **Arm A**– FOLFOX:
  - 4 cycles of FOLFOX (8 doses); administered days 1 and 15 of each 28 day cycle
  - Oxaliplatin 85 mg/m² IV and Leucovorin 200 mg/m², followed by 5-FU bolus 400 mg/m², then continuous 5-FU IV over 46-28 hours on days 1 and 15 for a total of 2400 mg/m²
- **Arm B**– CAPOX:
  - 6 cycles given (each cycle is 21 days)
  - Oxaliplatin 130 mg/m² IV on day 1; Capecitabine 1000 mg/m² orally days 1-14

**Step 2:**
- **Arm C**– Consolidative RT > FOLFOX:
  - Radiotherapy for up to 15 days followed by FOLFOX (per Arm A); 1 week break between completion of chemo in Step 1 and radiotherapy; FOLFOX 2-4 weeks post radiotherapy completion
- **Arm D**– FOLFOX Only: Continue FOLFOX (per Arm A) until disease progression/intolerable toxicity
- **Arm E**– Consolidative RT > CAPOX:
  - Radiotherapy for up to 15 days followed by CAPOX regimen (Arm B); 1 week break between completion of chemo in Step 1 and radiotherapy; CAPOX 2-4 weeks post radiotherapy completion
- **Arm F**– CAPOX Only: Continue CAPOX (per Arm B) until disease progression/intolerable toxicity

### Radiation Therapy:
- Administered using external beam photon RT, with 3D-CRT, IMRT, SBRT, or SRS per treating radiation oncologist (dose/fractionation per treating radiation oncologist as well)

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

### Protocol Information
ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!