# EA2192/APOLLO

For Patients with Resected Pancreatic Cancer

## Patient Population

**Step 0 (Pre-registration):**
- Age ≥ 18 years, ECOG PS 0-2, and adequate lab values
- Must have a diagnosis of pancreatic cancer and successfully undergone a curative intent surgical resection and must have no evidence of recurrent disease (this includes adenocarcinoma, acinar carcinoma, squamous cell carcinoma adenosquamous and variants thereof; patients with neuroendocrine tumors are excluded)
- Must be 1) planning to receive, 2) be receiving, or 3) received at least 12 weeks of perioperative (neoadjuvant/adjunct/combo of both) systemic, multi-agent chemotherapy
  - May have had up to 6 months of perioperative systemic therapy (may have received radiation/chemoradiation in addition to this 6 month course)
- Must be no more than 12 weeks from most recent treatment (i.e., chemotherapy, radiotherapy, or surgery)
- Known pathogenic/likely pathogenic germline or somatic mutation in BRCA1, BRCA2, or PALB2

**Step 1 (Randomization):**
- Adequate lab values; must have undergone/be willing to undergo germline testing
- No evidence of recurrent/metastatic pancreatic cancer at the time of randomization; no previous evidence of progressive pancreatic cancer while receiving platinum-based therapy
- Mut be ≥ 21 and ≤ 84 days from their last treatment
- Must not have any history of allergic reactions attributed to compounds of similar chemical/biological composition to olaparib; no concomitant use of potent CYP3A4/5 inhibitors
- No personal history of MDS or AML or features suggestive of MDS or AML
- No uncontrolled gastrointestinal disorder that would interfere with the ingestion/absorption of olaparib
- Must not have resting ECG indicating cardiac conditions per protocol

## Treatment Plan

**1 cycle= 28 days; patients randomized to “Arm X”**

**Arm A:**
- Olaparib 300 mg PO twice daily (total daily dosage of 600 mg), days 1-28
- Repeat cycle every 4 weeks for a total of 12 cycles

**Arm B:**
- Placebo 300 mg PO twice daily (total daily dosage of 600 mg), days 1-28
- Repeat cycle every 4 weeks for a total of 12 cycles

Patients will be followed for AEs for at least 30 days after the last dose. Then, patients will be followed for relapse-free survival and survival per protocol. All patients will be followed for response until progression and for survival for 10 years from the date of Step 1 randomization

**Notes:**
- All treatment will be administered on an outpatient basis
- Telemedicine visits may be used starting at the cycle 3 time point if allowed based on local laws and institutional practices (see protocol section 5.7 for details)
- Olaparib/placebo is supplied in either 100 or 150 mg tablets
- Take olaparib/placebo with water; may be taken with or without food (note: prohibited to consume grapefruit/Seville orange juice); tablets should be swallowed whole
- If a dose is missed, the patient will be permitted to take it up to 2 hours after the scheduled time

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**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!
Randomization is 2:1 (i.e., each patient has a two-thirds chance of being randomized to Arm A and a one-third chance of being randomized to Arm B).

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Please note that when a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm.

NOTE:

ECOG-ACRIN cancer research group

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