Version 06/16/22 (Add. #4)

NCI National Clinical Trials Network

EA2192/APOLLO

For Patients with Resected Pancreatic Cancer

EA2192 Available Through ECOG-ACRIN Cancer Research Group

APOLLO: A Randomized Phase II Double-Blind Study of Olaparib versus Placebo Following Curative Intent Therapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2, or PALB2 Mutation

Patient Population

See Section 3.0 for Complete Eligibility Details

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/adjuvant/combination 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 thearpy
- 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

See Section 5.0 for Complete Treatment Details

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 swalled whole*
- *If a dose is missed, the patient will be permitted to take it up to 2 hours after the scheduled time*

Study Chair:
Kim A. Reiss Binder, MD

Study Co-Chair:
Anup Kasi, MD

Patient Enrollment

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

Protocol Information

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

Please Enroll Your Eligible Patients!

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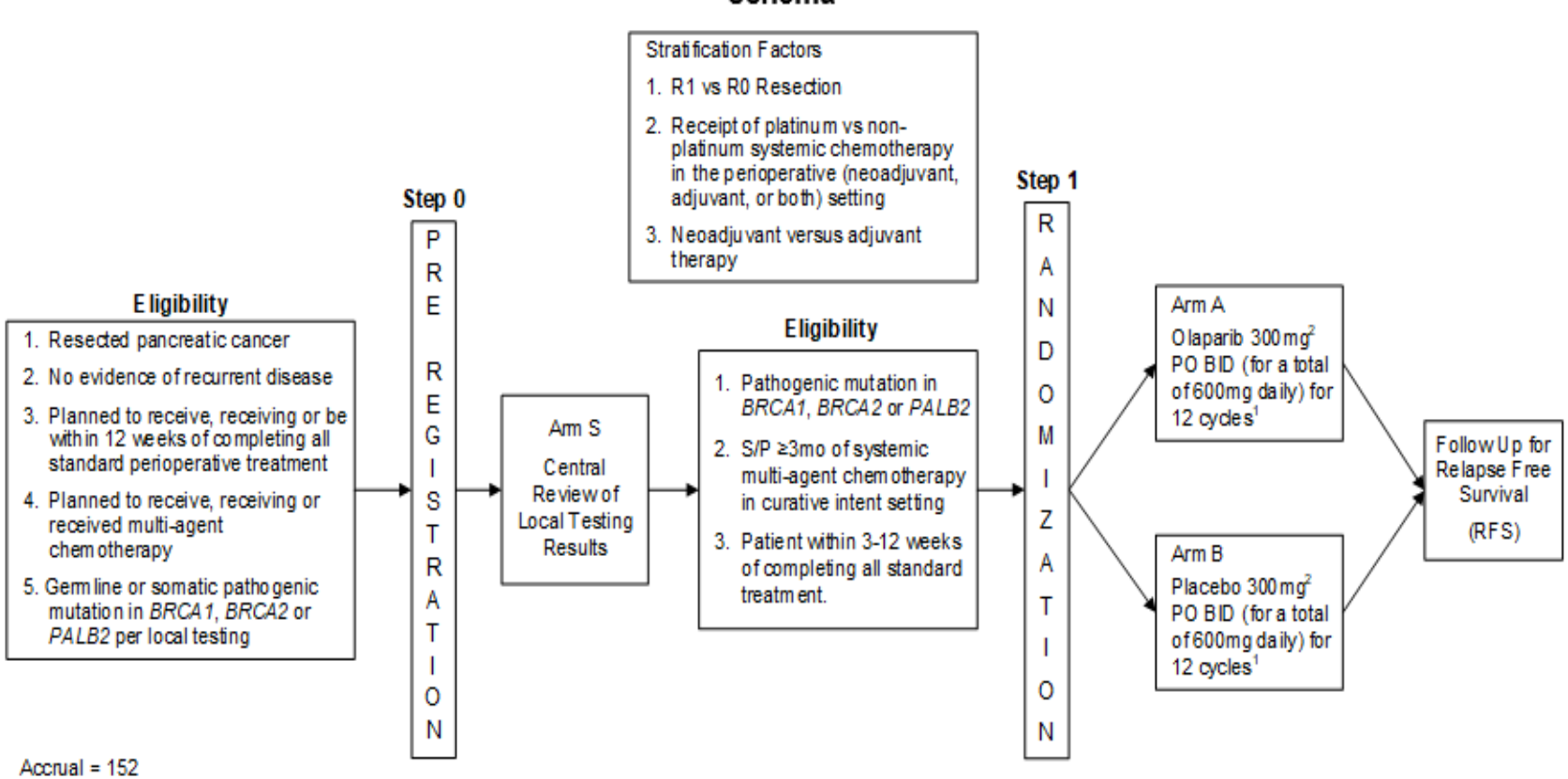
ECOG-ACRIN cancer research group

EA2192

Schema



[1] One cycle = 4 weeks

[2] Olaparib is supplied in either 100 mg or 150 mg tablets

NOTE: Please note that when a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm X. The patient will actually be randomized to Arm A or B, but as this is a double-blind trial, that information cannot be displayed.

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