A Randomized Study of Olaparib or Placebo in Patients with Surgically Removed Pancreatic Cancer who have a BRCA1, BRCA2 or PALB2 Mutation

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating pancreatic cancer.
- The usual approach for patients with curable (i.e., non-metastatic) pancreatic cancer is a combination of surgery, FDA-approved chemotherapy, radiation (in select cases), then surveillance monitoring. This means that patients are typically monitored by their oncologist for evidence that the cancer has returned (recurrence), but they receive no additional treatment after the completion of surgery and chemotherapy.
- The purpose of EA2192/APOLLO is to compare the usual approach (monitoring/observation) to treatment for one year with a drug called olaparib, in patients with BRCA or PALB2 mutations.
- EA2192/APOLLO will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if olaparib delays cancer recurrence compared to the usual approach of observation.

WHAT does this study involve?

- If you decide to participate in EA2192/APOLLO, you will be assigned by chance (randomized) to one of the groups listed below. Neither you nor your doctor will be told which group you are in. Each patient has a 2/3 chance of being in Group 1 and a 1/3 chance of being in Group 2.
  - **Group 1:** You will get a study drug called olaparib, which is a tablet. You will take two tablets by mouth twice daily for 12 months.
  - **Group 2:** You will get a tablet that looks like the study drug, but contains no medication (this is called a placebo). You will take two placebo tablets by mouth twice daily for 12 months.

- After you finish your study treatment, your doctor will continue to follow your condition every 8 weeks for up to 10 years.
**WHO will take part in this study?**

- Approximately 152 patients will participate in EA2192/APOLLO.
- Participants must have a mutation (as identified in saliva, blood, and/or tumor tissue samples) in one of the following genes in order to participate in EA2192/APOLLO: *BRCA1*, *BRCA2* or *PALB2*.
- You can decide to stop taking part in the study at any time, even after you have enrolled.

**WHAT are the costs of taking part in this study?**

- Just as you would if you were getting the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study. Check with your insurance company to find out what they will pay for.
- You/your insurance provider will **NOT** have to pay for olaparib while you take part in EA2192/APOLLO.
- Taking part in this study may mean that you need to visit the clinic or hospital more often than if you were getting the usual treatment for your cancer.
- You will not be paid for taking part in EA2192/APOLLO.

**IF you would like to know more**

- About the EA2192/APOLLO study, talk with your doctor, or:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EA2192, then select the link to EA2192.
    - For information about medical facilities where the study is available, scroll down the page to Locations and Contacts.
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
- About clinical trials:
  - General cancer information: visit the NCI website at [www.cancer.gov](http://www.cancer.gov)
- About ECOG-ACRIN:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org)
  - For a list of patient resources and links to patient advocacy groups, visit [https://ecog-acrin.org/patients/resources](https://ecog-acrin.org/patients/resources)