Information for healthcare professionals

Study of olaparib in pancreatic cancer (POLO)

POLO: A Phase 3 study of olaparib — an investigational PARP inhibitor — as maintenance monotherapy in patients with germline *BRCA*-mutated metastatic pancreatic cancer, whose disease has not progressed on first-line platinum-based chemotherapy

ClinicalTrials.gov number: NCT02184195

What is the POLO study?

The primary aim of the POLO study is to determine the efficacy of olaparib maintenance monotherapy, compared with placebo, as measured by progression-free survival in patients with germline *BRCA*-mutated metastatic pancreatic cancer, whose disease has not progressed on first-line platinum-based chemotherapy. Olaparib inhibits the action of a protein called poly (ADP-ribose) polymerase (PARP). Tumors in *BRCA*-mutated patients require PARP to repair DNA damage, enabling continued cell division and tumor growth. By inhibiting PARP, olaparib could potentially delay tumor progression.

Individuals with *BRCA* mutations have a 1–7% risk of developing pancreatic cancer during their lifetime. Phase 2 data indicate that olaparib shows evidence of clinical efficacy in patients with germline *BRCA*-mutated pancreatic cancer, which warrants further investigation.

Olaparib has been approved by the Food and Drug Administration (FDA) for the treatment of women with germline *BRCA* genetic mutations with advanced ovarian cancer, who have previously received three or more courses of chemotherapy.

What are the key eligibility criteria?

To be able to take part in the POLO study, a patient must:

- Be at least 18 years of age
- Have histologically or cytologically confirmed metastatic adenocarcinoma of the pancreas
- Have a documented genetic mutation in *BRCA1* or *BRCA2* that is known or predicted to be detrimental
- Be receiving their initial course of chemotherapy for metastatic disease with a platinum-containing regimen*, with the platinum component given for a minimum of 16 weeks. If the platinum was discontinued, chemotherapy must be continued until enrollment. Other drugs can be dropped as clinically indicated but no new drugs can be added and the last dose of chemotherapy must be completed 4-8 weeks before study drug treatment commences

  *Acceptable platinum agents include carboplatin, cisplatin, and oxaliplatin
- Show no evidence of disease progression at any time while on first-line chemotherapy; the tumor must have stabilized or improved during treatment
- Have reached a point in their chemotherapy where both they and their physician believe that having a pause or break from the chemotherapy treatment is appropriate
- Fulfill all inclusion criteria as defined in the study protocol

What will the study involve?

Patients will be randomized (3:2) to the following treatments:

- Olaparib tablets, 300 mg twice daily by mouth
- Matched placebo tablets, twice daily by mouth

Patients will continue to receive study treatment until their cancer progresses or they wish to withdraw from the study.

Further information

If you are in the USA or Canada, you can call the AstraZeneca Cancer Study Locator service toll free on 1-877-400-4656 to get more information about the POLO study.

Full details of the POLO study, including a list of study sites that are/will be recruiting, are available on the ClinicalTrials.gov website: https://clinicaltrials.gov/ct2/show/NCT02184195 (ClinicalTrials.gov number: NCT02184195).

Further information about the POLO study can also be found on the POLO study website: www.pancreaticcancertrial.com. Alternatively, please email the AstraZeneca olaparib clinical project team: olaparib@astrazeneca.com