Information for Healthcare Professionals

Studies of olaparib in ovarian cancer (SOLO)

SOLO3: A Phase 3 study of olaparib — an investigational PARP inhibitor — as monotherapy in women with platinum-sensitive relapsed ovarian cancer, peritoneal cancer, and/or fallopian tube cancer carrying inherited *BRCA1/2* mutations

ClinicalTrials.gov number: NCT02282020

What is the SOLO3 study?

The primary aim of the SOLO3 study is to assess the efficacy and safety of olaparib monotherapy versus physician's choice single agent chemotherapy in the treatment of platinum sensitive relapsed ovarian cancer in patients carrying germline BRCA1/2 mutations. This will be measured by progression-free survival in patients with inherited BRCA mutations with platinum-sensitive relapsed ovarian cancer. The patients must have received at least two prior lines of platinum-based chemotherapy and have progressed at least six months after their last line of platinum-based chemotherapy. Olaparib inhibits the action of poly (ADP-ribose) polymerase (PARP). PARP is required to repair DNA damage, enabling continued cell division and tumor growth in BCRA-mutated tumors; therefore by inhibiting PARP, olaparib could potentially delay tumor progression. Olaparib has been approved as a monotherapy for the treatment of patients with inherited BRCA mutations with advanced ovarian cancer, who have been treated with three or more lines of chemotherapy previously, by the Food and Drug Administration (FDA)

What are the key eligibility criteria?

To be able to take part in the SOLO3 study, a patient must:

- Have histologically diagnosed, relapsed or recurrent, high-grade serous/endometrioid ovarian cancer, primary peritoneal cancer, and/or fallopian tube cancer

- Have an inherited deleterious or potentially deleterious mutation in *BRCA1 or BRCA2*
- Have completed at least two previous lines of platinum-based chemotherapy (eg carboplatin, cisplatin, or oxalaplatin), with the last line completed at least six months before starting treatment
- Have a tumor that is sensitive or partially sensitive to platinum-based chemotherapy, ie the tumor must have shrunk or disappeared following the most recent line of platinum chemotherapy and must not have grown again for at least six months after that line of chemotherapy had finished
- Fulfill all inclusion criteria as defined in the study protocol

What will the study involve?

Patients will be randomized (2:1) to one of the following treatments:

- Olaparib tablets, 300 mg twice-daily by mouth
- Chemotherapy, given intravenously every four weeks, depending on the chemotherapy chosen by the physician (paclitaxel, topotecan, pegylated liposomal doxorubicin, or gemcitabine)

Patients will continue to receive study treatment until their cancer progresses and may continue treatment after disease progression, as long as the study investigator considers that they are continuing to benefit from the treatment.

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 for more information about the SOLO3 study.

Full details of the SOLO3 study, including a list of study sites that are/will be recruiting, are available on the ClinicalTrials.gov website: https://clinicaltrials.gov/ct2/show/NCT02282020 (ClinicalTrials.gov number: NCT02282020).

Further information about the SOLO3 study can also be found on the SOLO studies' website: www.ovariancancertrials.com

Alternatively, please email the AstraZeneca olaparib clinical project team: olaparib@astrazeneca.com

References

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- American Society of Clinical Oncology. FDA Approves Olaparib for Advanced Ovarian Cancer. http://www.asco.org/advocacy/fda-approves-olaparib-advanced-ovarian-cancer (last viewed 17/03/15)
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- National Cancer Institute. Ovarian Epithelial, Fallopian Tube, and Primary Peritoneal Cancer Treatment (PDQ®): Recurrent or Persistent Ovarian Epithelial, Fallopian Tube, and Primary Peritoneal Cancer Treatment. http://www.cancer.gov/cancertopics/pdq/treatment/ovarianepithelial/HealthProfessional/page6 (last viewed 17/03/15)