A Study of Niraparib Maintenance Treatment in Patients With Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy

This study is currently recruiting participants. (see Contacts and Locations)

Verified February 2017 by Tesaro, Inc.

Sponsor:
Tesaro, Inc.

Collaborators:
Gynecologic Oncology Group
European Network of Gynaecological Oncological Trial Group (ENGOT)
Myriad Genetics, Inc.

Information provided by (Responsible Party):
Tesaro, Inc.

ClinicalTrials.gov Identifier:
NCT02655016

First received: December 8, 2015
Last updated: February 21, 2017
Last verified: February 2017
History of Changes

Purpose

This study is a double-blind, randomized, placebo-controlled (2:1 niraparib:placebo) study in patients with Stage III or IV ovarian cancer. Patients must have completed front-line platinum based regimen with a physician-assessed response of Complete Response (CR) or Partial Response (PR). Stage III patients must have visual evidence of disease. Additionally, patients must have a normal or >90% decrease in cancer antigen 125 (CA-125) following front-line platinum treatment. The study will assess the efficacy of niraparib as maintenance treatment, as measured by PFS.

Condition	Intervention	Phase
Ovarian Cancer	Drug: Niraparib Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Participant, Care Provider, Investigator, Outcomes Assessor
Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients With Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy

Resource links provided by NLM:

Genetics Home Reference related topics: ovarian cancer

MedlinePlus related topics: Cancer Ovarian Cancer

Genetic and Rare Diseases Information Center resources: Ovarian Cancer

U.S. FDA Resources

Further study details as provided by Tesaro, Inc.:

Primary Outcome Measures:

- Progression Free Survival [Time Frame: From date of randomization until the date of first documented progression or date of death from any cause, whichever came first - Approximately 15 months]

  The time from treatment randomization to the earlier date of assessment of progression or death by any cause in the absence of progression.

Secondary Outcome Measures:

- Overall Survival [Time Frame: 48 months]

  From date of randomization until the date of first documented progression or date of death from any cause, whichever came first.

- Safety and tolerability of Niraparib versus Placebo as Number of participants with treatment-related adverse events as assessed by CTCAE v4.0. [Time Frame: 48 months]

  From date of screening until the date of study discontinuation or date of death from any cause, whichever came first

- Patient Reported Outcomes (PROs) [Time Frame: 48 months]
- Time to progression on the next anticancer therapy (PFS2) [Time Frame: 48 months]

  From date of start of next anticancer therapy to date of first documented progression of date of death from any cause, whichever comes first.

Other Outcome Measures:

- AUC0-last [Time Frame: Up to 32 weeks]

  AUC Area Under the Curve, time from 0 to the last quantifiable concentration

- AUC [Time Frame: Up to 32 weeks]

  AUC Area Under the Curve, time from 0 to the last quantifiable concentration

- Peak Plasma Concentration (Cmax) [Time Frame: Up to 32 weeks]

  Cmax Observed maximum plasma concentration

- HRD Diagnostic Test [Time Frame: Samples for BRCA and HRD diagnostic testing will be obtained at screening and tested during the study. Additional biomarkers may be tested from an optional tumor sample if available at study treatment discontinuation, approximately 48 months]

Estimated Enrollment:	330
Study Start Date:	April 2016
Estimated Primary Completion Date:	August 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Niraparib Administered once daily continuously during a 28 day cycle.	Drug: Niraparib Niraparib vs Placebo 2:1 ratio
Placebo Comparator: Placebo Administered once daily continuously over a 28 day cycle	Drug: Placebo

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Main Inclusion Criteria:

- Patient must have histologically confirmed, advanced (FIGO Stage III or IV) high-grade predominantly serous or endometrioid ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who have completed first line platinum based chemotherapy (neoadjuvant or adjuvant)
- Patient must have clinical complete response or partial response following completion of chemotherapy course.
- All Stage IV patients are eligible, irrespective of residual disease, after primary or interval debulking. Stage III patients are required to have visible residual disease after primary surgery. Patients with inoperable Stage III and IV disease are eligible
- Patient must agree to undergo tumor HRD testing
- Patients of childbearing potential must have negative pregnancy serum test within 72 hours of being dosed
- Patient must be randomized within 12 weeks of the first day of the last cycle of chemotherapy

Main Exclusion Criteria:

- Patient has mucinous or clear cell subtypes of epithelial ovarian cancer, carcinosarcoma or undifferentiated ovarian cancer
- Patient has undergone more than 2 debulking surgeries
- Patient has received bevacizumab with first-line platinum based therapy
- Patient is pregnant, breastfeeding, or expecting to conceive children, while receiving study treatment and for 3 months after the last dose of study treatment

- Patient has had prior treatment with a known PARP inhibitor
- Patient has been diagnosed and/or treated for invasive cancer (other than ovarian cancer)

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02655016

Contacts

Contact: Beth Zaharoff 781- 209-5485 bzaharoff@tesarobio.com

Show 72 Study Locations

Sponsors and Collaborators

Tesaro, Inc.

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Myriad Genetics, Inc.

More Information

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Other Study ID Numbers:	**PR-30-5017-C**
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Keywords provided by Tesaro, Inc.:

Ovarian Cancer
PARP Inhibitor
HRD
HRD positive
PRIMA
PRIMA Clinical Trial
PRIMA Study

Additional relevant MeSH terms:

Ovarian Neoplasms
Endocrine Gland Neoplasms
Neoplasms by Site
Neoplasms
Ovarian Diseases
Adnexal Diseases
Genital Diseases, Female
Genital Neoplasms, Female
Urogenital Neoplasms
Endocrine System Diseases
Gonadal Disorders
Niraparib
Poly(ADP-ribose) Polymerase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents

ClinicalTrials.gov processed this record on March 29, 2017