ForPatients
by Roche

Peritoneal NeoplasmsCâncer do Tubo UterinoCâncer Ovariano

Um ensaio clínico comparando atezolizumabe com um placebo quando administrado com quimioterapia (paclitaxel e carboplatina) e bevacizumabe em pessoas recém-diagnosticadas com câncer avançado de ovário, trompa de Falópio ou peritoneal

A Study of Atezolizumab Versus Placebo in Combination With Paclitaxel, Carboplatin, and Bevacizumab in Participants With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Trial Status	Trial Runs In	Trial Identifier
Concluído	22 Countries	NCT03038100 2016-003472-52 YO39523

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

A Phase III, Multicenter, Randomized, Study of Atezolizumab Versus Placebo Administered in Combination With Paclitaxel, Carboplatin, and Bevacizumab to Patients With Newly-Diagnosed Stage III or Stage IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Trial Summary:

This is a Phase III, global, double-blind, 2-arm randomized study designed to compare the efficacy and safety of atezolizumab + paclitaxel + carboplatin + bevacizumab versus placebo + paclitaxel + carboplatin + bevacizumab. Study participants will have Stage 3 or 4 ovarian cancer (OC), fallopian tube cancer (FTC), or primary peritoneal cancer (PPC) with macroscopic residual disease postoperatively (i.e., after primary tumor reductive surgery) or who will undergo neoadjuvant therapy followed by interval surgery.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT03038100 2016-003472-52 YO39523
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

© 2022 F. Hoffmann-La Roche Ltd

ForPatients
by Roche

Female	#18 Years	No

What happens if I am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03038100

Inclusion Criteria:

- Participants receiving a histologic diagnosis of epithelial ovarian cancer (EOC), peritoneal primary carcinoma, or fallopian tube cancer
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2
- Life expectancy greater than (>) 12 weeks
- For participants who receive therapeutic anticoagulation: stable anticoagulant regimen
- Availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen in paraffin blocks (preferred) or at least 20 unstained slides (for detailed tissue requirements at screening)

Exclusion Criteria:

- Received a current diagnosis of borderline epithelial ovarian tumor (formerly tumors of low malignant potential)
- Have recurrent invasive epithelial ovarian, fallopian tube, or primary peritoneal cancer that was treated only with surgery (example [e.g.], participants with Stage IA or Stage IB epithelial ovarian or fallopian tube cancers)
- Have non-epithelial ovarian tumors (e.g., germ cell tumors, sex cord stromal tumors)
- Received prior radiotherapy to any portion of the abdominal cavity or pelvis
- Received prior chemotherapy for any abdominal or pelvic tumor that include neoadjuvant chemotherapy (NACT) for ovarian, primary peritoneal or fallopian tube cancer
- Received any biological and/or targeted therapy (including but not limited to vaccines, antibodies, tyrosine kinase inhibitors) or hormonal therapy for management and/or treatment of epithelial ovarian or peritoneal primary cancer
- Have synchronous primary endometrial cancer
- Have a prior history of primary endometrial cancer, except: Stage IA cancer; superficial myometrial invasion, without lymphovascular invasion; grade less than (<) 3 or poorly differentiated subtypes, and this includes papillary serous, clear cell or other International Federation of Gynecological Oncologists (FIGO) Grade 3 lesions
- With the exception of non-melanoma skin cancer and other specific malignancies as noted above, other invasive malignancies with any evidence of other cancers present within the last 5 years or previous cancer treatment that contraindicates this protocol therapy
- Have a known hypersensitivity or allergy to biopharmaceutical agents produced in Chinese hamster ovary cells or any component of the atezolizumab and/or bevacizumab formulations
- Undergo major surgical procedure within 28 days prior to first bevacizumab dose, or anticipation of the need for a major surgical procedure during the course of the study except participants who receive NACT and will need interval surgery. This may include but is not limited to laparotomy.

© 2022 F. Hoffmann-La Roche Ltd

- Have prior allogeneic bone marrow transplantation or solid organ transplant
- Have any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results
- Have any approved or investigational anti-cancer therapy, including chemotherapy or hormonal therapy, with exceptions: Hormone-replacement therapy or oral contraceptives
- Are administered treatment with any other investigational agent or participation in another clinical study with anti-cancer therapeutic intent
- Have core biopsy or other minor surgical procedures within 7 days prior to the first dose of bevacizumab
- Have known sensitivity to any component of bevacizumab
- Have known sensitivity to any component of paclitaxel
- Current treatment with anti-viral therapy for hepatitis B virus (HBV)
- History of leptomeningeal disease

© 2022 F. Hoffmann-La Roche Ltd