A Clinical Study of Cobimetinib Administered in Combination With Niraparib, With or Without Atezolizumab to Patients With Advanced Platinum-sensitive Ovarian Cancer

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria

• Ability to comply with the study protocol, in the investigator's judgment

• Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures, including the completion of patient-reported outcome questionnaires

• Histological diagnosis of high-grade serous or Grade 2 or Grade 3 endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer

• Previous treatment with a minimum of one and a maximum of two prior platinum based treatment regimens

• Platinum-sensitive disease

• Availability of tumor biopsy tissue prior to first dose of study treatment with confirmation by the central laboratory that the sample is not only of adequate quality but also assignable to a molecularly defined subgroup based on breast cancer susceptibility gene (BRCA) and loss of heterozygosity (LOH) status

• Measurable disease, as defined by Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST v1.1)

• Adequate hematologic and organ function

• Eastern Cooperative Oncology Group Performance Status of 0 or 1

• Life expectancy of at least 12 weeks

• Resolved or stabilized toxicities resulting from previous therapy to Grade 1

• Negative HIV test at screening

• Negative hepatitis B surface antigen and total hepatitis B core antibody (HBcAb) test, or positive total HBcAb test followed by quantitative hepatitis B virus (HBV) DNA < 500 IU/mL test at screening

• Negative hepatitis C virus (HCV) antibody test, or positive HCV antibody test followed by a negative HCV RNA test at screening

• For women of childbearing potential: Women must remain abstinent or use two contraceptive methods with a failure rate of <1% per year during the treatment period and for at least 3 months after the last dose of cobimetinib, 6 months after the last dose of niraparib, and 5 months after the last dose of atezolizumab. Women must refrain from donating eggs during this same period Exclusion Criteria

• Prior treatment with mitogen-activated protein kinase inhibitor, polyadenosine diphosphate-ribose polymerase inhibitor, or immune checkpoint inhibitor therapies

• Prior chemotherapy, hormonal therapy, radiotherapy, antibody therapy, or other immunotherapy, gene therapy, vaccine therapy, or treatment with experimental drugs within 14 days prior to first dose of study treatment

• Treatment with systemic immunostimulatory agents within 28 days or 5 half-lives of the drug prior to initiation of study treatment

• Treatment with systemic immunosuppressive medication 14 days prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during the study

• History of other malignancy that could affect compliance with the protocol or interpretation of results, or known to have potentially fatal outcome

• Symptomatic and/or untreated central nervous system metastases

• Surgical procedure, significant traumatic injury within 14 days prior to enrollment, or anticipation of need for major surgical procedure during the study

• Minor surgical procedure within 3 days

• History or evidence of retinal pathology on ophthalmic examination

• Left ventricular ejection fraction below institutional lower limit of normal

• History of clinically significant cardiovascular dysfunction

• History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on the screening chest computed tomography scan

• History or evidence of inherited bleeding diathesis or significant coagulopathy at risk for bleeding

• History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins, or to any component of the atezolizumab formulation

• Known allergy or hypersensitivity to any component of the cobimetinib or niraparib formulation

• Active or history of autoimmune disease or immune deficiency including, but not limited to, myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, anti-phospholipid antibody syndrome, Wegener granulomatosis, Sjögren syndrome, Guillain-Barre syndrome, or multiple sclerosis

• Uncontrolled serious medical or psychiatric illness

• History of malabsorption or other condition that would interfere with absorption of oral study drugs, including preexisting duodenal stent or ongoing intestinal obstruction

• Active tuberculosis

• Severe infection within 14 days prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia

• Treatment with therapeutic oral or IV antibiotics within 7 days prior to initiation of study treatment

• Treatment with a live, attenuated influenza vaccine within 28 days prior to study treatment initiation, at any time during the study, and for at least 5 months after the last dose of study drug

• Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications

• Previous treatment with strong CYP3A inhibitors (such as ketoconazole and clarithromycin), strong CYP3A inducers (such as carbamazepine and phenytoin), and moderate CYP3A inducers (such as efavirenz, modafinil) within 7 days prior to the initiation of study treatment or with ongoing requirements for these medications

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• Pregnancy or breastfeeding, or intention to become pregnant during the study

Conditions & Interventions

Interventions:
Drug: Cobimetinib, Drug: Niraparib, Drug: Atezolizumab
Conditions:
Ovarian Cancer

More Information

Contact(s): Reference Study ID Number: YO40482 https://forpatients.roche.com/ - global-roche-genentech-trials@gene.com
Principal Investigator:
Phase: Phase 1
IRB
Number:
System ID: NCT03695380
