ForPatients
by Roche

Solid Tumors

A study of a medicine (GDC-0919) combined with another medicine (atezolizumab) in patients with cancer that has grown or spread

A Study of GDC-0919 and Atezolizumab Combination Treatment in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT02471846 2015-001741-88 GO29779

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib, Open-Label, Dose-Escalation Study of the Safety and Pharmacology of GDC-0919 Administered With Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This study will evaluate the safety, tolerability, and pharmacokinetics of the combination of GDC-0919 and atezolizumab in participants with locally advanced, recurrent, or metastatic incurable solid malignancy that has progressed after available standard therapy or for which standard therapy is ineffective, intolerable, or inappropriate. Participants will be enrolled in two stages, including a dose-escalation stage and an expansion stage.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT02471846 2015-001741-88 GO29779
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Researchers wanted to find out what dose of the study medicine (GDC-0919) was safe to combine with another medicine (atezolizumab). Both of these medicines have an effect on the immune system of the patient. The combination treatment was given to cancer patients to find out what effects, good and/or bad, GDC-0919 and atezolizumab had on patients

and on their cancers. All patients received the same dose of atezolizumab; GDC-0919 was given at different doses to different groups of patients.

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy at least 12 weeks
- Adequate hematologic and end organ function
- Negative pregnancy test and willingness to utilize contraception among women of childbearing potential
- Locally advanced, recurrent, or metastatic incurable solid malignancy with measurable disease per RECIST v1.1
- Progression following at least one standard therapy; or standard therapy considered ineffective, intolerable, or inappropriate; or use of an investigational agent recognized as a standard of care
- For the expansion stage, histologically confirmed renal cell cancer (RCC), urothelial bladder cancer (UBC), triple-negative breast cancer (TNBC), non-small cell lung cancer (NSCLC), melanoma, head and neck squamous cell carcinoma (HNSCC), gastric cancer, ovarian cancer, cervical cancer, endometrial cancer, or Merkel cell cancer
- For the expansion stage, evaluable for PD-L1 expression
- Anti PD-1/PD-L1 relapsed cohorts (I and II), participants whose most recent anti-cancer therapy consisted of single-agent PD-1/PD-L1 blockade will be enrolled

Exclusion Criteria:

- Significant cardiovascular or liver disease
- Major surgery within 28 days of study drug
- Any anti-cancer therapy within 3 weeks of study drug
- Malabsorption syndrome or poor upper gastrointestinal integrity
- Primary central nervous system (CNS) malignancy or active metastases within 5 years
- Uncontrolled tumor pain
- Autoimmune disease other than stable hypothyroidism or vitiligo
- Human immunodeficiency virus (HIV), active hepatitis B or C, or tuberculosis
- Signs/symptoms of infection, or use of antibiotics within 2 weeks of study drug
- Live attenuated vaccine within 4 weeks of study drug
- Known history or predisposition to QT interval prolongation
- Prior cancer immunotherapy, specifically indoleamine 2,3-dioxygenase (IDO) or tryptophan 2,3-dioxygenase (TDO) inhibitors, T-cell costimulatory receptor agonist antibodies, or checkpoint inhibitors among certain participants