ForPatients
by Roche

NeoplasmsCancer

A Study to Assess Pharmacokinetics and Safety of Atezolizumab Administered Intravenously (IV) as a Single Agent or in Combination With Chemotherapy to Chinese Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02825940 YO29233

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 I, Open-Label Study to Assess the Pharmacokinetics, Efficacy, and Safety of Atezolizumab Administered Intravenously as a Single Agent or in Combination With Chemotherapy in Chinese Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This Phase I, open-label, multicenter study will evaluate the pharmacokinetics, safety, and preliminary anti-tumor activity of atezolizumab as monotherapy in Chinese participants with locally advanced or metastatic gastric cancer, nasopharyngeal cancer, esophageal cancer, and hepatocellular carcinoma (HCC) that are refractory to standard therapeutic modalities and for whom no further standard therapy is available or who have refused standard therapy; and the safety and preliminary anti-tumor activity of atezolizumab in combination with gemcitabine and cisplatin in Chinese participants with Stage IV, treatment-naive non-small cell lung cancer (NSCLC). The study will consist of a pharmacokinetic (PK) phase and an extension phase.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT02825940 YO29233
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Histologically documented, incurable or metastatic solid tumor that is advanced (non-resectable) or recurrent and progressing since the last the anti-tumor therapy and for which no recognized standard curative therapy exists or who have refused the standard therapy
- Adequate hematologic and end organ function
- Measurable disease per RECIST v1.1 or mRECIST
- Eastern Cooperative Oncology Group Performance Status of 0 or 1
- Women who are not postmenopausal (greater than or equal to (>=) 12 months of non-therapy-induced amenorrhea) or surgically sterile must have a negative serum pregnancy test result within 14 days prior to initiation of study treatment
- A representative formalin-fixed paraffin-embedded (FFPE) tumor specimen in paraffin block (preferred) or 15 or more unstained, freshly cut, serial sections (on slides) from an FFPE tumor specimen is required for participation in this study. This specimen must be accompanied by the pathology report
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of less than (<) 1% per year during the treatment period and for at least 90 days 5 months after the last dose of atezolizumab, or 6 months after the last dose of cisplatin or gemcitabine, whichever is longer, if combined. Women must refrain from donating eggs during this same period
- For men in the NSCLC cohort only: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm
- For participants in the NSCLC Cohort: Histologically or cytologically confirmed Stage IV NSCLC (per the Union Internationale contre le Cancer/American Joint Committee on Cancer staging system)
- For participants in the NSCLC Cohort: No prior chemotherapy for Stage IV NSCLC
- For participants in the NSCLC Cohort: Participants who have received prior neo-adjuvant, adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a treatment-free interval of at least 6 months from enrollment since the last chemotherapy, radiotherapy, or chemoradiotherapy cycle

Exclusion Criteria:

- Pregnant or lactating
- Any approved anti-cancer therapy, including chemotherapy, targeted therapy or hormonal therapy less than (<) 5 half-lives prior to initiation of study treatment
- Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 28 days prior to enrollment
- Uncontrolled hypercalcemia (greater than (>) 1.5 millimoles per liter (mmol/L) ionized calcium or calcium >12 milligram per deciliter (mg/dL) or corrected serum calcium greater than the upper limit of normal) or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy
- Known clinically significant liver disease, including active viral, alcoholic, or other hepatitis, cirrhosis, fatty liver, and inherited liver disease, uncontrolled major seizure disorder, or superior vena cava syndrome
- Participants with acute leukemia, accelerated/blast-phase chronic myelogenous leukemia, chronic lymphocytic leukemia, Burkitt lymphoma, plasma cell leukemia, or non-secretory myeloma
- Symptomatic, actively progressing, or untreated central nervous system metastases as determined by computed tomography or magnetic resonance imaging evaluation during screening and prior radiographic assessments
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Participants with prior allogenic stem cell or solid organ transplantation

- 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 or renders the participant at high risk from treatment complications
- Positive test for HIV
- Participants with active hepatitis B infection (defined as having a positive hepatitis B surface antigen [HBsAg] test at screening) or hepatitis C infection (for the non-HCC cohorts only)
- For participants in the NSCLC Cohort: Known tumor programmed death-ligand 1 (PD-L1) expression status as determined by an immunohistochemistry assay during participation in other clinical studies (e.g., participants whose PD-L1 expression status was determined during screening for entry into a study with anti-programmed death 1 or anti-PD-L1 antibodies but were not eligible are excluded)