ForPatients
by Roche

NeoplasmsSolid TumorsTumorCancer

A study to look at how safe different doses of atezolizumab were for patients – and how this medicine was processed through the body

A Study of Atezolizumab (an Engineered Anti-Programmed Death-Ligand 1 [PDL1] Antibody) to Evaluate Safety, Tolerability and Pharmacokinetics in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT01375842 2011-001422-23 GO27831 PCD4989g

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, Dose-Escalation Study of the Safety and Pharmacokinetics of Atezolizumab (MPDL3280A) Administered Intravenously as a Single Agent to Patients With Locally Advanced or Metastatic Solid Tumors or Hematologic Malignancies

Trial Summary:

This Phase I, multicenter, first-in-human, open-label, dose-escalation study will evaluate the safety, tolerability, and pharmacokinetics of atezolizumab (MPDL3280A) administered as single agent to participants with locally advanced or metastatic solid malignancies or hematologic malignancies. The study will be conducted in two cohorts: Dose-escalation cohort and Expansion cohort.

Genentech, Inc.	Phase 1
Sponsor	Phase

NCT01375842 2011-001422-23 GO27831 PCD4989g
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Atezolizumab is a new medicine designed to work on the immune system, and this type of medicine is known as an immunotherapy. Patients with different types of cancers received

different amounts of the study medicine to find out which dose of atezolizumab was safe, and which dose could be given to patients in future studies.

Inclusion Criteria:

- Participants who are 16 to 17 years old would be enrolled after consultation with the Medical Monitor
- Histologically or cytologically documented, incurable or metastatic solid tumor or hematologic malignancy that is advanced (non-resectable) or recurrent and progressing since the last anti-tumor therapy and for which no recognized standard curative therapy exists
- Representative tumor specimens in paraffin blocks (preferred) or at least 15 unstained slides, with an associated pathology report
- Adequate hematologic and end organ function
- Measurable disease per RECIST v1.1 for participants with solid malignancies. Disease-specific criteria for participants with prostate cancer, glioblastoma multiforme (GBM), malignant lymphoma, or multiple myeloma
- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- For participants who will undergo serial biopsy in dose-escalation cohort, baseline tumor tissue samples should be of core needle biopsies for deep tumor tissue or organs or excisional or punch biopsies for cutaneous or subcutaneous lesions (>/=5 millimeter [mm] in diameter amenable to serial biopsy)

Exclusion Criteria:

- Known primary central nervous system (CNS) malignancy or symptomatic CNS metastases
- Known hypersensitivity to pharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
- History or risk of autoimmune disease (for example, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, vascular thrombosis associated with antiphospholipid syndrome, Wegener's granulomatosis, Sjögren's syndrome, Bell's palsy, Guillain-Barré syndrome, multiple sclerosis, autoimmune thyroid disease, vasculitis, or glomerulonephritis)
- History of human immunodeficiency virus (HIV) infection, active hepatitis B (chronic or acute), or hepatitis C infection
- Signs or symptoms of infection within 2 weeks prior to Cycle 1, Day 1
- Malignancies other than disease under study within 5 years prior to Cycle 1, Day 1
- Participants with prior allogeneic bone marrow transplantation or prior solid organ transplantation