ForPatients
by Roche

NeoplasmsCancer

A Study of Atezolizumab in Advanced Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	18 Countries	NCT02458638 2015-000269-30 MO29518

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:

An Open-Label, Multicohort, Phase II Study of Atezolizumab in Advanced Solid Tumors

Trial Summary:

The primary efficacy objective for this study is to evaluate non-progression rate (NPR) at 18 weeks in participants with advanced solid tumors treated with atezolizumab, defined as the percentage of participants with complete response (CR), partial response (PR), or stable disease (SD) as assessed by the investigator according to Response Evaluation Criteria in Solid Tumors (RECIST) Version (v) 1.1, or according to disease-specific criteria for prostate cancer and malignant pleural mesothelioma.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Histologically documented advanced solid tumors that meet protocol-defined cohort specifications, have progressive disease at study entry, and have received at least one line of prior systemic therapy or for which no alternative therapy to prolong survival exists
- Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens in paraffin blocks (preferred) or in freshly cut and unstained slides (exceptional cases) with an associated pathology report for central testing

- Measurable disease as defined by RECIST v1.1 or disease-specific criteria for prostate cancer and malignant pleural mesothelioma
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Negative serum pregnancy test result within 14 days prior to study drug among women of childbearing potential
- Life expectancy > 3 months

Exclusion Criteria:

- Malignancies other than disease under study within 5 years prior to Day 1 of Cycle 1 except those with a negligible risk of metastasis or death
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures >/=1 time per month
- History of asymptomatic or symptomatic central nervous system (CNS) metastasis
- Leptomeningeal disease
- Spinal cord compression not definitively treated with surgery and/or radiation, or previously diagnosed and treated but without evidence that disease has been clinically stable for >/=2 weeks prior to Day 1 of Cycle 1
- Pregnant and lactating women
- Significant cardiovascular disease within 3 months prior to Day 1 of Cycle 1
- Severe infection within 4 weeks prior to Day 1 of Cycle 1
- Oral or IV antibiotics within 2 weeks prior to Day 1 of Cycle 1
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or to any component of the atezolizumab formulation
- History of autoimmune disease except treated/stable hypothyroidism, Type 1 diabetes mellitus, and protocol-specified dermatologic conditions
- Active tuberculosis
- Signs or symptoms of infection within 2 weeks prior to Day 1 of Cycle 1
- Prior treatment with cluster of differentiation (CD) 137 agonists or immune checkpoint blockade therapies, or anti-programmed cell death-1 (PD-1) or anti-PD-L1 therapeutic antibodies
- Treatment with systemic corticosteroids or other systemic immunosuppressive medications within 2 weeks prior to Day 1 of Cycle 1, or anticipated requirement for systemic immunosuppressive medications during the trial