ForPatients
by Roche

NeoplasmsSolid Tumors

A study to look at how safe different doses of MOXR0916 were for patients with cancer – when combined with one or two other medicines

A Study to Assess the Safety and Pharmacokinetics of MOXR0916 and Atezolizumab (Also Known as MPDL3280A or Anti-PD-L1) in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT02410512 2015-000516-18 GO29674

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 Pharmacokinetics of MOXR0916 and Atezolizumab in Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This Phase Ib, open-label, dose-escalation study will evaluate the safety, tolerability, and pharmacokinetics of the combination of MOXR0916 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 has proven to be ineffective or intolerable or is considered inappropriate; or for which a clinical trial of an investigational agent is a recognized standard of care. Participants will be enrolled in two stages: a dose-escalation stage and an expansion stage.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT02410512 2015-000516-18 GO29674
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

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This clinical trial was done to study a new medicine called, “MOXR0916”, for the treatment of patients with cancer. This study was done to find out if MOXR0916 given with atezolizumab with and without bevacizumab – was safe for patients. Researchers also wanted to find out if the treatment had any effect on cancer. Two hundred and ninety-eight patients took part in this study at 25 study centers in 7 countries.

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Life expectancy of at least 12 weeks
- Adequate hematologic and end organ function
- Histologic documentation of locally advanced, recurrent, or metastatic incurable solid malignancy that has progressed after available standard therapy; or for which standard therapy is ineffective, intolerable, or considered inappropriate; or for which a clinical trial of an investigational agent is recognized standard of care
- Tumor specimen availability
- Measurable disease according to RECIST v1.1

Exclusion Criteria:

- Any anti-cancer therapy, whether investigational or approved, including chemotherapy, hormonal therapy, or radiotherapy, within 3 weeks prior to initiation of study treatment
- Malignancies other than disease under study within 5 years prior to D1 of C1
- Primary central nervous system (CNS) malignancy, or untreated/active CNS metastases
- History of leptomeningeal disease
- History of idiopathic pulmonary fibrosis, pneumonitis (including drug-induced), organizing pneumonia, or evidence of active pneumonitis on screening chest computed tomography scan; history of radiation pneumonitis in the radiation field (fibrosis) is permitted
- History of autoimmune disease
- Positive human immunodeficiency virus test result
- Active hepatitis B, hepatitis C, or tuberculosis
- Severe infection within 4 weeks prior to D1 of C1
- Prior allogeneic bone marrow or solid organ transplantation
- Significant cardiovascular disease
- Known clinically significant liver disease