ForPatients
by Roche

NeoplasmsSolid TumorsTumor

A study to look at how safe different doses of the study medicine (MOXR0916) were for patients with solid tumor cancer that had spread and did not respond to previous treatment(s), and how this medicine was processed by the body

A Study to Assess Safety and Pharmacokinetics of MOXR0916 in Participants With Locally Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT02219724 2014-001474-34 GO29313

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 MOXR0916 Administered Intravenously as a Single Agent to Patients With Locally Advanced or Metastatic Solid Tumors

Trial Summary:

This is a first-in-human, Phase 1, open-label, multicenter, dose-escalation study designed to evaluate the safety, tolerability, and pharmacokinetics of MOXR0916 administered intravenously in participants with locally advanced or metastatic solid tumors that have progressed after all available standard therapy or for which standard therapy has proven to be ineffective or intolerable, or is considered inappropriate. This study will consist of a screening period, an initial treatment period, a re-treatment period (for participants who discontinue MOXR0916 after demonstration of prolonged clinical benefit), and a post-treatment follow-up period. Participants will be enrolled in two stages: a dose-escalation stage and an expansion stage. The planned duration of the study is approximately 3 years.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT02219724 2014-001474-34 GO29313
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

MOXR0916 is a new medicine (immunotherapy) designed to work on the immune system. Researchers wanted to find out what dose of MOXR0916 was safe to give to cancer patients and what effects, good and/or bad, it had on patients and on their cancers. This was the first time MOXR0916 was given to humans.

Inclusion Criteria:

- Histologic documentation of locally advanced, recurrent or metastatic incurable solid malignancy that has progressed after all available standard therapy or for which standard therapy has proven to be ineffective or intolerable, or is considered inappropriate
- Confirmed availability of representative tumor specimens in paraffin blocks/unstained slides
- Measurable disease per RECIST v1.1
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate hematologic and end organ function
- For female participants of childbearing potential, agreement to use highly effective form(s) of contraception and to continue its use for 6 months after the last dose of MOXR0916

Exclusion Criteria:

- Any anti-cancer therapy, including chemotherapy, hormonal therapy, or radiotherapy, within 3 weeks prior to initiation of study treatment (hormonal therapy with gonadotropin-releasing hormone agonists or antagonists for prostate cancer and palliative radiotherapy greater than (>) 2 weeks prior to Cycle 1, Day 1 are allowed)
- Eligibility based on prior treatment with immunomodulatory agents depends on the mechanistic class of the drug and the cohort for which the participant is being considered
- Adverse events from prior anti-cancer therapy that have not resolved to Grade less than or equal to (</=) 1 except for alopecia or endocrinopathy managed with replacement therapy
- Primary central nervous system (CNS) malignancy, or untreated/active CNS metastases
- Leptomeningeal disease
- Malignancies other than disease under study within 5 years
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis, pneumonitis (including drug induced), organizing pneumonia, or evidence of active pneumonitis on screening chest computed tomography (CT) scan; history of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Positive test for human immunodeficiency virus infection
- Active hepatitis B or active hepatitis C
- Severe infections within 4 weeks or signs or symptoms of infection within 2 weeks prior to Cycle 1
- Prior allogeneic bone marrow transplantation or prior solid organ transplantation
- Significant cardiovascular disease
- Known clinically significant liver disease