ForPatients
by Roche

NeoplasmsCancer

A Study of Emactuzumab and RO7009789 Administered in Combination in Participants With Advanced Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT02760797 2015-004348-21 BP29427

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, Multicenter, Dose-Escalation Phase Ib Study With Expansion Phase to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Therapeutic Activity of Emactuzumab and RO7009789 Administered in Combination in Patients With Advanced Solid Tumors

Trial Summary:

This is an open-label, multicenter study designed to assess the safety, pharmacokinetics, pharmacodynamics, and therapeutic activity of emactuzumab and RO7009789 administered in combination in participants with locally advanced or metastatic solid tumors that are not amenable to standard treatment. This study will be conducted in two parts: a dose-finding stage (Part I) and an expansion stage (Part II).

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT02760797 2015-004348-21 BP29427
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group performance status 0 or 1

- Histologically confirmed diagnosis of locally advanced, recurrent, and/or metastatic triple-negative breast cancer, ovarian cancer, gastric cancer, colorectal cancer, pancreatic cancer, melanoma, or mesothelioma
- Radiologically measurable and clinically evaluable disease as per RECIST v1.1
- Life expectancy of greater than or equal to (>/=) 16 weeks
- Ability to comply with the collection of tumor biopsies; tumors accessible for biopsy
- Adequate bone marrow, liver, cardiac, and renal function

Exclusion Criteria:

- Allergy or hypersensitivity to components of either study drug formulation
- Active or untreated central nervous system (CNS) metastases as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening or prior radiographic assessments. Participants with radiographically stable, asymptomatic, previously irradiated lesions are eligible provided participant is >/=4 weeks beyond completion of cranial irradiation and >/=3 weeks off of corticosteroid therapy
- Participants with leptomeningeal disease; metastases to the brain stem, midbrain, pons, medulla, or within 10 millimeters (mm) of the optic apparatus (optic nerves and chiasm)
- History of human immunodeficiency virus (HIV)
- Participants with active hepatitis B, active hepatitis C, or active tuberculosis
- Pregnant or lactating women