ForPatients
by Roche

Solid Tumors

A Study of RO6958688 in Participants With Locally Advanced and/or Metastatic Carcinoembryonic Antigen Positive Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT02324257 2014-003075-30 RG7802 BP29541

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 I Study to Evaluate the Safety, Pharmacokinetics, and Therapeutic Activity of RO6958688, A Novel T-cell Bispecific Antibody That Targets the Human Carcinoembryonic Antigen (CEA) on Tumor Cells and CD3 on T Cells, Administered Intravenously in Patients With Locally Advanced and/or Metastatic CEA(+) Solid Tumors

Trial Summary:

Study BP29541 is a first-in-human, open-label, multi-center, dose-escalation Phase I clinical study of single-agent RO6958688 in participants with locally advanced and/or metastatic carcinoembryonic antigen (CEA) positive solid tumors who have progressed on standard treatment, are intolerant to standard of care (SOC), and/or are non-amenable to SOC. The study will be conducted in two parts. Part I of the study will investigate the safety and pharmacokinetics of a single dose of RO6958688 in single participant cohorts with dosing starting from a minimal anticipated biological effect level dose of 0.05 milligrams (mg) and up to a maximum dose of 2.5 mg. Part II will establish the appropriate therapeutic dose based on safety, pharmacokinetics, and the maximum tolerated dose (MTD) of RO6958688 for the once per week (QW) regimen, every three weeks (Q3W) regimen, and for the step up dosing regimen.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#18 Years	No

Inclusion Criteria:

- For dose escalation, locally advanced and/or metastatic gastrointestinal (GI) solid tumor in participants who have progressed on a standard therapy, are intolerant to SOC, and/or are non-amenable to SOC and other solid tumors expressing CEA. Only locally advanced and/or metastatic colorectal cancer participants should be included in the scheduled comparison expansion
- Radiologically measurable disease according to RECIST v1.1
- Life expectancy, in the opinion of the investigator of greater than or equal (>/=) to 12 weeks and LDH= 2.5 x ULN
- Eastern Cooperative Oncology Group Performance Status of 0-1
- All acute toxic effects of any prior radiotherapy, chemotherapy, or surgical procedure must have resolved to Grade less than or equal to 1 or returned to baseline except alopecia (any grade) and Grade 2 peripheral neuropathy
- Adequate hematological, liver, and renal function
- Participants must agree to remain abstinent or be willing to use effective methods of contraception as defined in the protocol
- Non-GI solid tumors (like non-small cell lung cancer or breast cancer) should have confirmed CEA expression in tumor tissue >/= 20% of tumor cells staining with at least moderate to high intensity of CEA expression are required (immunohistochemistry [IHC]2+ and IHC 3+). For CRC, pancreatic and gastric cancer participants, the CEA assessment will be performed retrospectively and the result is not needed to enroll the participant

Exclusion Criteria:

- Participants with a history or clinical evidence of central nervous system primary tumors or metastases including leptomeningeal metastases unless they have been previously treated, are asymptomatic, and have had no requirement for steroids or enzyme-inducing anticonvulsants in the last 14 days before screening
- Spinal cord compression not definitively treated with surgery and/or radiation or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for at least 2 weeks prior to enrollment
- Leptomeningeal disease
- Participants with paraspinal, paratracheal and mediastinal pathologic lesions larger than 2 centimeters unless they are previously irradiated. Irradiation of lesions must be completed at least 14 days prior to initiation of study treatment
- Participants with another invasive malignancy in the last 2 years (with the exception of basal cell carcinoma and tumors deemed by the investigator to be of low likelihood for recurrence)
- Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results or contraindicate the use of an investigational drug, including diabetes mellitus, history of relevant cardio-pulmonary disorders, and known autoimmune diseases
- Participants with bilateral lung lesions and dyspnea and/or with bilateral lung lesions and an oxygen saturation (SaO2) level less than 92% or participants with lobectomy or pneumonectomy with lung metastases in the remaining lung and either dyspnea or SaO2 less than 92% at baseline
- Uncontrolled hypertension (systolic blood pressure [BP] greater than [>] 150 millimeters of mercury [mmHg] and/or diastolic BP > 100 mmHg), unstable angina, congestive heart failure of any New York Heart Association classification, serious cardiac arrhythmia that requires treatment with the exceptions of atrial fibrillation and paroxysmal supraventricular tachycardia, and history of myocardial infarction within 6 months of enrollment
- Active or uncontrolled infections

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- Known human immunodeficiency virus (HIV) or known active hepatitis B or hepatitis C infection for participants not receiving obinutuzumab pretreatment
- Known HIV (HIV testing will be performed at screening if required by local regulations) in participants to be pretreated with obinutuzumab
- Pregnant or breastfeeding women
- Known hypersensitivity to any of the components of RO6958688 and/or obinutuzumab
- Concurrent therapy with any other investigational drug
- Last dose of any chemotherapy less than 28 days prior to the first RO6958688 infusion
- Expected need for regular immunosuppressive therapy
- Regular dose of corticosteroids the 28 days prior to Day 1 of this study or anticipated need for corticosteroids that exceeds prednisone 10 mg/day or equivalent within 28 days prior to the first RO6958688 infusion. Inhaled and topical steroids are permitted
- Radiotherapy within the last 28 days prior to the first RO6958688 infusion with the exception of limited-field palliative radiotherapy.

Additional Exclusion Criteria for Participants to be Pretreated with Obinutuzumab:

- Positive test results for human T-lymphotropic virus 1 (HTLV-1) or active HIV infection
- Positive test results for chronic hepatitis B infection or hepatitis C
- Known active tuberculosis (TB) requiring treatment within 3 years prior to baseline or latent TB that has not been appropriately treated
- Active bacterial, viral, fungal, or other infection, or any major episode of infection requiring treatment with intravenous (IV) antibiotics within 4 weeks of Cycle 1, Day 1
- Known hypersensitivity to any of the components of obinutuzumab; hypersensitivity to Chinese hamster ovary cell products or other recombinant human antibodies
- History of progressive multifocal leukoencephalopathy (PML)

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