ForPatients
by Roche

Solid TumorsCancer

A Study of Selicrelumab (RO7009789) in Combination With Atezolizumab in Participants With Locally Advanced and/or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT02304393 2014-002835-32 BP29392

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 to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Therapeutic Activity of Selicrelumab (CD40 Agonist) in Combination With Atezolizumab (Anti PD-L1) in Patients With Locally Advanced and/or Metastatic Solid Tumors

Trial Summary:

This is an open-label, multicenter study designed to assess the safety, pharmacokinetics, pharmacodynamics and activity of Selicrelumab administered in combination with Atezolizumab (ATZ) in participants with metastatic or locally advanced solid tumors. The study will be conducted in two Parts (I and II), with Part I divided into Parts IA and IB. All participants will be followed up for survival until death or loss of follow-up after the last visit or withdrawal of consent.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT02304393 2014-002835-32 BP29392
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Histologically confirmed diagnosis of locally advanced and/or metastatic solid tumors, which are not amenable to standard therapy
- Part I: histologically confirmed diagnosis of advanced/metastatic small and large bowel carcinomas (small bowel and CRC), CPI-experienced non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC)
- Part II: CPI-experienced NSCLC patients must have experienced documented disease progression on or after PD-L1 or PD-1 inhibitor therapy (investigational or approved): screening tumor assessment should confirm prior progression
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy greater than or equal to (>/=) 16 weeks
- Adequate hematologic and end organ function
- Measurable disease per RECIST Version 1.1
- Ability to comply with the protocol requirements
- Female participants of childbearing potential must have a negative pregnancy test (urine/serum) within seven days prior to the first study drug administration
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of less than (<) 1% per year during the treatment period and for at least 5 months after the last dose of study treatment
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm during the treatment period and for at least 28 days after the last dose of study treatment

Exclusion Criteria:

- If one of the following laboratory results obtained within 14 days prior to the first study treatment (Cycle 1 Day 1) are: soluble interleukin 2 receptor (sCD25) greater than (>) 2 × upper limit of normal (ULN); Serum ferritin >1000 nanograms per milliliter (ng/mL)
- Any approved anti-cancer therapy that includes chemotherapy, hormonal therapy, or radiotherapy within 2 weeks prior to the first dose of study treatment; the following is, however, allowed: Palliative radiotherapy for bone metastases less than or equal to (</=) 2 weeks prior to Cycle 1 Day 1
- Adverse events from prior anti-cancer therapy that have not resolved to Grade </= 1 except for any grade alopecia and </= Grade 2 peripheral neuropathy
- Bisphosphonate therapy for symptomatic hypercalcemia. Use of bisphosphonate therapy for other reasons (example: bone metastasis or osteoporosis) is allowed
- Uncontrolled pleural effusion, pericardial effusion, or ascites that require recurrent drainage procedures (one monthly or more frequently). Participants with indwelling catheters are allowed
- Known clinically significant liver disease which includes active viral, alcoholic, or other hepatitis, cirrhosis, fatty liver, and inherited liver disease
- History (within the previous year) of congestive heart failure, stroke, arrhythmia, or myocardial infarction
- History of peripheral venous thrombosis or thromboembolic event (within 12 months prior to Cycle 1 Day 1)
- Significant cardio- or cerebrovascular disease within 6 months prior to Cycle 1 Day 1
- Known hereditary or acquired coagulopathies
- Clinically meaningful proteinuria
- Requiring dialysis (peritoneal or hemodialysis)
- Known primary central nervous system (CNS) malignancy or symptomatic or untreated CNS metastases: participants with asymptomatic-treated CNS metastases may be enrolled after consultation with the Medical Monitor, provided they meet the following criteria:
- Radiographic demonstration of improvement upon completion of CNS-directed therapy and no evidence of interim progression between the completion of CNS-directed therapy and the screening radiographic study
- No stereotactic radiation or whole-brain radiation within 28 days prior to Cycle 1 Day 1

- Pregnancy, lactation, or breastfeeding
- Allergy or hypersensitivity to components of the RO7009789 formulation or to components of atezolizumab formulation
- History of autoimmune diseases (participants with a history of autoimmune hypothyroidism on a stable dose of thyroid replacement hormone may be eligible; participants with controlled Type 1 diabetes mellitus on a stable insulin regimen may be eligible for this study)
- History of idiopathic pulmonary fibrosis, pneumonitis (excluding infectious disease-induced), organizing pneumonia, or evidence of active pneumonitis
- History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Participants with human immunodeficiency virus (HIV) infection, active hepatitis B (chronic or acute), or hepatitis C infection
- Active tuberculosis
- Severe infections within 4 weeks prior to Cycle 1 Day 1
- Signs or symptoms of infection within 2 weeks prior to Cycle 1 Day 1
- Received oral or IV antibiotics within 2 weeks prior to Cycle 1 Day 1
- Major surgical procedure within 28 days prior to Cycle 1 Day 1 or anticipation of need for a major surgical procedure during the course of the study
- Administration of a live, attenuated vaccine within 4 weeks before Cycle 1 Day 1 or anticipation that such a live attenuated vaccine will be required during the study
- Malignancies other than disease under study within 3 years prior to Cycle 1 Day 1 with the exception of those with a negligible risk of metastasis or death and with expected curative outcome
- Previous treatment with any other compound that targets cluster of differentiation 40 (CD40) (like Chi Lob 7/4 and ADC1013)
- Treatment with systemic immunostimulatory agents (including but not limited to interferon (IFN)-alpha, Interleukin-2 (IL-2) within 4 weeks or 5 times the half-life of the drug, whichever is shorter, prior to Cycle 1 Day 1
- Treatment with investigational agent within 4 weeks prior to Cycle 1 Day 1 (or within 5 times the half-life of the investigational product, whichever is longer)
- Concomitant treatment with anticoagulants (example: coumadin, heparin) except low dose molecular weight heparin for prophylactic purposes and direct factor Xa inhibitors
- Treatment with systemic immunosuppressive medications (including but not limited to prednisone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor (TNF) agent within 2 weeks prior to Cycle 1 Day 1
- Participants who have received acute, low-dose, systemic immunosuppressant medications (example: a one-time dose of dexamethasone for nausea) may be enrolled in the study after discussion with and approval by the Medical Monitor
- The use of corticosteroids as premedication in case of dye allergy previous to computed tomography (CT) scan is allowed
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Participants with prior allogeneic bone marrow transplantation or prior solid organ transplantation
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the participants at high risk from treatment complications