ForPatients
*by Roche*

Solid TumorsCancer

# A Study of the Safety, Pharmacokinetics, and Therapeutic Activity of RO6958688 in Combination With Atezolizumab in Participants With Locally Advanced and/or Metastatic Carcinoembryonic Antigen (CEA)-Positive Solid Tumors

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 7 Countries | NCT02650713 RG7802 WP29945 |

*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 and Expansion Phase Ib Study to Evaluate the Safety, Pharmacokinetics, and Therapeutic Activity of RO6958688 in Combination With Atezolizumab in Patients With Locally Advanced and/or Metastatic CEA-Positive Solid Tumors

## *Trial Summary:*

This is an open-label, multicenter, dose-escalation and expansion Phase Ib clinical study of RO6958688 in combination with atezolizumab. Part I of the study is subdivided into parts IA and IB. Part IA is dose escalation with a starting dose of 5 mg of RO6958688 given QW (once a week) and a fixed, flat dose of 1200 mg given Q3W (every 3 weeks) of atezolizumab, to evaluate the safety and determine the MTD of RO6958688 in combination with atezolizumab. Part IB is a dose/schedule finding part that will explore different administration schedules of RO6958688 in combination with atezolizumab (1200 mg Q3W) to establish the appropriate dose/schedule of RO6958688 in combination with atezolizumab.

**Hoffmann-La Roche**
Sponsor

**Phase 1**
Phase

**NCT02650713 RG7802 WP29945**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- Confirmed locally advanced and/or metastatic solid tumor, with at least one tumor lesion of accessible non-critical location to biopsy, in participants who have progressed on a standard therapy, are intolerant to standard therapy, and/or are non-amenable to standard therapy
- Radiologically measurable and clinically evaluable disease (as per RECIST v1.1)
- Life expectancy (in the opinion of the investigator) of at least 12 weeks and lactate dehydrogenase (LDH) levels </= 2.5 ULN (upper limit of normal)
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-1
- All acute toxic effects of any prior radiotherapy, chemotherapy, or surgical procedure must have resolved to Grade </= 1 or returned to baseline except alopecia (any grade) and Grade 2 peripheral neuropathy
- Adequate hematological, liver, and renal function
- Negative serum pregnancy test within 7 days prior to study treatment in premenopausal women and women </= 2 years after start of menopause (menopause is defined as amenorrhea for more than 2 years)
- Participants must agree to remain abstinent or be willing to use effective methods of contraception as defined in the protocol
- Participants with non-colorectal cancer should have confirmed CEA expression in tumor tissue. For colorectal cancer (CRC), the CEA assessment should be performed but the result is not required for participant selection

## *Exclusion Criteria:*

- Active or untreated central nervous system (CNS) metastases as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening and prior radiographic assessments
- 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 pathological lesions larger than 2 cm unless they are previously irradiated
- Malignancies within 5 years prior to enrollment, with the exception of those with a negligible risk of metastasis or death and treated with expected curative outcome
- Significant, uncontrolled concomitant diseases which could affect compliance with the protocol or interpretation of results
- Uncontrolled hypertension, unstable angina, congestive heart failure (CHF), serious cardiac arrhythmia requiring treatment history of myocardial infarction within 6 months of enrollment
- Administration of a live, attenuated vaccine within 28 days before Cycle 1 Day 1 or anticipation that such a live attenuated vaccine will be required during the study
- Human Inmmunodeficiency Virus (HIV), active Hepatitis B or Hepatitis C (HCV)
- Severe infections within 28 days prior to Cycle 1 Day 1, including but not limited to hospitalization for complications of infection, bacteremia, or severe pneumonia or active tuberculosis
- Received oral or intravenous (IV) antibiotics within 14 days prior to Day 1
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that would contraindicate the use of an investigational drug
- Major surgery or significant traumatic injury less than 28 days prior to Cycle 1 Day 1 (excluding biopsies) or anticipation of the need for major surgery during study treatment
- Known history of autoimmune disease as defined in the protocol

- History of idiopathic pulmonary fibrosis, pneumonitis (including drug induced), organizing pneumonia (i.e., bronchiolitis obliterans, cryptogenic organizing pneumonia, etc.), or evidence of active pneumonitis (including drug induced) on screening chest CT scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted
- Participants with bilateral lung lesions and dyspnea and/or oxygen saturation level (SaO2) less than 92% (at rest, room air and exertion) or participants with lobectomy or pneumonectomy with lung metastases in the remaining lung and either dyspnea or SaO2 less than 92% (at rest, room air and exertion) at baseline
- Pregnant or breast-feeding
- Known hypersensitivity to any of the components of RO6958688 and atezolizumab; hypersensitivity to Chinese hamster ovary cell products or other recombinant human antibodies
- Investigational therapy (defined as treatment for which there is no regulatory authority approved indication) or last dose of prior immunotherapies within 28 days prior to Cycle 1 Day 1. Participants previously treated with anti-programmed death-ligand 1 (PD-L1), or anti-PD-1 are excluded
- Last dose of any approved anti-cancer therapy within 28 days prior to the first RO6958688 infusion
- Prior systemic corticosteroids greater than 10mg prednisone (or equivalent) within 14 days of Cycle 1 Day 1. Inhaled and/or topical steroids are permitted
- Expected need for regular immunosuppressive therapy
- Radiotherapy within the last 28 days before Cycle 1 Day 1 with the exception of limited-field palliative radiotherapy