ForPatients
by Roche

Metastatic MelanomaNon-Small Cell Lung Cancer (NSCLC)Small Cell Lung CancerSolid TumorsEsophageal Squamous Cell CarcinomaCancer

A Dose Escalation and Expansion Study of RO7121661, a PD-1/TIM-3 Bispecific Antibody, in Participants With Advanced and/or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT03708328 2018-000982-35 NP40435

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 1 Study to Evaluate Safety, Pharmacokinetics, and Preliminary Anti-Tumor Activity of RO7121661, a PD-1/TIM-3 Bispecific Antibody, in Patients With Advanced and/or Metastatic Solid Tumors

Trial Summary:

This is a first-in-human, open-label, multicenter, Phase I multiple-ascending dose (MAD) study of single agent lomvastomig (RO7121661), an anti PD-1 (programmed death-1) and TIM-3 (T-cell immunoglobulin and mucin domain 3) bispecific antibody, for participants with advanced and/or metastatic solid tumors. The study consists of 2 parts: Dose Escalation (Part A) and Expansion (Parts B1, B2, B3, B4, and B5). The Dose Escalation part will be conducted first to determine the maximum tolerated dose (MTD) and/or recommended dose for expansion (RDE) based on safety, tolerability, pharmacokinetic, and/or the pharmacodynamic profile of escalating doses of lomvastomig. The Expansion part will enroll tumor-specific cohorts to evaluate anti-tumor activity of the MTD and/or RDE of lomvastomig from Part A (Q2W) and to confirm safety and tolerability in participants with selected tumor types.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT03708328 2018-000982-35 NP40435
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

General Inclusion Criteria:

- Part A: Patient must have histologically or cytologically confirmed advanced and/or metastatic solid tumor malignancies for which standard curative or palliative measures do not exist, are no longer effective, or are not acceptable to the patient
- Eastern Cooperative Oncology Group Performance Status 0-1
- Measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST v1.1)
- Fresh biopsies may be required
- Negative HIV, hepatitis B, or hepatitis C test result
- Women of childbearing potential and male participants must agree to remain abstinent or use contraceptive methods as defined by the protocol

Additional Specific Inclusion Criteria for Participants with Melanoma:

- Histologically confirmed, unresectable stage III or stage IV melanoma
- Previously treated with approved anti-programmed death-ligand 1 (PD-L1)/anti-programmed death-1 (PD-1) agents with or without approved anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) therapy and up to one additional treatment regimen

Additional Specific Inclusion Criteria for Participants with Non-small Cell Lung Cancer (NSCLC) who Previously Received Treatment for Metastatic Disease:

- Histologically confirmed advanced NSCLC
- Previously treated with approved PD-L1/PD-1 inhibitors and platinum-based chemotherapy
- Not more than 2 prior lines of treatment for metastatic disease are allowed prior to enrolling to the study
- Participants must have experienced initial clinical benefit (stable disease or better) from most recent checkpoint inhibitor (CPI) therapy
- Tumor PD-L1 expression as determined by immunohistochemistry assay of archival tumor tissue or tissue obtained at screening

Additional Specific Inclusion Criteria for Participants with Non-small Cell Lung Cancer (NSCLC) who Previously Did Not Receive Treatment for Metastatic Disease:

- Histologically confirmed advanced NSCLC
- Tumor PD-L1 expression as determined by immunohistochemistry assay of archival tumor tissue or tissue obtained at screening

Additional Specific Inclusion Criteria for Participants with Small Cell Lung Cancer (SCLC):

- Histologically confirmed SCLC
- Participants may have had prior chemotherapy, radiation therapy, or declined approved therapies for SCLC

Additional Specific Inclusion Criteria for Participants with Esophageal Squamous Cell Carcinoma (ESCC):

- Participants whose major lesion was histologically confirmed as squamous cell carcinoma or adenosquamous cell carcinoma of the esophagus
- Patients who have previously received not more than 1 prior line of treatment for metastatic disease prior to enrolling to the study

Exclusion Criteria:

General Exclusion Criteria:

- Pregnancy, lactation, or breastfeeding
- Known hypersensitivity to any of the components of RO7121661
- Active or untreated central nervous system (CNS) metastases
- An active second malignancy
- Evidence of concomitant diseases, metabolic dysfunction, physical examination findings, or clinical laboratory findings 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 participant at high risk from treatment complications
- Known active or uncontrolled bacterial, viral, fungal, mycobacterial, parasitic, or other infection
- Treatment with oral or IV antibiotics within 2 weeks prior to Cycle 1 Day 1
- Active or history of autoimmune disease or immune deficiency
- Prior treatment with adoptive cell therapies, such as CAR-T therapies
- Concurrent therapy with any other investigational drug <28 days or 5 half-lives of the drug, whichever is shorter, prior to the first RO7247669 administration
- Regular immunosuppressive therapy
- Radiotherapy within the last 4 weeks before start of study drug treatment, with the exception of limited palliative radiotherapy
- Prior treatment with a T-cell immunoglobulin and mucin domain-3 (TIM-3) inhibitor

Additional Specific Exclusion Criteria for Participants with NSCLC who Previously Received Treatment for Metastatic Disease:

- Patients with the following mutations, rearrangements, translocations are not eligible: epidermal growth factor receptor (EGFR); anaplastic lymphoma kinase (ALK); ROS proto-oncogene 1 (ROS1), BRAFV600E, and neurotrophic receptor tyrosine kinase (NTRK)

Additional Specific Exclusion Criteria for Participants with NSCLC who Did Not Previously Receive Treatment for Metastatic Disease:

- Prior therapy for metastatic disease
- Adjuvant anti-PD-1 or anti-PD-L1 therapy

Additional Specific Exclusion Criteria for Participants with Small-Cell Lung Cancer (SCLC):

- Prior therapy with any immune CPIs (such as anti-PD-L1/PD-1, CTLA-4)

Additional Specific Exclusion Criteria for Participants with Esophageal Squamous Cell Carcinoma (ESCC):

- Prior therapy with any immunomodulatory agents