

Solid TumorsAdvanced Solid TumorsMetastatic Solid Tumors

A Study of RO7821657 in Participants With Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07883577 2026-526150-14-00 BP46447

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:

A First In-Human, Multicenter, Phase I Clinical Study of RO7821657, a Protease Activated TCB Antibody That Targets CEACAM5, in Participants With Locally Advanced and/or Metastatic Solid Tumors

Trial Summary:

The aim of this study is to characterize the safety and tolerability of RO7821657, describe its pharmacokinetics (PK), and evaluate pharmacodynamic and biomarker effects to support selection of the recommended Phase 2 dose(s) (RP2D[s]) The study consists of two parts, namely Part 1 and Part 2: Part 1: Evaluation of RO7821657 as monotherapy in participants with microsatellite-stable (MSS) colorectal cancer (CRC). Part 2: Evaluation of RO7821657 as monotherapy in participants with non-squamous non-small cell lung cancer (NSCLC)

Hoffmann-La Roche	Phase 1
Sponsor	Phase
NCT07883577 2026-526150-14-00 BP46447	
Trial Identifiers	

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Life expectancy estimated by the Investigator to be #12 weeks.
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-1.

- Presence of measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1; previously irradiated lesions are considered measurable if progression has been demonstrated in such lesions after the irradiation.
- Availability of archival tumor tissue or tissue obtained from a fresh biopsy at screening if formalin-fixed paraffin-embedded [FFPE]-preserved archival tissue is not available. The archival tumor tissue should come from a core biopsy, a punch biopsy, an excisional biopsy, or a surgical specimen. Lymph node biopsy, bone biopsy (unless from soft tissue), or fine needle aspiration are unacceptable for submission. Lesions that are intended to be biopsied should not be counted as target lesions.
- Adequate cardiovascular function:

New York Heart Association (NYHA) Heart Failure Class # 1.

- Agreement to adhere to the contraception requirements.

Exclusion Criteria:

- Participants with active Central Nervous System (CNS) metastases.
- Any unresolved toxicities from prior therapy, i.e., radiotherapy, chemotherapy, targeted or checkpoint inhibitor therapy or surgical procedure, greater than CTCAE Grade 1 at the time of starting study treatment, except for alopecia and Grade 2 neuropathy.

a) Stable endocrine AEs managed with hormone replacement are permitted, including hypothyroidism on stable thyroid hormone replacement.

- History of interstitial pulmonary disease, drug-induced pneumonitis, or evidence of active pneumonitis on screening computed tomography (CT) scan.
- Participants with pulmonary miliary metastatic pattern (innumerable small lesions) or pulmonary lymphangitic carcinomatosis.
- Active autoimmune disease that has required systemic treatment (except replacement treatment) within the last 2 years or any disease requiring immunosuppressive therapy while on study.