ForPatients
by Roche

Skin CancerMucosal MelanomaCutaneous Melanoma

A Study of RO7293583 in Participants With Unresectable Metastatic Tyrosinase Related Protein 1 (TYRP1)-Positive Melanomas

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT04551352 2020-000793-18 BP42169

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, Phase 1 Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7293583, A TYRP1-Targeting CD3 T-Cell Engager, in Participants With Metastatic Melanoma

Trial Summary:

This is a first-in-human, multi-center clinical study to determine the safety, Maximum Tolerated Dose (MTD) and/or Optimal Biological Dose (OBD) as well as the optimal schedule for intravenous (IV) and/or subcutaneous (SC) administrations of RO7293583 with or without obinutuzumab pretreatment, in participants with unresectable metastatic TYRP1-positive melanomas who have progressed on standard of care (SOC) treatment, are intolerant to SOC, or are non-amenable to SOC. This study will include an initial single participant dose-escalation part one followed by a multiple participant dose-escalation part two with the possibility of expansion.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT04551352 2020-000793-18 BP42169
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Participants with unresectable stage III or stage IV cutaneous melanoma or participants with unresectable, metastatic uveal or mucosal melanoma for whom SOC is not available or who are intolerant or non-amenable to SOC.
- Participants with cutaneous melanoma need to have known BRAF status.
- Radiologically measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
- Availability of a representative tumor specimen that is suitable for determination of TYRP1 status by means of central testing.
- For participants in Part II, willingness to provide mandatory on-treatment biopsies.
- Life expectancy (in the opinion of the Investigator) of #12 weeks.
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1.
- Absence of rapid disease progression, threat to vital organs or non-irradiated lesions > 2 cm in diameter at critical sites.
- All acute toxic effects of any prior radiotherapy, chemotherapy, targeted or checkpoint inhibitor therapy, or surgical procedure must have resolved to Grade #1 or returned to baseline, except for alopecia (any grade), for Grade 2 clinically controlled sequelae of immune-related toxicities related to checkpoint inhibitor therapy like adrenal insufficiency and hypopituitarism, and for Grade 2 peripheral neuropathy.
- Adequate hematological, liver and renal function.

Exclusion Criteria:

- Participants with a history or clinical evidence of central nervous system (CNS) 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.
- Participants with another invasive malignancy in the last 2 years.
- Active, acute, or chronic inflammatory diseases of the skin affecting more than 5% of the body surface area. History of Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug rash with eosinophilia and systemic symptoms.
- Participants with defects in the Bruch's membrane of the eye or at risk of such defects. Participants with a history of recurrent uveitis or medical conditions that are associated with frequent uveitis.
- History of or existing damage to inner ear.
- Uncontrolled hypertension.
- Significant cardiovascular disease.
- Known active or uncontrolled bacterial, viral, fungal, mycobacterial, parasitic or other infection, or any major episode of infection requiring treatment with IV antibiotics or hospitalization within 4 weeks prior to the start of drug administration.
- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug.
- Major surgery or significant traumatic injury <28 days prior to the first RO7293583 administration or anticipation of the need for major surgery during study treatment.
- Last dose of checkpoint inhibitors, targeted therapies, chemotherapy, immunostimulating or immunosuppressive therapy or other investigational drug <28 days prior to the first RO7293583 administration.
- Prior treatment with a T-cell engaging drug

Specific Exclusion Criteria if Pre-treatment with Obinutuzumab is Implemented:

- Known human immunodeficiency virus (HIV)
- History of progressive multifocal leukoencephalopathy.
- Active Tuberculosis (TB) requiring treatment within 3 years prior to baseline.
- Latent TB diagnosed during Screening.

- Positive test results for human T-lymphotropic virus 1.

Specific Exclusion Criteria if Pre-treatment with Adalimumab is Implemented:

- History of untreated tuberculosis or untreated active infection with mycobacterium tuberculosis.
- Known hypersensitivity to any of the components of adalimumab.