ForPatients
by Roche

Skin CancerAdvanced Melanoma

A Study to Evaluate The Efficacy And Safety Of RO7198457 In Combination With Pembrolizumab Versus Pembrolizumab Alone In Participants With Previously Untreated Advanced Melanoma.

A Study to Evaluate the Efficacy and Safety of Autogene Cevumeran (RO7198457) in Combination With Pembrolizumab Versus Pembrolizumab Alone in Participants With Previously Untreated Advanced Melanoma.

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT03815058 2018-001773-24 2023-507389-15-00 GO40558

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 Phase II, Open-Label, Multicenter, Randomized Study of the Efficacy and Safety of RO7198457 in Combination With Pembrolizumab Versus Pembrolizumab in Patients With Previously Untreated Advanced Melanoma

Trial Summary:

This study will evaluate the efficacy, safety, pharmacokinetics, and patient-reported outcomes (PROs) of autogene cevumeran (RO7198457) plus pembrolizumab compared with pembrolizumab alone in patients with previously untreated advanced melanoma.

Genentech, Inc.	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically confirmed metastatic (recurrent or de novo Stage IV) or unresectable locally advanced (Stage IIIC or IIID) cutaneous, acral, or mucosal melanoma;
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1;
- Life expectancy >/= 12 weeks;
- Adequate hematologic and end-organ function;
- Naive to prior systemic anti-cancer therapy for advanced melanoma with some exceptions;
- Tumor specimen availability;
- Measurable disease per RECIST v1.1.

Exclusion Criteria:

- Ocular/uveal melanoma;
- Any anti-cancer therapy with the exceptions as specified in the protocol;
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases;
- Previous splenectomy;
- History of autoimmune disease;
- Prior allogeneic bone marrow transplantation or prior solid organ transplantation;
- Positive test for Human Immunodeficiency Virus (HIV) infection;
- Active hepatitis B or C or tuberculosis;
- Significant cardiovascular disease;
- Known clinically significant liver disease.