ForPatients
by Roche

Skin CancerMelanoma

Atezolizumab in Combination With Bevacizumab in Patients With Unresectable Locally Advanced or Metastatic Mucosal Melanoma

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04091217 ML41186

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:

Atezolizumab in Combination With Bevacizumab in Patients With Unresectable Locally Advanced or Metastatic Mucosal Melanoma

Trial Summary:

This study will evaluate the efficacy and safety of atezolizumab in combination with bevacizumab in patients with unresectable locally advanced or metastatic mucosal melanoma.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04091217 ML41186
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

- Histologically confirmed unresectable locally advanced(stage III) or metastatic(Stage IV) mucosal melanoma
- May have received prior systemic treatment or treatment naive at enrollment
- Measurable disease per RECIST v1.1
- ECOG Performance Status of 0-1
- Life expectancy >= 12 weeks
- Adequate hematologic and end-organ function

- Negative HIV test at screening
- Negative hepatitis B surface antigen test at screening
- Negative hepatitis B core antibody at screening, or positive total HBcAb test followed by quantitative hepatitis B virus DNA<500 IU/mL at screening.
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm

Exclusion Criteria:

- Symptomatic or actively progressing central nervous system (CNS) metastases
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency, including, but not limited to, myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, antiphospholipid antibody syndrome, Wegener granulomatosis, Sjögren syndrome, Guillain-Barré syndrome, or multiple sclerosis, with the following exceptions: 1) Patients with a history of autoimmune-related hypothyroidism who are on thyroid-replacement hormone are eligible for the study. 2) Patients with controlled Type 1 diabetes mellitus who are on an insulin regimen are eligible for the study. 3) Patients with eczema, psoriasis, lichen simplex chronicus, or vitiligo with dermatologic manifestations only are eligible for the study provided all of following conditions are met: (i) Rash must cover < 10% of body surface area (ii) Disease is well controlled at baseline and requires only low-potency topical corticosteroids (iii) No occurrence of acute exacerbations of the underlying condition requiring psoralen plus ultraviolet A radiation, methotrexate, retinoids, biologic agents, oral calcineurin inhibitors, or high-potency or oral corticosteroids within the previous 12 months
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Active tuberculosis
- Significant cardiovascular disease (such as New York Heart Association Class II or greater cardiac disease, myocardial infarction, or cerebrovascular accident) within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- History of malignancy other than melanoma within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death, such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer
- Prior allogeneic stem cell or solid organ transplantation
- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications
- Current treatment with anti-viral therapy for HBV
- Current, recent (within 28 days prior to initiation of study treatment) or planned treatment with any other investigational agent or participation in another clinical study with anti-cancer therapeutic intent
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of atezolizumab, 6 months after the final dose of bevacizumab