SUPRAME-ACTengine® IMA203 vs. Investigator's Choice of Treatment in Previously Treated, Unresectable or Metastatic Cutaneous Melanoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Pathologically confirmed and documented cutaneous melanoma- CM patients (including acral melanoma) with unresectable or metastatic disease * HLA-A*02:01 positive * Adequate selected organ function per protocol * Eastern Cooperative Oncology Group (ECOG) performance status 0-1 * Disease progression (resistance, toxicity) on or after at least one PD-1 inhibitor, applied either as monotherapy or in combination with other therapies as treatment for unresectable or metastatic cutaneous melanoma * Patients with BRAF mutation should have been treated with one prior line of BRAF-directed therapy (with or without a MEK inhibitor) prior to initial eligibility assessment, unless deemed not clinically indicated at Investigator's discretion due to concurrent medical condition, prior toxicity, or if declined by the patient * Life expectancy more than 6 months * Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST 1.1) * Female patient of childbearing potential must use adequate contraception from randomization until 12 months after the infusion of IMA203 or in line with the instructions provided for investigator's choice treatment (in the control arm) * Male patient must agree to use effective contraception or be abstinent while on study and for 6 months after the infusion of IMA203 or in line with the instructions provided for investigator's choice treatment (in the control arm) * The patient must have recovered from any side effects of prior therapy to Grade 1 or lower prior to randomization.

Exclusion Criteria:

* Primary mucosal or uveal melanoma and melanoma of unknown primary * History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within the last 3 years * Serious autoimmune disease Note: At the discretion of the investigator, these patients may be included if their disease is well controlled without the use of immunosuppressive agents. * History of cardiac conditions as per protocol * Prior allogenic stem cell transplantation or solid organ transplantation * Concurrent severe and/or uncontrolled medical disease that could compromise participation in the study * History of or current immunodeficiency disease or prior treatment compromising immune function at the discretion of the treating physician * History of hypersensitivity to CY, FLU, or IL-2 or presence of any contraindications and other limitations for planned treatment with investigator's choice as laid down in the current versions of the respective PIs / SmPCs * Known hypersensitivity to any of the rescue medications * History of or current immunodeficiency disease or prior treatment compromising immune function at the discretion of the investigator * Positive for HIV infection or with active hepatitis B virus (HBV) or active hepatitis C virus (HCV) infection. * Any condition contraindicating leukapheresis * Pregnant or breastfeeding * Any other condition that would, in the investigator's or sponsor's judgment, contraindicate the patient's participation in the clinical trial because of safety concerns or compliance with clinical trial procedures (e.g., psychiatric disorders or substance dependence, neurological impairment) * Patient has received systemic corticosteroids within 2 weeks prior to leukapheresis, * Patient has received surgery or other anti-cancer therapies, any agent that is likely to suppress bone marrow function, or investigational medicinal products within 7 days prior to leukapheresis. * Patients with any active infection or ongoing reactivation of infection * Patients who underwent non-myeloablative lymphodepletion prior to cell therapy within the last 6 months * Prior treatment with IMA203 * Patients with ascites, pleural or pericardial effusion which requires repeated (2 within 4 weeks) or continuous paracentesis, thoracentesis or pericardiocentesis within last 2 months * Patients with LDH greater than 2.0-fold ULN * Concurrent treatment in another clinical trial or a device study that could interfere with the IMA203 treatment or planned investigator's choice treatment * Patients with active brain metastases or leptomeningeal metastases * Patient has received any investigational therapies, inactivated vaccines, chronic use of systemic corticosteroids or IV antibiotics within 1 week prior to randomization, or live vaccines within 4 weeks prior to randomization * Patient has received any anti-cancer therapy (prior anti-cancer treatment or bridging therapy) or radiotherapy within 1 week prior to start of trial treatment * Other protocol defined inclusion/exclusion criteria could apply

Conditions & Interventions

Interventions:
BIOLOGICAL: IMA203, BIOLOGICAL: nivolumab plus relatlimab, BIOLOGICAL: lifileucel, BIOLOGICAL: nivolumab, BIOLOGICAL: pembrolizumab, BIOLOGICAL: ipilimumab, DRUG: Dacarbazine, DRUG: temozolomide, DRUG: paclitaxel, DRUG: paclitaxel plus carboplatin, DRUG: Albumin-Bound Paclitaxel
Conditions:
Melanoma, Cutaneous Malignant

More Information

Contact(s): Immatics US, Inc. - ctgovinquiries@immatics.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06743126
