A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician s Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- at least 12 years old - confirmed metastatic Stage IIIb through IV/M1a through M1d cutaneous melanoma that cannot be surgically removed - disease progression (PD) on an approved anti-PD-1 and an anti-CTLA-4 treatment, administered either as a combination regimen (eg, nivolumab + ipilimumab) or in sequence for at least 8 weeks - documented BRAF V600 mutation status - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- more than 2 lines of systemic therapy for advanced melanoma - known acute or chronic hepatitis - known human immunodeficiency virus (HIV) infection - prior cancer in the previous 3 years, except for locally curable cancers that have apparently been cured - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Biological: Nivolumab, Biological: Nivolumab + Relatlimab, Biological: Pembrolizumab, Drug: Single-agent chemotherapy, Biological: Vusolimogene Oderparepvec
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Advanced Melanoma, Melanoma

More Information

Description: The purpose of this research is to compare the effects of nivolumab with vusolimogene oderparepvec (VO) against standard of care treatment drug(s) currently available for patients with advanced melanoma. We expect that taking part in this research will last up to 60 months.
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