KURZPROTOKOLL
PD-1

Öffentlicher Titel	Nivolumab im Vergleich zu einer Therapie nach Wahl des Arztes bei fortgeschrittenen Melanomen
Wissenschaftl. Titel	A Randomized Open-Label Phase 3 Trial of BMS-936558 (Nivolumab) Versus Investigator's Choice in Advanced (Unresectable or Metastatic) Melanoma Patients Progressing Post Anti-CTLA-4 Therapy
Kurztitel	PD-1
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Haut: Hautkrebs: Schwarzer Hautkrebs (Malignes Melanom) - Zweitlinie oder höher
Ziele	- To compare the objective response rate (ORR) and overall survival (OS) of BMS-936558 to investigator’s choice in subjects with advanced melanoma
Einschlusskriterien	- men & women >= 18 years of age - ECOG PS 0-1 - Histologically confirmed Stage III (unresectable)/Stage IV melanoma - Measurable disease by CT/MRI per RECIST 1.1 criteria - RECIST defined disease progression during or after <= 2 prior treatment regimens - Pre-treatment fresh core or excision tumor biopsy. - Archival FFPE tumor material if available.
Ausschlusskriterien	- Any treatment in a BMS-936558 trial. - Subjects with condition requiring systemic treatment with either corticosteroids (> 10mg QD prednisone/equivalent) or other immunosuppressive medications within 14 days of study drug administration. - Active, known or suspected autoimmune disease - Unknown BRAF status - Active brain metastasis or leptomeningeal metastasis. - Ocular melanoma - Prior therapy with anti-PD-1, anti-PD-L1 or anti-PD-L2.
Alter	18 Jahre und älter
Sponsor	Bristol-Myers Squibb (Hauptsponsor)
Förderer	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01721746 EudraCT 2012-001828-35