

## **KURZPROTOKOLL** **PD-1**

<b>Öffentlicher Titel</b>	Nivolumab im Vergleich zu einer Therapie nach Wahl des Arztes bei fortgeschrittenen Melanomen
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	PD-1
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Haut: Hautkrebs: Schwarzer Hautkrebs (Malignes Melanom) - Zweitlinie oder höher
<b>Ziele</b>	<ul style="list-style-type: none"><li>- To compare the objective response rate (ORR) and overall survival (OS) of BMS-936558 to investigator's choice in subjects with advanced melanoma</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- men &amp; women <math>\geq</math> 18 years of age</li><li>- ECOG PS 0-1</li><li>- Histologically confirmed Stage III (unresectable)/Stage IV melanoma</li><li>- Measurable disease by CT/MRI per RECIST 1.1 criteria</li><li>- RECIST defined disease progression during or after <math>\leq</math> 2 prior treatment regimens</li><li>- Pre-treatment fresh core or excision tumor biopsy.</li><li>- Archival FFPE tumor material if available.</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Any treatment in a BMS-936558 trial.</li><li>- Subjects with condition requiring systemic treatment with either corticosteroids (<math>&gt;</math> 10mg QD prednisone/equivalent) or other immunosuppressive medications within 14 days of study drug administration.</li><li>- Active, known or suspected autoimmune disease</li><li>- Unknown BRAF status</li><li>- Active brain metastasis or leptomeningeal metastasis.</li><li>- Ocular melanoma</li><li>- Prior therapy with anti-PD-1, anti-PD-L1 or anti-PD-L2.</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Sponsor</b>	Bristol-Myers Squibb (Hauptsponsor)
<b>Förderer</b>	Bristol-Myers Squibb
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT01721746 EudraCT 2012-001828-35