

**KURZPROTOKOLL**  
**CA209032**

<b>Öffentlicher Titel</b>	Phase I/II Studie zu Nivolumab mit oder ohne Ipilimumab bei soliden Tumoren
<b>Wissenschaftl. Titel</b>	A Phase 1/2, Open-label Study of Nivolumab Monotherapy or Nivolumab combined with Ipilimumab in Subjects with Advanced or Metastatic Solid Tumors
<b>Kurztitel</b>	CA209032
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase I/II
<b>Erkrankung</b>	Geschlechtsorgane: Brustkrebs: Erstlinie Lunge: Lungenkrebs: Kleinzelliges Lungenkarzinom (SCLC) - Erstlinie Verdauung: Darmkrebs (Kolorektales Karzinom): Erstlinie Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Erstlinie
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Subjects with histologically confirmed locally advanced or metastatic disease of the following tumor types:</li><li>- Triple Negative Breast Cancer</li><li>- Gastric Cancer</li><li>- Pancreatic Cancer</li><li>- Small Cell Lung Cancer</li><li>- Subjects must have measurable disease</li><li>- Eastern Cooperative Oncology Group (ECOG) of 0 or 1</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Active brain metastases or leptomeningeal metastases</li><li>- Subjects with active, known or suspected autoimmune disease</li><li>- Subjects with a condition requiring systemic treatment with either corticosteroids (&gt;10 mg daily prednisone equivalents) or other immunosuppressive medications within 14 days of treatment</li><li>- Prior therapy with experimental anti-tumor vaccines; any T cell co-stimulation or checkpoint pathways, such as anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody, including Ipilimumab; or other medicines specifically targeting T cell is also prohibited</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Molekularer Marker</b>	Triple neg (HER2/ER/PR neg)
<b>Fallzahl</b>	240
<b>Prüfzentren</b>	<b>Krankenhaus Nordwest GmbH</b> (Rekrutierung beendet) Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med. Akin Atmaca <a href="mailto:atmaca.akin@khnw.de">atmaca.akin@khnw.de</a>
<b>Sponsor</b>	Bristol-Myers Squibb
<b>Förderer</b>	Bristol-Myers Squibb
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT01928394 EudraCT 2013-002844-10