

## **KURZPROTOKOLL** **CA20977T**

<b>Öffentlicher Titel</b>	Phase III Studie zu Nivolumab neoadjuvant und adjuvant bei nicht-kleinzelligem Lungenkrebs
<b>Wissenschaftl. Titel</b>	A Phase 3, Randomized, Double-blind Study of Neoadjuvant Chemotherapy plus Nivolumab versus Neoadjuvant Chemotherapy plus Placebo, followed by Surgical Resection and Adjuvant Treatment with Nivolumab or Placebo for Participants with Resectable Stage II-III B Non-small Cell Lung Cancer
<b>Kurztitel</b>	CA20977T
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - neoadjuvant
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Participants with suspected or histologically confirmed Stage IIA (&gt; 4 cm) to IIIB (T3N2) non-small cell lung carcinoma (NSCLC) with disease that is considered resectable</li><li>- No brain metastasis</li><li>- Treatment-naive for NSCLC (no prior systemic anti-cancer treatment)</li><li>- Eastern Cooperative Oncology Group (ECOG) Performance Status of &lt;= 1</li><li>- Ability to provide surgical or biopsy tumor tissue for biomarkers</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Participants with an active, known or suspected autoimmune disease are excluded</li><li>- Any positive test for hepatitis B virus or hepatitis C virus or human immunodeficiency virus (HIV) indicating acute or chronic infection</li><li>- Any previous anti-cancer treatment including cytotoxic, IO treatment, targeted agents, or radiotherapy</li></ul>
<b>Alter</b>	18 - 99 Jahre
<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>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT04025879 EudraCT 2019-000262-38