

**KURZPROTOKOLL  
HANNA (CA209-99K)**

<b>Öffentlicher Titel</b>	Nicht-interventionelle Studie mit Nivolumab bei progredienten Kopf-Hals-Tumoren nach platinbasierter Therapie
<b>Wissenschaftl. Titel</b>	Eine nationale, prospektive, nicht-interventionelle Studie (NIS) mit Nivolumab (BMS-936558) bei Patienten mit Plattenepithelkarzinomen im Kopf-Hals-Bereich, die eine Tumorprogression während oder nach einer platinbasierten Therapie aufweisen.
<b>Kurztitel</b>	HANNA (CA209-99K)
<b>Studienart</b>	multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, einarmig, Pharma-Studie, nicht-interventionelle Studie
<b>Studienphase</b>	nicht zutreffend
<b>Erkrankung</b>	Kopf-Hals: Kopf-Hals-Tumoren: sonstige Studien für Kopf-Hals-Tumoren
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Adult patients (at least 18 years of age at time of treatment decision)</li><li>- Diagnosis of SCCHN and patients are progressing on or after platinum-based therapy</li><li>- Diagnosis of SCCHN has been confirmed by histology or cytology (either at initial diagnosis or any time later during the course of the disease)</li><li>- Treatment decision to initiate a treatment with nivolumab for the first time for the treatment of SCCHN (according to the label approved in Germany) has already been taken</li><li>- Patients who provided informed consent to participate in the study</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patients with a current primary diagnosis of a cancer other than SCCHN, ie, a cancer other than SCCHN that requires systemic or other treatment, or has not been treated curatively (as per discretion of the investigator)</li><li>- Patients previously treated with nivolumab and/or ipilimumab, an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways (applicable for any indication)</li><li>- Patients currently included in an interventional clinical trial for their SCCHN. Patients who have completed their participation in an interventional trial; or who are not receiving study drug anymore and who are only followed-up for OS can be enrolled</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Prüfzentren</b>	<b>Strahlentherapie</b> (Nachbeobachtung) Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. Maximilian Fleischmann Tel: 069 6301 5130 <a href="mailto:studien-strahlen@kgu.de">studien-strahlen@kgu.de</a> <b>Universitätsklinikum Gießen und Marburg, Standort Gießen</b> (Aktiv) Hals-, Nasen- und Ohrenheilkunde Rudolf-Buchheim-Straße 8 35392 Gießen Dr. med. Christine Langer Tel: 00641 98543701 <b>Universitätsklinikum Frankfurt</b> (Nachbeobachtung) Klinik für Strahlentherapie und Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. Maximilian Fleischmann Tel: 069 6301 5130 <a href="mailto:studien-strahlen@kgu.de">studien-strahlen@kgu.de</a>
<b>Sponsor</b>	Bristol-Myers Squibb
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03114163