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

| | |
|---|---|
| **Öffentlicher Titel** | Nicht-interventionelle Studie mit Nivolumab bei progredienten Kopf-Hals-Tumoren nach platinbasierter Therapie |
| **Wissenschaftl. Titel** | 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. |
| **Kurztitel** | HANNA (CA209-99K) |
| **Studienart** | multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, einarmig, Pharma-Studie, nicht-interventionelle Studie |
| **Studienphase** | nicht zutreffend |
| **Erkrankung** | Kopf-Hals: Kopf-Hals-Tumoren: sonstige Studien für Kopf-Hals-Tumoren |
| **Einschlusskriterien** | - Adult patients (at least 18 years of age at time of treatment decision)<br>- Diagnosis of SCCHN and patients are progressing on or after platinum-based therapy<br>- Diagnosis of SCCHN has been confirmed by histology or cytology (either at initial diagnosis or any time later during the course of the disease)<br>- 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<br>- Patients who provided informed consent to participate in the study |
| **Ausschlusskriterien** | - 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)<br>- 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)<br>- 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 |
| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Universitätsklinikum Gießen und Marburg, Standort Gießen** (Aktiv)<br>Hals-, Nasen- und Ohrenheilkunde<br>Rudolf-Buchheim-Straße 8<br>35392 Gießen<br>Dr. med. Christine Langer<br>Tel: 00641 98543701<br><br>**Universitätsklinikum Frankfurt** (Nachbeobachtung)<br>Klinik für Strahlentherapie und Onkologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Dr. Maximilian Fleischmann<br>Tel: 069 6301 5130<br>studien-strahlen@kgu.de |
| **Sponsor** | Bristol-Myers Squibb |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT03114163 |