

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

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| <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)<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Dr. Maximilian Fleischmann<br>Tel: 069 6301 5130<br><a href="mailto:studien-strahlen@unimedizin-ffm.de">studien-strahlen@unimedizin-ffm.de</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Sponsor</b>                                   | Bristol-Myers Squibb                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT03114163                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |