KURZPROTOKOLL
AliCe

Öffentlicher Titel	Phase II Studie zu Avelumab plus Cetuximab bei nicht reserzierbarem Stadium III oder IV Plattenepithelkarzinom
Wissenschaftl. Titel	Einarmige, offene, multizentrische Phase II Studie zur Untersuchung der klinischen Aktivität und Sicherheit von Avelumab in Kombination mit Cetuximab bei Studienteilnehmern mit nicht reserzierbarem Stadium III oder IV Plattenepithelkarzinom
Kurztitel	AliCe
Studienart	prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase II
Erkrankung	Haut: Hautkrebs: Plattenepithelkarzinom
Einschlusskriterien	- Male or female subjects aged >=18 years on day of signing informed consent - Histologically proven cSCC in stage III, not amendable to surgery / curative radiation, or stage IV (according to the 8th AJCC edition; see chapter 18.6) - ECOG performance status of 0 or 1 - Measurable disease, i.e. at least one measurable lesion per RECIST, v1.1 - Required values for initial laboratory tests: Absolute neutrophil count (ANC) >=1.5 × 10^9/L, Platelet count >=100 × 10^9/L, Hemoglobin >=9 g/dL (may have been transfused), Total bilirubin level <= 1.5 × the upper limit of normal (ULN), ALT and AST <=2.5 × ULN (for subjects with documented metastatic disease to the liver: <=5 x ULN), Estimated creatinine clearance >=30 mL/min according to the Cockcroft-Gault formula (or local institutional standard method) - No active or chronic infection with HIV, Hepatitis B or C - Negative serum pregnancy test for women of childbearing potential - Highly effective contraception for both male and female patients throughout the study and for at least 30 days after last dose of study medication administration if the risk of conception exists. Highly effective contraception has to be in line with the definition of the CTFG (Clinical Trial Facilitation Group) recommendation (see 18.7) - Signed written informed consent and capacity of understanding the informed consent
Ausschlusskriterien	- Known prior severe hypersensitivity to investigational product or any component in its formulations, including known severe hypersensitivity reactions to monoclonal antibodies (NCI CTCAE v5.0 Grade >= 3) - Patients with brain metastases - Current use of immunosuppressive medication, EXCEPT for the following: Intranasal, inhaled, topical steroids, or local steroid injection (e.g., intra-articular injection), Systemic corticosteroids at physiologic doses <=10 mg/day of prednisone or equivalent, Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication) - Active autoimmune disease that might deteriorate when receiving an immuno-stimulatory agent. Patients with diabetes type I, vitiligo, psoriasis, or hypo- or hyperthyroid diseases not requiring immunosuppressive treatment are eligible - Prior organ transplantation including allogeneic stem-cell transplantation - Active infection requiring systemic therapy - Known history of testing positive for HIV or known acquired immunodeficiency syndrome - Vaccination with any live vaccine (e.g. intranasal flu vaccine) within 4 weeks before the first dose of avelumab or planned vaccination with live vaccine during the trial - Clinically significant (i.e., active) cardiovascular disease: cerebral vascular accident/stroke (< 6 months prior to enrollment), myocardial infarction (< 6 months prior to enrollment), unstable angina, congestive heart failure (>= New York Heart Association Classification Class II), or serious cardiac arrhythmia requiring medication

- Current other malignancies, except malignancies NOT requiring therapy such as B-CLL, adequately treated cone-biopsied in situ carcinoma of the cervix uteri and basal carcinoma of the skin
- Other severe acute or chronic medical conditions including colitis, inflammatory bowel disease, pneumonitis, pulmonary fibrosis or psychiatric conditions including recent (within the past year) or active suicidal ideation or behavior; or laboratory abnormalities that may increase the risk associated with study participation or study treatment administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the patient inappropriate for entry into this study
- Radiotherapy within 14 days prior to first dose of study treatment with the exception of palliative bone-directed radiotherapy, or radiotherapy administered on non-target superficial lesions
- Any other systemic anti-tumor therapy in the last 4 weeks
- Patients who discontinued prior check-point inhibitor therapy due to adverse reactions
- Major surgery (excluding prior diagnostic biopsy) within 28 days prior to first dose of study treatment
- Cytokine therapy (except erythropoietin) within 28 days prior to first dose of study treatment
- Persisting toxicity related to prior therapy (NCI CTCAE v. 5.0 Grade > 1); however, alopecia, sensory neuropathy Grade <=2, or other Grade <= 2 not constituting a safety risk based on investigator's judgment are acceptable
- Currently participating in or having participated in the treatment phase of a study of an investigational agent or using an investigational device within 4 weeks before registration and/or during study participation
- Pregnancy or lactation period
- Medical or psychological conditions that would not permit the patient to complete the study or sign informed consent
- Known alcohol or drug abuse
- Legal incapacity or limited legal capacity

Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Gießen und Marburg, Standort Marburg** (Geschlossen) Klinik für Dermatologie und Allergologie Baldingerstraße 35043 Marburg Anna Estor Tel: 06421 58 62919 anna.estor@med.uni-marburg.de
Sponsor	Alcedis GmbH
Registrierung in anderen Studienregistern	EudraCT 2018-001708-12 Deutsches Register Klinischer Studien DRKS00017255 (primäres Register)