KURZPROTOKOLL
KESTREL

Öffentlicher Titel	Phase III Studie zu MEDI4736 allein oder mit Tremelimumab vs. Standardtherapie bei der Erstlinienbehandlung von rezidiviertem oder metastasiertem Plattenepithelkarzinom des Kopfes und Halses
Wissenschaftl. Titel	A Phase III Randomized, Open-label, Multi-center, Global Study of MEDI4736 Alone or in Combination With Tremelimumab Versus Standard of Care in the Treatment of First-line Recurrent or Metastatic Squamous Cell Head and Neck Cancer Patients
Kurztitel	KESTREL
Studienart	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, dreiarmig
Studienphase	Phase III
Erkrankung	Kopf-Hals: Kopf-Hals-Tumoren: Zweitlinie oder höher
Einschlusskriterien	- Age 18 years at the time of screening - Documented evidence of recurrent or metastatic SCCHN (oral cavity, oropharynx, hypopharynx, or larynx). - A fresh tumor biopsy for the purpose of screening or an available archival tumor sample. Tumor lesions used for fresh biopsies should not be the same lesions used as RECIST target lesions, unless there are no other lesions suitable for biopsy. - No prior systemic chemotherapy for recurrent or metastatic disease - World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at enrollment - No prior exposure to immune-mediated therapy,
Ausschlusskriterien	- Histologically or cytologically confirmed head and neck cancer of any other primary anatomic location in the head and neck not specified in the inclusion criteria including patients with SCCHN of unknown primary or non-squamous histologies (eg, nasopharynx or salivary gland) - Tumor progression or recurrence within 6 months of last dose of platinum therapy in the primary treatment setting - Receipt of any radiotherapy or hormonal therapy for cancer treatment within 30 days prior to first dose of study treatment - Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease [eg, colitis, Crohn's disease], diverticulitis
Alter	18 Jahre und älter
Fallzahl	628
Prüfzentren	**Universitätsklinikum Frankfurt** (Rekrutierung beendet) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Häma/Onko
Sponsor	Astra Zeneca
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02551159