KURZPROTOKOLL
GS-US-576-6220

Öffentlicher Titel	Phase II Studie zu Sacituzumab Govitecan als Erstlinientherapie bei Nichtkleinzelligem Lungenkarzinom
Wissenschaftl. Titel	An Open-label, Multicenter, Phase 2 Study of Sacituzumab Govitecan Combinations in First-line Treatment of Patients with Advanced or Metastatic NonSmall-Cell Lung Cancer (NSCLC) Without Actionable Genomic Alterations
Kurztitel	GS-US-576-6220
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, Pharma-Studie, mehrarmig
Studienphase	Phase II
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
Einschlusskriterien	- Individuals with pathologically documented evidence of Stage IV non-small cell lung Cancer (NSCLC) disease at the time of enrollment - Measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) as per RECIST Version 1.1 criteria by investigator - No prior systemic treatment for metastatic NSCLC - Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 - Adequate hematologic counts - Adequate hepatic function
Ausschlusskriterien	- Mixed SCLC and NSCLC histology - Active second malignancy - NSCLC that is eligible for definitive local therapy alone - Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy - Has an active autoimmune disease that has required systemic treatment in past 2 years - Has had an allogenic tissue/solid organ transplant. - Has severe (Grade 3) hypersensitivity to SG, pembrolizumab, carboplatin, or cisplatin, their metabolites, or formulation excipient - Has received radiation therapy to the lung - Individuals may not have received systemic anticancer treatment within the previous 6 months - Is currently participating in or has participated in a study of an investigational agent - Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses - Known active central nervous system (CNS) metastases - History of cardiac disease - Active chronic inflammatory bowel disease - Active serious infection requiring antibiotics - Active or chronic hepatitis B infection - Positive hepatitis C antibody - Positive serum pregnancy test or women who are lactating
Alter	18 Jahre und älter

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Prüfzentren	**Innere Medizin 2** (Nachbeobachtung) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Christina Wabbels Tel: 069 6301-80429 wabbels@med.uni-frankfurt.de **Universitätsmedizin Frankfurt** (Nachbeobachtung) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Christina Wabbels Tel: 069 6301-80429 wabbels@med.uni-frankfurt.de
Sponsor	GILEAD
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT05186974 EudraCT 2021-004280-27 (primäres Register)
Links	Zu den Ein- und Ausschlusskriterien