KURZPROTOKOLL
BMS CA224-060

Öffentlicher Titel	Phase II Studie zu Relatlimab (anti-LAG-3) plus Nivolumab und Chemotherapie als Erstlinientherapie beim Magen-/Ösophaguskarzinom
Wissenschaftl. Titel	A Randomized, Open-label, Phase II Clinical Trial of Relatlimab (anti-LAG-3) plus Nivolumab in Combination with Chemotherapy Versus Nivolumab in Combination with Chemotherapy as First-Line Treatment in Patients with Gastric or Gastroesophageal Junction Adenocarcinoma
Kurztitel	BMS CA224-060
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): Erstlinie
Einschlusskriterien	- Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 - Histologically- or cytologically-confirmed diagnosis of unresectable, locally advanced, or metastatic gastric cancer or GEJ adenocarcinoma - No prior treatment with systemic treatment (including HER 2 inhibitors) given as primary therapy for unresectable, locally advanced, or metastatic GC or GEJ adenocarcinoma - Tumor tissue must be provided for biomarker analyses
Ausschlusskriterien	- Participants with HER2 positive status - Participants with known untreated central nervous system (CNS) metastases - Uncontrolled or significant cardiovascular disease
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg.
Sponsor	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03662659 (primäres Register) EudraCT 2018-001069-18