Studienname	**Ascent 04** **A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1**
Sponsor/ Studiencode	Gilead Sciences, Inc. GS-US-592-6173
Setting	TNBC PD-L1 pos. mBC in der ersten Linie
Primäres Studienziel	PFS
Studiendesign	• Experimental: Sacituzumab Govitecan-hziy (SG) + Pembrolizumab Participants will receive SG 10 mg/kg on Days 1 and 8 of 21-day cycles and pembrolizumab 200 mg on Day 1 of 21-day cycles Pembrolizumab will be administered for a maximum of 35 cycles. Interventions: ○ Drug: Sacituzumab Govitecan-hziy ○ Drug: Pembrolizumab • Active Comparator: Pembrolizumab + Treatment of Physician's Choice (TPC) Participants will receive pembrolizumab 200 mg on Day 1 of each 21-day cycle (maximum 35 cycles) plus TPC determined prior to randomization from 1 of the 3 allowed regimens: ○ Paclitaxel 90 mg/m^2 on Days 1, 8, and 15 of 28-day cycles ○ nab-Paclitaxel 100 mg/m^2 on Days 1, 8, and 15 of 28-day cycles ○ Gemcitabine 1000 mg/m^2 + carboplatin area under the curve (AUC) 2 on Days 1 and 8 of 21-day cycle
Einschluss-kriterien (Auswahl)	• TNBC (zentrale Testung) • Keine Therapie in M1 • PD-L1 positiv (PD-L1 neg. → Ascent3 Studie) • Messbare Läsion nach RECISCT v1.1 • Systemische Therapie/Operation vor > 6 Monate abgeschlossen
Ausschluss-kriterien (Auswahl)	• ER > 1% • Maligne Vorgeschichte < 3 Jahren • Aktive Hirnmetastasen (stable/treated i.O.)
Teilnehmende Zentren	KEM Essen