Studienname	**Ascent 03** **Study of Sacituzumab Govitecan-hziy Versus Treatment of Physician's Choice in Patients With Previously Untreated Metastatic Triple-Negative Breast Cancer (ASCENT-03)**
Sponsor/ Studiencode	Gilead Sciences, Inc. GS-US-592-**6238**
Setting	TNBC PD-L1 neg. mBC in der ersten Linie
Primäres Studienziel	PFS
Studiendesign	**Experimental: Sacituzumab Govitecan-hziy (SG)** Participants will receive SG 10 mg/kg on Days 1 and 8 of a 21-day cycle. **Active Comparator: Treatment of Physician's Choice (TPC)** Participants will receive TPC determined prior to randomization from 1 of the 3 allowed regimens: • Paclitaxel 90 mg/m^2 on Days 1, 8, and 15 of a 28-day cycle • Nab-paclitaxel 100 mg/m^2 on Days 1, 8, and 15 of a 28-day cycle • Gemcitabine 1000 mg/m^2 + carboplatin area under the curve (AUC) 2 on Days 1 and 8 of a 21-day cycle
Einschluss-kriterien (Auswahl)	• TNBC • Keine Therapie in M1 • PD-L1 negativ (pos. bei vorheriger anti-PD-L1 Therapie erlaubt) • Messbare Läsion nach RECISCT v1.1 • Systemische Therapie/Operation vor > 6 Monate abgeschlossen • Individuals, regardless of race and ethnic group, with previously untreated locally advanced, inoperable or metastatic triple-negative breast cancer (TNBC) o Individuals whose tumors are programmed cell death ligand 1 (PD-L1) negative at screening or individuals whose tumors are PD-L1 positive at screening if they have received an anti-PD-(L)1 inhibitor in the (neo)adjuvant setting o Centrally confirmed TNBC and PD-L1 status on fresh or archival tissue o Individuals must have completed treatment for Stage I-III breast cancer, if indicated, and ≥ 6 months must have elapsed between completion of treatment with curative intent and first documented local or distant disease recurrence o Individuals presenting with de novo metastatic TNBC are eligible
Ausschluss-kriterien (Auswahl)	• Maligne Vorgeschichte < 3 Jahren • Aktive Hirnmetastasen (stable/treated i.O.) • Kardiale Vorgeschichte (z.b. Myokardinfarkt < 6 Monate)
Teilnehmende Zentren	➢ KEM Essen