Studienname	**CONTRAST** **Phase 1/2a Open-label Clinical Trial of BI-1607, an Fc-Engineered Monoclonal Antibody to CD32b (FcγRIIB), in Combination with Trastuzumab in Subjects with HER2-positive Advanced Solid Tumors**
Sponsor/ Studiencode	Syneos Health 21-BI-1607-01
Setting	HER2 pos. mBC in jeder Therapielinie
Primäres Studienziel	Sicherheit und Toleranzprofil, DLT (dose limiting toxicity)
Studiendesign	The **Phase 1** part of the trial is a dose escalation study of BI-1607 combined with trastuzumab in HER2+ advanced or metastatic solid tumors, the aim is to assess safety and tolerability and to **determine the recommended phase II dose of BI-1607 in combination with trastuzumab**. The selected dose of BI-1607 will be studied in a subsequent **Phase 2a** part of the trial along with trastuzumab in 2 open-label, expansion cohorts of 15 evaluable subjects each. The first cohort will enroll subjects with locally advanced or metastatic HER2+ breast cancer, and the second will recruit subjects with HER2+ metastatic gastric or gastroesophageal junction adenocarcinoma. The aim of the phase 2a is to collect additional safety data to further support the recommended dose, and to detect early signs of clinical activity.
Einschluss-kriterien (Auswahl)	• HER2 pos. metastasierter Brustkrebs • Mind. eine messbare Läsion (RECIST v1.1) • Vortherapie (adj/neoadj) mit Trastuzumab, CTX und einem ADC (z.B. T-DXd)
Ausschluss-kriterien (Auswahl)	• Aktive/unbehandelte Hirnmetastasen • Aktuelle Therapie mit > 10 mg Prednison • Autoimmunerkrankung • Pulmonale Vorgeschichte < 6 Monate (Steoridgabe, akutelle Pneumonitis)
Teilnehmende Zentren	➢ KEM Essen