CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**DESTINY-Breast05: A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in Subjects with High-Risk HER2-Positive Primary Breast Cancer Who Have Residual Invasive Disease in Breast or Axillary Lymph Nodes Following Neoadjuvant Therapy**	
EudraCT-Nummer	**2020-003982-20**	
ClinicalTrials.gov Identifier	**NCT04622319**	
Sponsor	Daiichi Sankyo Inc.	
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Wichtigste Einschlusskriterien	• Adults ≥18 years old (local regulatory requirements will apply if the legal age of consent for study participation is >18 years old) • Pathologically documented HER2-positive breast cancer (BC): o HER2-positive expression defined as an immunohistochemistry (IHC) score of 3+ and/or positive by in situ hybridization (ISH) confirmed prior to study randomization • Histologically confirmed invasive breast carcinoma • Clinical stage at disease presentation: T1-4, N0-3, M0; patients presenting with T1N0 tumors are not eligible • Pathologic evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of neoadjuvant therapy meeting one of the following high-risk criteria: o Inoperable breast cancer at presentation (prior to neoadjuvant therapy), defined as clinical stages T4, N0-3, M0 or T1-3, N2-3, M0	

	o Operable at presentation, defined as clinical stages T1-3,N0-1,M0, with axillary node positive disease (ypN1-3) following neoadjuvant therapy • Completion of neoadjuvant systemic chemotherapy, including taxane and HER2-directed treatment prior to surgery o Systemic therapy must consist of at least 6 cycles of chemotherapy with a total duration of at least 16 weeks, including at least 9 weeks of trastuzumab (± pertuzumab) and at least 9 weeks of taxane based chemotherapy. Patients may have received an anthracycline as part of neoadjuvant therapy in addition to taxane chemotherapy. • Adequate excision as confirmed per medical records: surgical removal of all clinically evident disease in the breast and lymph nodes. • An interval of no more than 12 weeks between the date of last surgery and the date of randomization. • Known hormone receptor (HR) status, per local laboratory assessment, as defined by ASCO-CAP guidelines (≥1%): HR positive status defined by either positive estrogen receptor (ER) and/or positive progesterone receptor (PR) status. HR-negative status defined by both known negative ER and known negative PR. • Left ventricular ejection fraction (LVEF) ≥50% within 28 days prior to randomization. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at Screening. • Has adequate organ function within 14 days before randomization.