KURZPROTOKOLL
DS-8201A

Öffentlicher Titel	Phase I Studie zu Trastuzumab Deruxtecan und Nilolumab bei HER2-positivem Brustkrebs und Blasenkrebs
Wissenschaftl. Titel	A Phase 1b, Multicenter, Two-Part, Open-Label Study of Trastuzumab Deruxtecan (DS-8201a), an Anti-Human Epidermal Growth Factor Receptor-2 (HER2)-Antibody Drug Conjugate (ADC), in Combination With Nivolumab, an Anti-PD-1 Antibody, for Subjects With HER2-expressing Advanced Breast and Urothelial Cancer
Kurztitel	DS-8201A
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase I/II
Erkrankung	Niere/Harnwege: Harnblasenkrebs: Zweitlinie oder höher Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	- Is the age of majority (adulthood) in their country - Has an Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 to 1 - Has pathologically documented breast cancer or urothelial cancer that is unresectable or metastatic, and refractory to or intolerant of existing therapy(ies) known to provide clinical benefit, and as specified in each study cohort - Has an adequate archival tumor sample available for the central laboratory to determine eligibility to participate - Has at least 1 measurable lesion per RECIST version 1.1 - Has cardiac, bone marrow, kidney, liver, blood and clotting test results required per protocol - Has had an adequate washout period before enrollment since previous surgery and other treatment - If reproduction is possible, agrees to use protocol-defined methods of contraception (or completely abstain from heterosexual intercourse) from screening to at least 5 months (females) or 7 months (males) after the last dose of study drug - Agrees to avoid harvesting sperm or ova for any reason from screening to at least 5 months (females) or 7 months (males) after the last dose of study drug - Has a life expectancy of at least 3 months - If eligible for Part 2, is eligible for Part 1
Ausschlusskriterien	- Has received prior treatment with nivolumab or trastuzumab deruxtecan - Has medical history of myocardial infarction within 6 months before enrollment, symptomatic congestive heart failure (CHF) (New York Heart Association classes II-IV), or troponin levels consistent with myocardial infarction 28 days before enrollment - Has a corrected QT interval by Fredericia (QTcF) prolongation to > 470 ms (females) or > 450 ms (males) based on an average of the screening triplicate 12-lead electrocardiogram - Has history of non-infectious interstitial lung disease (ILD) (that required steroids), has ILD currently, or it cannot be ruled out by imaging at screening - Has a condition (other than active autoimmune disease) that requires systemic treatment with either corticosteroids (>10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of starting study treatment - Is pregnant or breastfeeding, or planning to become pregnant - Is suspected to have certain other protocol-defined diseases based on past medical history, physical exam, blood tests, eye test and imaging at screening period - Has received a live vaccine within 30 days before the first dose of study drug - Is related to the investigator or another employee of the sponsor or the study site - Is pregnant, breastfeeding, or planning to become pregnant

	- Has or had any disease, psychiatric or medical condition, metastatic condition, drug/medication use or other condition that might, per protocol or in the opinion of the investigator, compromise: safety or well-being of the participant or offspring safety of study staff analysis of results
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Prüfzentren	**Universitätsmedizin Frankfurt** (Rekrutierung beendet) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Christina Wabbels Tel: 069 6301-80429 wabbels@med.uni-frankfurt.de
Sponsor	Daiichi Sankyo, Inc.
Registrierung in anderen Studienregistern	EudraCT 2018-000371-32 ClinicalTrials.gov NCT03523572