KURZPROTOKOLL
IMMU-132-09

Öffentlicher Titel	Phase III Studie zu Sacituzumab Govitecan bei rezidiviertem/refraktärem HR+/HER2- metastasiertem Brustkrebs
Wissenschaftl. Titel	Phase 3 Study of Sacituzumab Govitecan (IMMU-132) Versus Treatment of Physician's Choice (TPC) in subjects with Hormonal Receptor-Positive (HR+) Human Epidermal Growth Factor Receptor 2 (HER2) Negative Metastatic Breast Cancer (MBC) who have failed at least two prior chemotherapy regimens
Kurztitel	IMMU-132-09
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	- Female or male subjects aged >=18 years at the time of signing the informed consent form - Documented evidence of hormone receptor-positive HER2-negative (HR+/HER2-) MBC confirmed - Refractory to or relapsed after at least 2, and no more than 4, prior systemic chemotherapy regimens for MBC including: At least 1 prior anticancer hormonal treatment, At least 1 cyclin-dependent kinase inhibitor 4/6 in the metastatic setting - Eligible for one of the chemotherapy options listed in the TPC arm - Documented disease progression after the most recent therapy - Adequate bone marrow function (hemoglobin > 9 g/dL, ANC > 1,500 per mm3, platelets > 100,000 per mm3) - Adequate renal function: calculated creatinine clearance >=30 mL/minute according to the Cockcroft and Gault formula - Adequate hepatic function (bilirubin <=1.5 IULN, AST and ALT <= 2.5 x IULN or 5.0 x IULN) - Females must not be lactating or pregnant at Screening or Baseline (as documented by a negative beta human chorionic gonadotropin [ß-hCG]
Ausschlusskriterien	- Previous treatment with Topoisomerase 1 Inhibitors as a free form or as other formulations - History of significant cardiovascular disease or clinically significant ECG abnormality - Patients with Gilbert's disease - Active infection requiring intravenous antibiotic use - Patients with a history of an anaphylactic reaction to irinotecan - Other concurrent medical or psychiatric conditions that, in the Investigator's opinion, may be likely to confound study interpretation or prevent completion of study procedures and follow-up examinations - Locally advanced MBC (stage IIIc) in subjects who are candidates for curative intent therapy at the time of study enrollment
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg. PR HER2/neu neg./ER pos. ER HER2/neu neg./PR pos.

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Sponsor	Immunomedics
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03901339 EudraCT 2018-004201-33