Study of Sacituzumab Govitecan-hziy and Pembrolizumab Versus Treatment of Physician's Choice in Patients With Triple Negative Breast Cancer Who Have Residual Invasive Disease After Surgery and Neoadjuvant Therapy (ASCENT-05/AFT-65 OptimICE-RD/GBG 119/NSABP B-63)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Age \> 18 years, with residual invasive triple negative breast cancer (TNBC) in the breast or lymph nodes after neoadjuvant therapy and surgery: * TNBC criteria for the study is defined as estrogen receptor (ER) and progesterone receptor (PR) ≤ 10%, human epidermal growth factor receptor 2 (HER2)-negative per American Society of Clinical Oncology and College of American Pathologists (ASCO/CAP) guidelines (immunohistochemistry (IHC) and/or in situ hybridization (ISH)). * Adequate excision and surgical removal of all clinically evident of disease in the breast and/or lymph nodes and have adequately recovered from surgery. * Submission of both pre-neoadjuvant treatment diagnostic biopsy and resected residual invasive disease tissue. * Eastern Cooperative Oncology Group (ECOG) performance status 0-1. * Individuals must have received appropriate radiotherapy and have recovered prior to starting study treatment. * Adequate organ function. Key

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Exclusion Criteria:

* Stage IV (metastatic) breast cancer as well as history of any prior (ipsi- or contralateral) invasive breast cancer. * Prior treatment with another stimulatory or coinhibitory T-cell receptor agent (eg, cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4), OX-40, cluster of differentiation 137 (CD137), prior treatment with any HER2-directed agent, prior endocrine therapy for \> 4 weeks or planned concurrent endocrine therapy while receiving on-study treatment. * Evidence of recurrent disease following preoperative therapy and surgery. * Prior treatment with topoisomerase 1 inhibitors or antibody-drug conjugates (ADCs) containing a topoisomerase inhibitor. * Individuals with germline breast cancer gene (BRCA) mutations. * Myocardial infarction or unstable angina pectoris within 6 months of enrollment or history of serious ventricular arrhythmia (ie, ventricular tachycardia or ventricular fibrillation), high-grade atrioventricular block, or other cardiac arrhythmias or Left ventricular ejection fraction (LVEF) of \< 50% * Active serious infections requiring anti-microbial therapy. Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:
DRUG: Sacituzumab govitecan-hziy (SG), DRUG: Pembrolizumab, DRUG: Capecitabine
Conditions:
Triple Negative Breast Cancer
Keywords:
AFT-65, GBG 119, NSABP B-63, OptimICE-RD

More Information

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