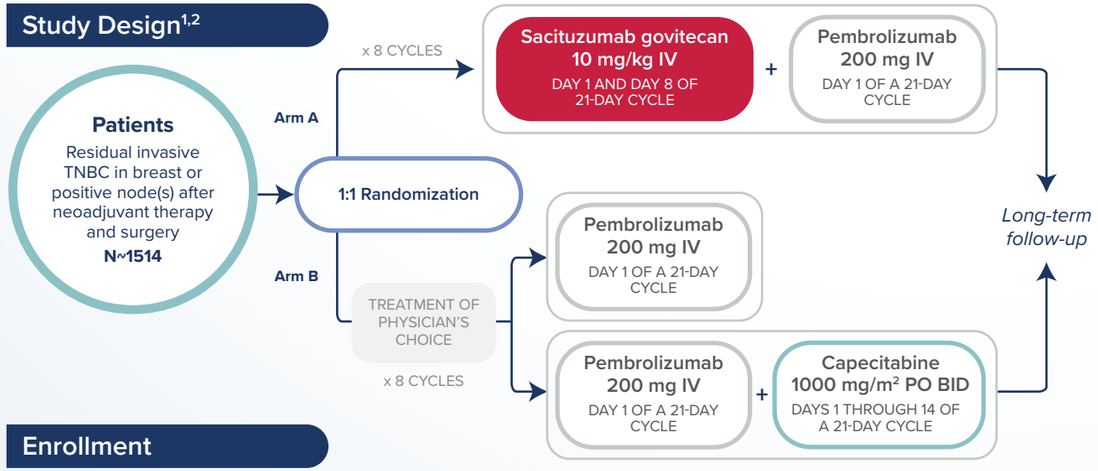
ClinicalTrials.gov Identifier: NCT05633654

ASCENT-05/OptimICE-RD: A Randomized, Open-Label, Phase 3 Study of Adjuvant Sacituzumab Govitecan + Pembrolizumab Versus Treatment of Physician's Choice in Patients With TNBC Who Have Residual Disease After Neoadjuvant Therapy and Surgery

Study Design[1,2]



Enrollment

Residual invasive TNBC in breast or positive node(s) after neoadjuvant therapy and surgery

- History of cT1, cN1-2 or cT2-4, cN0-2 disease
- Received at least 6 cycles of neoadjuvant anthracycline- and/or taxane-based chemotherapy with or without an anti-PD-(L)1 agent
- TNBC diagnosis: ER and PR <10%, HER2- negative per ASCO/CAP
- Known gBRCA mutants excluded

Stratification Factors:

- Prior anti-PD-(L)1 therapy (yes vs no)
- Prior anthracycline-based therapy (yes vs no)
- Pathologic nodal status at the time of surgery (ypNO vs ypN+)
- Geographic region (US vs East Asia vs RoW)

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Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- Age ≥18 years of age
- ECOG performance status of 0 or 1
- Adequate renal and hepatic function
- Adequate excision and surgical removal of all clinically evident disease in the breast and/or lymph nodes
- Submission of both pre-neoadjuvant treatment diagnostic biopsy and resected residual invasive disease tissue
- Patients must have received appropriate radiotherapy and have recovered prior to starting study treatment

Key Exclusion Criteria

- Positive serum pregnancy test or women who are breastfeeding
- Stage IV breast cancer as well as history of any prior ipsilateral or contralateral invasive breast cancer
- Prior treatment with another stimulatory or coinhibitory T-cell receptor agent, prior treatment with any HER2 directed agent
- Evidence of recurrent disease following preoperative therapy and surgery
- Prior treatment with topoisomerase 1 inhibitors or ADCs containing a topoisomerase inhibitor
- Myocardial infarction within 6 months of enrollment or history of serious ventricular arrhythmia or LVEF <50%
- Active serious infection requiring anti-microbial treatment

Endpoints[1,2]

Primary Endpoint

- iDFS

Secondary Endpoints

- OS
- dDFS
- Safety
- QoL
- RFS

ADC, antibody-drug conjugate; ASCO, American Society of Clinical Oncology; BID, twice daily; CAP, College of American Pathologists; d, day; dDFS, distant disease free survival; ECOG, Eastern Cooperative Oncology Group; ER, estrogen receptor; gBRCA, germline breast cancer gene; HER2, human epidermal growth factor receptor 2; iDFS, invasive disease free survival; IV, intravenous; LVEF, left ventricular ejection fraction; OS, overall survival; PD-(L)1, programmed death (ligand) 1; Pembro, pembrolizumab; PO, orally; PR, progesterone receptor; QoL, quality of life; RoW, rest of the world; RFS, Recurrence-free Survival; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer; TPC, treatment of physician's choice; US, United States.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT05633654
2. Data on file. Gilead Sciences, Inc.; 2022.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that they will become commercially available. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT05633654

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