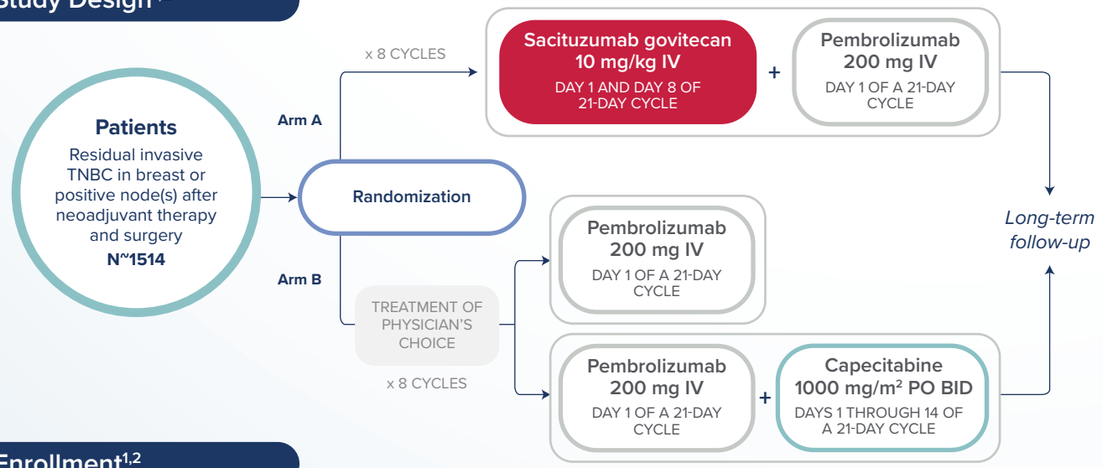
ClinicalTrials.gov Identifier: NCT05633654

ASCENT-05/AFT-65 OptimICE-RD/NSABP B-63: A Randomized, Open-Label, Phase 3 Study of Adjuvant Sacituzumab Govitecan + Pembrolizumab Versus Treatment of Physician's Choice (TPC) in Patients With TNBC Who Have Residual Invasive Disease After Neoadjuvant Therapy and Surgery[a]

Study Design[1,2]



Enrollment[1,2]

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 aPD-(L)1 agent or platinum agent
- TNBC diagnosis: ER and PR <10%, HER2- negative per ASCO/CAP
- gBRCA mutants excluded

Stratification Factors:

- Prior aPD-(L)1 therapy (yes vs no; cap no to ~10%)
- 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

- ≥18 years of age
- ECOG PS 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, prior or concurrent endocrine therapy
- 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

[a]In collaboration with Alliance Foundation Trials, LLC. and the National Surgical Adjuvant Breast and Bowel Project Foundation, Inc.

ADC, antibody-drug conjugate; aPD-(L)1, anti-programmed death-(ligand) 1; 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-L1, programmed death ligand 1; Pembro, pembrolizumab; PO, orally; PR, progesterone receptor; PS, performance status; QoL, quality of life; RFS, recurrence-free survival; RoW, rest of the world; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer; US, United States; vs, versus.

References

1. Clinicaltrials.gov website. Accessed November 14, 2024. https://www.clinicaltrials.gov/study/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.

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