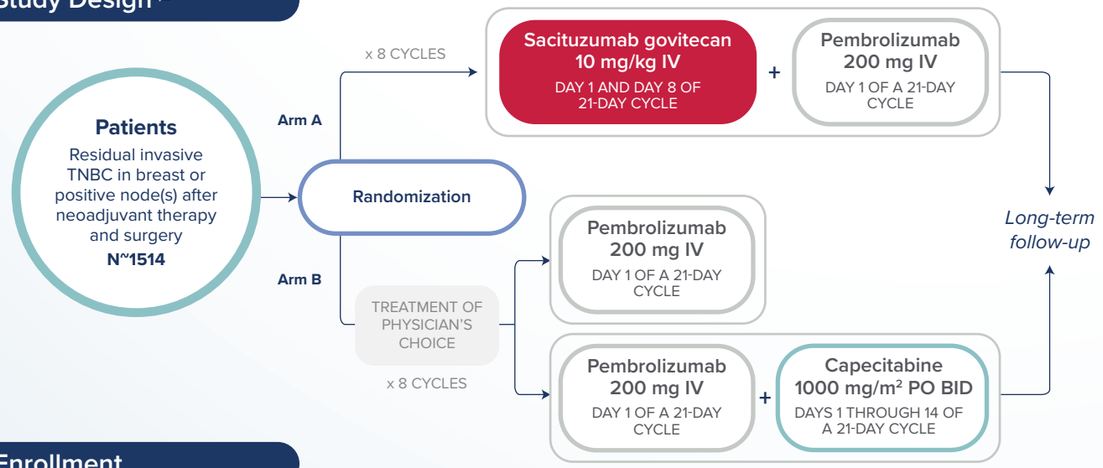
ClinicalTrials.gov Identifier: NCT05633654

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

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 anti-PD-(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)

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; TPC, treatment of physician's choice; US, United States; vs, versus.

References

1. Clinicaltrials.gov website. Accessed May 3, 2024. https://clinicaltrials.gov/ct2/show/NCT05633654
2. Data on file. Gilead Sciences, Inc.; 2022.

The safety and efficacy of these investigational agents have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT05633654