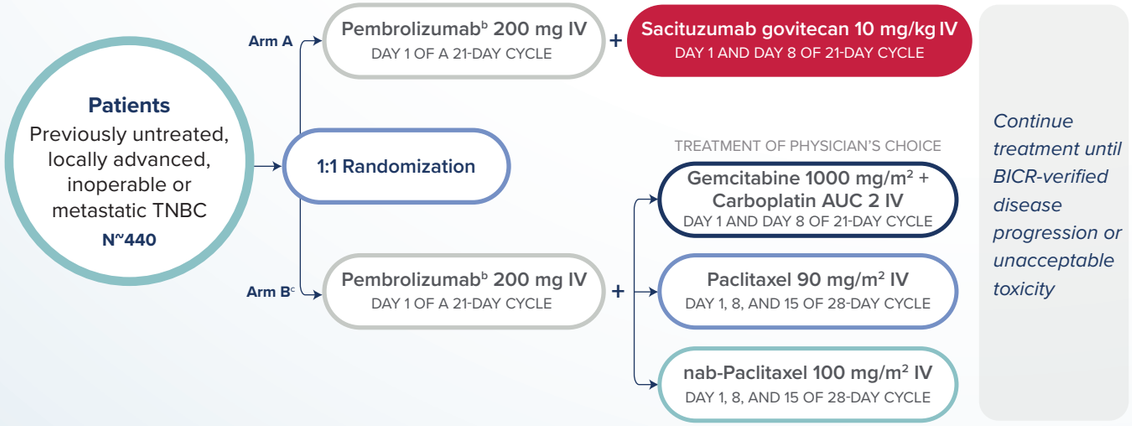
ClinicalTrials.gov Identifier: NCT05382286

ASCENT-04: A Randomized, Open-Label, Phase 3 Study of Sacituzumab Govitecan (SG) and Pembrolizumab Versus Treatment of Physician's Choice (TPC) and Pembrolizumab in Patients With Previously Untreated, Locally Advanced, Inoperable, or Metastatic Triple Negative Breast Cancer Whose Tumors Express PD-L1[a]

Study Design[1,2]



Enrollment[1,2]

Study Population 1L mTNBC

- Previously untreated, locally advanced, inoperable or de novo metastatic TNBC
- PD-L1+ by 22C3 CPS ≥10
- ≥6 months since treatment in curative setting
- Prior aPD-(L)1 use allowed in the curative setting
- PD-L1 and TNBC status centrally confirmed

ascent-04

ASCENT-04 is active, not recruiting.

Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- ≥18 years of age
- ECOG PS of 0 or 1
- Adequate renal and hepatic function
- Patients who have not received previous systemic therapy for advanced disease and whose tumors are PD-L1 positive at screening. Patients presenting with de novo mTNBC are eligible
- At least 6 months must have elapsed between completion of treatment with curative intent and first documented local or distant disease recurrence

Key Exclusion Criteria

- Positive serum pregnancy test or women who are lactating
- Active CNS metastases and/or carcinomatous meningitis
- No prior systemic anticancer treatment (with the exception of endocrine therapy) within the previous 6 months or radiation therapy within 2 weeks prior to enrollment
- May not be participating in a study with an investigational agent or investigational device within 4 weeks prior to randomization
- Previously received topoisomerase 1 inhibitors or antibody drug conjugates containing a topoisomerase inhibitor
- Active second malignancy

Endpoints[1,2]

Primary Endpoint

- PFS[d]

Secondary Endpoints

- OS
- ORR[d]
- DOR[d]
- TTR[d]
- PROs
- Safety

[a]In collaboration with Merck. [b]Maximum 35 cycles of pembrolizumab. [c]Crossover to SG in eligible patients allowed after BICR-verified disease progression. [d]By BICR using RECIST v1.1.

1L, first line; ADC, antibody-drug conjugate; aPD-(L)1, anti-programmed death-(ligand) 1; AUC, area under the curve; BICR, blinded independent central review; CNS, central nervous system; CPS, combined positive score; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; IV, intravenous; mTNBC, metastatic TNBC; ORR, objective response rate; OS, overall survival; PD-L1, programmed death ligand 1; PFS, progression-free survival; PRO, patient-reported outcome; PS, performance status; RECIST, Response Evaluation Criteria in Solid Tumors; TNBC, triple-negative breast cancer; TTR, time to onset of response; v, version.

References

1. Clinicaltrials.gov website. Accessed November 14, 2024. https://www.clinicaltrials.gov/study/NCT05382286
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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