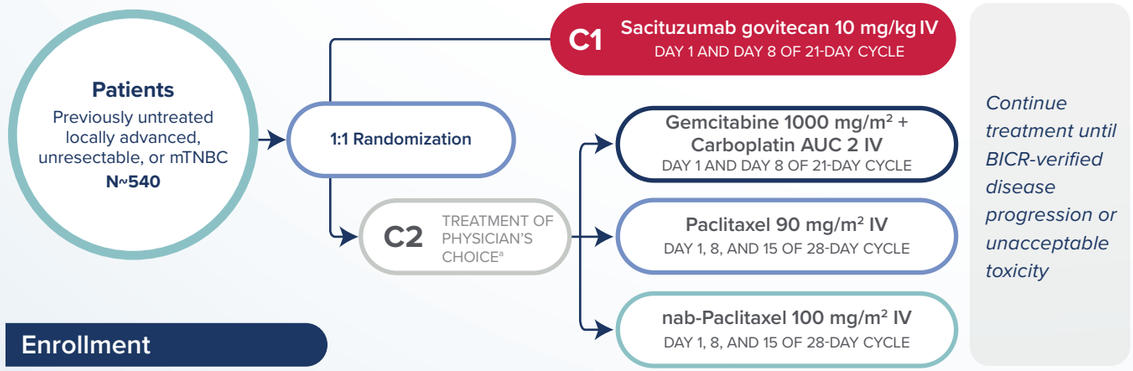
ClinicalTrials.gov Identifier: NCT05382299

ASCENT-03: A Randomized, Open-Label, Phase 3 Study of Sacituzumab Govitecan (SG) Versus Treatment of Physician's Choice (TPC) in Patients With Previously Untreated Locally Advanced, Inoperable, or Metastatic TNBC Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors Do Express PD-L1

Study Design[1,2]



Enrollment

Study Population 1L mTNBC

- Previously untreated locally advanced, unresectable, or metastatic TNBC
- PD-L1- by 22C3 CPS <10 or PD-L1+ by 22C3 CPS ≥10 in patients previously treated with an aPD-(L)1 agent in the curative setting
- ≥6 months since treatment in the curative setting
- Prior aPD-(L)1 use allowed in the curative setting
- PD-L1 and TNBC status centrally confirmed

[a]Crossover to SG in eligible patients allowed after BICR-verified disease progression.

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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
- Patients with locally advanced, inoperable, or metastatic TNBC who have not received previous systemic therapy for advanced disease and whose tumors are PD-L1 negative at screening. Alternatively, patients whose tumors are PD-L1 positive at screening will be eligible if they received a PD-(L)1 inhibitor (ie, checkpoint inhibitor) in the adjuvant or neoadjuvant setting
- 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 anticancer treatment within the previous 6 months or radiation therapy within 2 weeks prior to enrollment

Endpoints[1,2]

Primary Endpoint

- PFS[b]

Secondary Endpoints

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

[b]By BICR using RECIST v1.1

1L, first line; aPD-(L)1, anti–PD-(L)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; ITT, intent to treat; IV, intravenous; mTNBC, metastatic TNBC; ORR, objective response rate; OS, overall survival; PD-(L)1, programmed death (ligand) 1; PFS, progression-free survival; PRO, patient-reported outcome; PS, performance status; RECIST, Response Evaluation Criteria in Solid Tumors; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer; TPC, treatment of physician's choice; TTR, time to onset of response.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://www.clinicaltrials.gov/ct2/show/NCT05382299
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: NCT05382299

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