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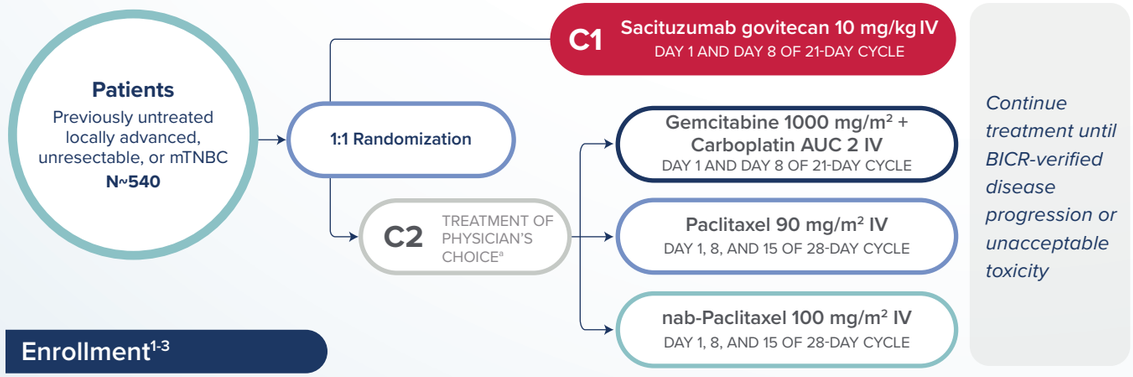
ASCENT-03: A Randomized, Open-Label, Phase 3 Study of Sacituzumab Govitecan (SG) Versus Treatment of Physician's Choice (TPC) in Patients With Previously Untreated Locally Advanced, Inoperable, or Metastatic TNBC Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents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

Study Design[1-3]



Enrollment[1-3]

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.

Key Eligibility Criteria[1-3]

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[1-3]

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.
3. Clinicaltrialsregister.eu website

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.