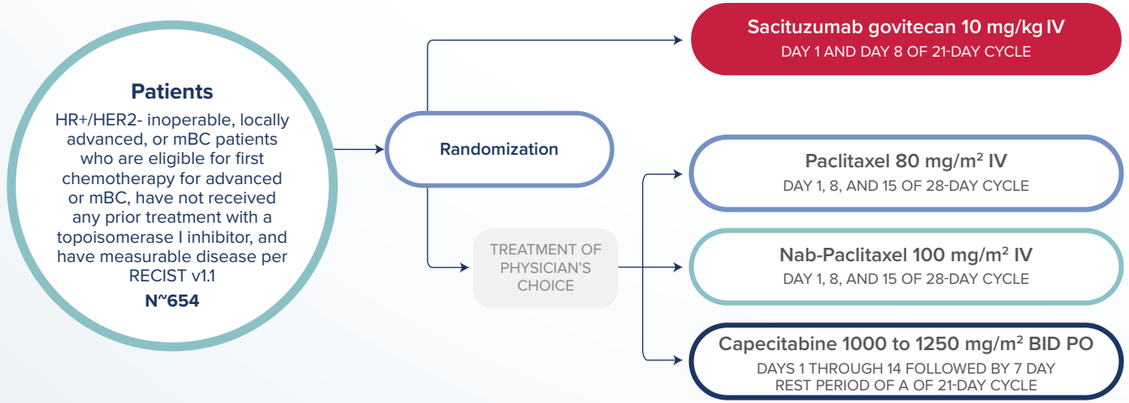
ClinicalTrials.gov Identifier: NCT05840211

ASCENT-07: A Randomized, Open-Label, Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice (TPC) in Patients With HR+/HER2- Negative (HER2 IHC0 or HER2-low [IHC 1+, IHC 2+/ISH-]) Inoperable, Locally Advanced, or Metastatic Breast Cancer and Have Received Endocrine Therapy

Study Design[1,2]



Enrollment

Patients must have 1 of the following:

- PD on ≥2 previous lines of ET +/- a targeted therapy in the metastatic setting
  - Disease recurrence while on the first 24 months of starting adjuvant ET will be considered a line of therapy; these patients will only require 1 line of ET in the metastatic setting
- PD within 6 months of starting first-line ET +/- CDK 4/6i in the metastatic setting
- Disease recurrence while on the first 24 months of starting adjuvant ET with CDK4/6i and if the patient is no longer a candidate for additional ET in the metastatic setting

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Key Eligibility Criteria[1,2]

Key Inclusion Criteria

- ≥18 years of age (or minimum age according to country-specific requirements)
- Must have adequate tissue sample preferably from locally recurrent or metastatic site
- Documented evidence of HR+ mBC confirmed with most recently available tumor biopsy from a locally recurrent or metastatic site
- Documented evidence of HER2- status
- Documented PD by CT or MRI after most recent therapy per RECIST v1.1 criteria
- Candidate for first chemotherapy in the locally advanced or metastatic setting and eligible for capecitabine, nab-paclitaxel, or paclitaxel
- Patients may have received prior targeted therapy, including but not limited to PI3Ki (for those with PIK3CA mutations) or mTOR inhibitors. However, patients can no longer be candidates for additional endocrine treatment with or without targeted therapies
- ECOG performance status of 0 or 1

Key Exclusion Criteria

- PD within 6 months of completing (neo)adjuvant chemotherapy
- Locally advanced metastatic breast cancer (Stage IIIc) in patients who are candidates for curative intent therapy
- Prior treatment containing a chemotherapeutic agent targeting topoisomerase I or any prior treatment with a Trop-2 directed ADC

Endpoints[1,2]

Primary Endpoint

- PFS[a]

Secondary Endpoints

- OS
- ORR[a,b]
- PFS[b]
- DOR[a,b]
- Safety
- Change from baseline in Physical Functioning and TTD of Global Health Status/QoL

[a]By BICR using RECIST v1.1. [b]By INV using RECIST v1.1

ADC, antibody-drug conjugate; BICR, blinded independent central review; BID, twice daily; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CT, computed tomography; d, day; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; IHC, immunohistochemistry; INV, investigator; ISH, in situ hybridization; IV, intravenous; mBC, metastatic breast cancer; MRI, magnetic resonance imaging; mTOR, mammalian target of rapamycin; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PI3Ki, phosphatidylinositol 3-kinase inhibitor; PO, orally; QoL, quality of life; RECIST, Response Evaluation Criteria in Solid Tumors; Trop-2, trophoblast cell-surface antigen 2; TTD, time to deterioration.

References

1. Clinicaltrials.gov website. Accessed May 3, 2024. https://www.clinicaltrials.gov/ct2/show/NCT05840211
2. Data on file. Gilead Sciences, Inc.; 2023.

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: NCT05840211

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