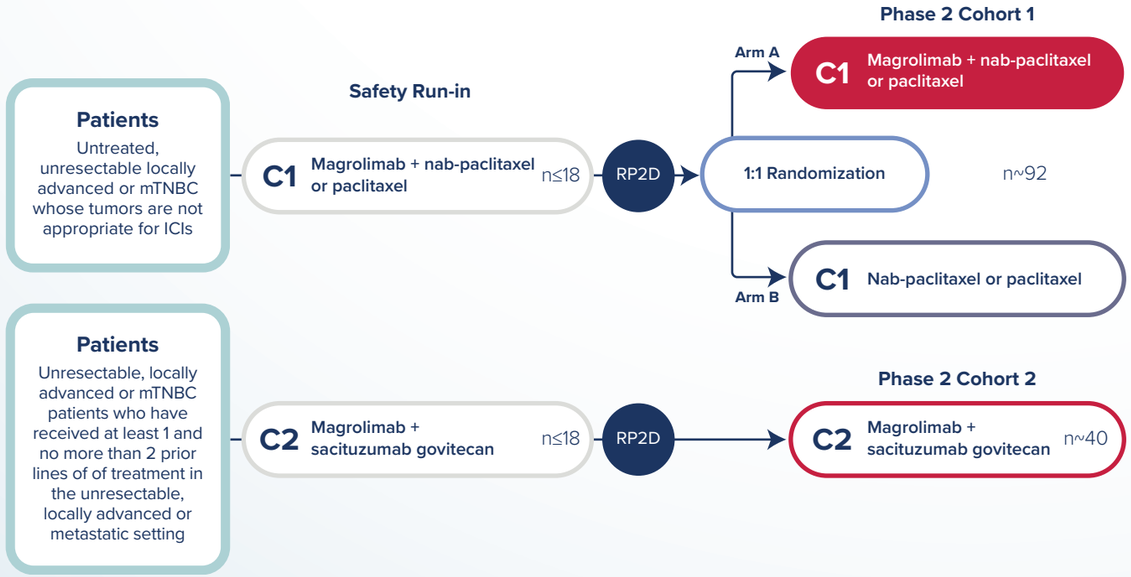
ClinicalTrials.gov Identifier: NCT04958785

ELEVATE TNBC: An Open-Label, Phase 2 Study of Magrolimab Combination Therapy in Patients With Unresectable, Locally Advanced or Metastatic Triple-Negative Breast Cancer

Study Design[1,2,3]



AE, adverse event; DLT, dose-limiting toxicity; ICIs, immune checkpoint inhibitors; mTNBC, metastatic triple-negative breast cancer; ORR, objective response rate; PFS, progression-free survival; RP2D, recommended phase 2 dose.

ELEVATE TRIPLE NEGATIVE BREAST CANCER

Key Eligibility Criteria[1,2,3]

Key Inclusion Criteria

- Measurable disease according to RECIST version 1.1
- ECOG PS of 0 or 1
- Age ≥18 years, male or female with histologically or cytologically confirmed unresectable locally advanced or metastatic TNBC either previously untreated with systemic therapy **(Cohort 1)** or at least 1 and no more than 2 prior lines of treatment in the unresectable locally advanced or metastatic setting **(Cohort 2)**
- Prior systemic treatment for neoadjuvant and/or adjuvant therapy and/or curative intent radiation therapy is permitted if completed at least 6 months prior to enrollment. (Note: maintenance therapies are not counted as separate lines of therapy) **(Safety Run-in Cohort 1 and Phase 2 Cohort 1)**
- Tumors are considered PD-L1 negative, as determined by an approved test according to local regulations **(Safety Run-in Cohort 1 and Phase 2 Cohort 1)**
- Prior treatment with immune checkpoint inhibitor for first-line treatment of locally advanced/metastatic disease for patients with tumors considered positive for PD-L1 expression **(Safety Run-in Cohort 2 and Phase 2 Cohort 2)**
- Therapy including at least 1 and no more than 2 prior lines of systemic therapy in the unresectable locally advanced/metastatic setting; must have been previously treated with a taxane in the neoadjuvant, adjuvant, or locally advanced/metastatic setting **(Safety Run-in Cohort 2 and Phase 2 Cohort 2)**

Key Exclusion Criteria

- Prior treatment with CD47- or SIRPα-targeting agents
- History of hemolytic anemia, autoimmune thrombocytopenia, or Evans syndrome in the last 3 months
- RBC transfusion dependence
- Significant disease or medical conditions, as assessed by the investigator and sponsor, that would substantially increase the risk-benefit ratio of participating in the study
- Active CNS disease. Patients with asymptomatic and stable, treated CNS lesions who have been off steroids, radiation and/or surgery, and/or CNS-directed therapy for at least 4 weeks are allowed
- Known inherited or acquired bleeding disorders
- Known active or chronic hepatitis B or C infection or human immunodeficiency virus infection in medical history
- Prior anticancer therapy within the specified timeframes prior to start of magrolimab is not permitted: 2 weeks for chemotherapy, ET, or targeted small molecule therapy; 3 weeks for mAbs, ADCs, immunotherapy, or investigational agents

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ADC, antibody-drug conjugate; CD, cluster of differentiation; CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; ET, endocrine therapy; PD-L1, programmed death ligand 1; PS, performance status; RBC, red blood cell; RECIST, Response Evaluation Criteria in Solid Tumors; SIRPα, signal regulatory protein alpha; TNBC, triple-negative breast cancer.

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: NCT04958785

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Cohort-specific Exclusion Criteria[1,2,3]

Safety Run-in Cohort 1 and Phase 2 Cohort 1

- Disease progression within 6 months following neoadjuvant/adjuvant therapy or prior lines of systemic therapy for unresectable locally advanced or metastatic breast cancer

Note: Exceptions to this exclusion criteria include: localized non-CNS radiotherapy, hormonal therapy for breast cancer in the curative setting, and treatment with bisphosphonates and receptor activator of nuclear factor kappa B ligand inhibitors.

Safety Run-in Cohort 2 and Phase 2 Cohort 2[a]

- Active chronic inflammatory bowel disease, and patients with a history of bowel obstruction or gastrointestinal perforation within 6 months of enrollment
- Received topoisomerase I inhibitors or antibody-drug conjugates containing a topoisomerase inhibitor
- High-dose systemic corticosteroids within 2 weeks of Cycle 1 Day 1
- Have not recovered (ie, ≥ Grade 2 considered not recovered) from AEs due to a previously administered agent
  - Patients with any grade of neuropathy, alopecia, hypo- or hyperthyroidism, or other endocrinopathies that are well controlled with hormone replacement and those who recovered adequately from surgery are eligible

Endpoints[1,2,3]

Safety Run-in Cohorts 1 and 2:

- DLTs
- AEs and laboratory abnormalities

Phase 2 Cohort 1:

- PFS

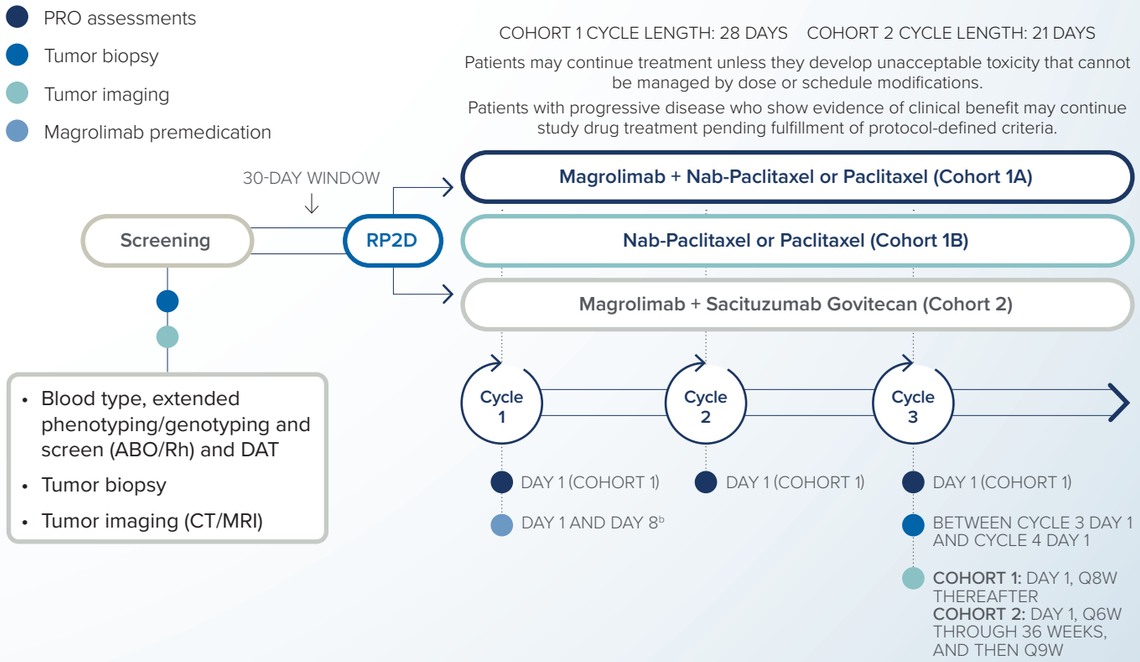
Safety Run-in Cohort 2 and Phase 2 Cohort 2:

- Confirmed ORR

[a]Localized non-CNS radiotherapy is not criteria for exclusion. Patients should be recovered from the effects of radiation.

ABO, any of the 4 blood groups A, B, AB, and O comprising the ABO system; AEs, adverse events; CT, computed tomography; DLTs, dose-limiting toxicities; MRI, magnetic resonance imaging; ORR, objective response rate; PFS, progression-free survival; PRO, patient-reported outcome; Q6W, every 6 weeks; Q8W, every 8 weeks; Q9W, every 9 weeks; RANKL, receptor activator of nuclear factor kappa B ligand; Rh, Rhesus factor.

Timeline with Key Assessments (for Phase 2 Cohorts)[1,2,3]



[b]Premedication should include oral acetaminophen, oral or IV diphenhydramine, and IV dexamethasone, or comparable regimen before the initial 2 doses of magrolimab or in the case of repriming.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT04958785
2. Rainey N, et al. Poster presentation at ESMO Annual Meeting 2023 (TPS1130).
3. Data on file. Gilead Sciences, Inc.; 2023.

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