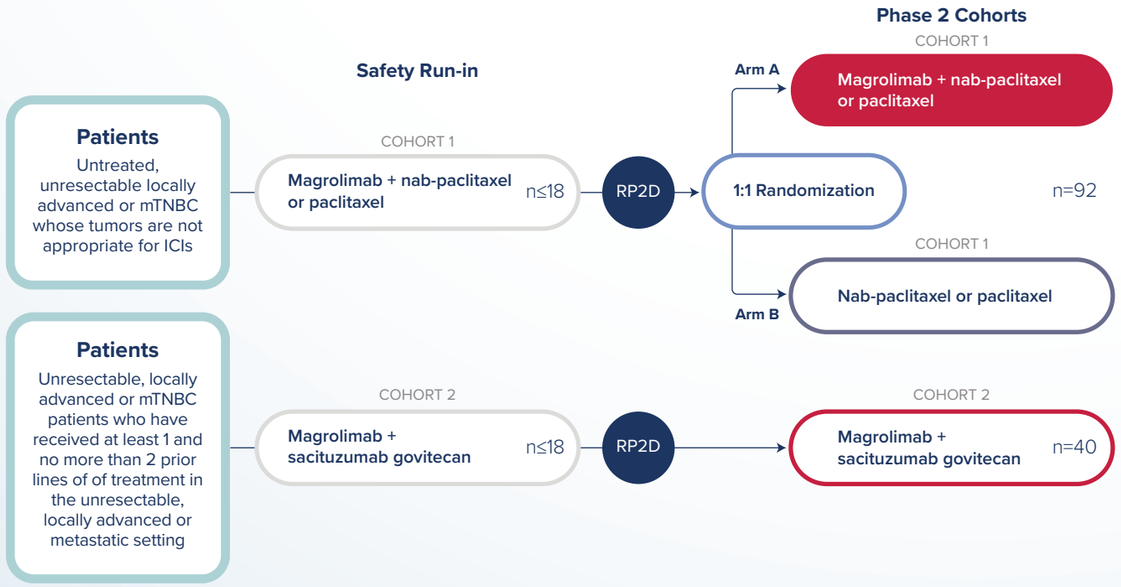
ClinicalTrials.gov Identifier: NCT04958785 • EudraCT Identifier: 2021-001074-27

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[1-4]



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.

Key Eligibility Criteria[1-4]

ELEVATE TNBC is active, not recruiting

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 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.

IHQ-UNB-5457 March 2024

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Cohort-specific Exclusion Criteria[1-4]

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[1-4]

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.

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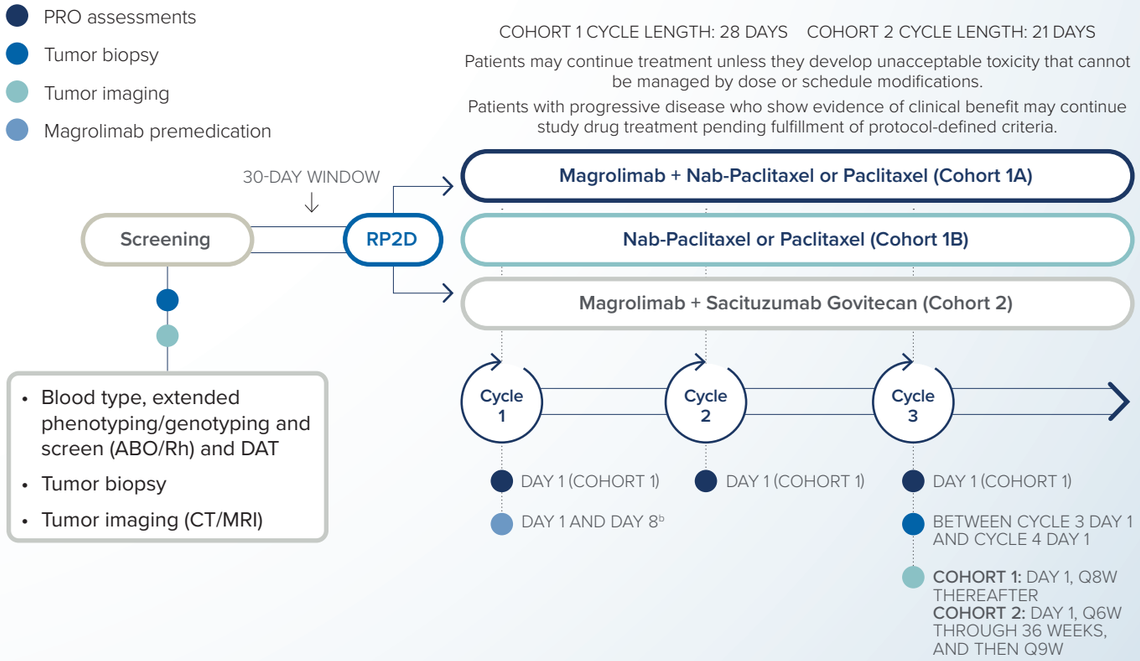
Timeline with Key Assessments (for Phase 2 Cohorts)[1-4]



[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.
4. Clinicaltrialsregister.eu website

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