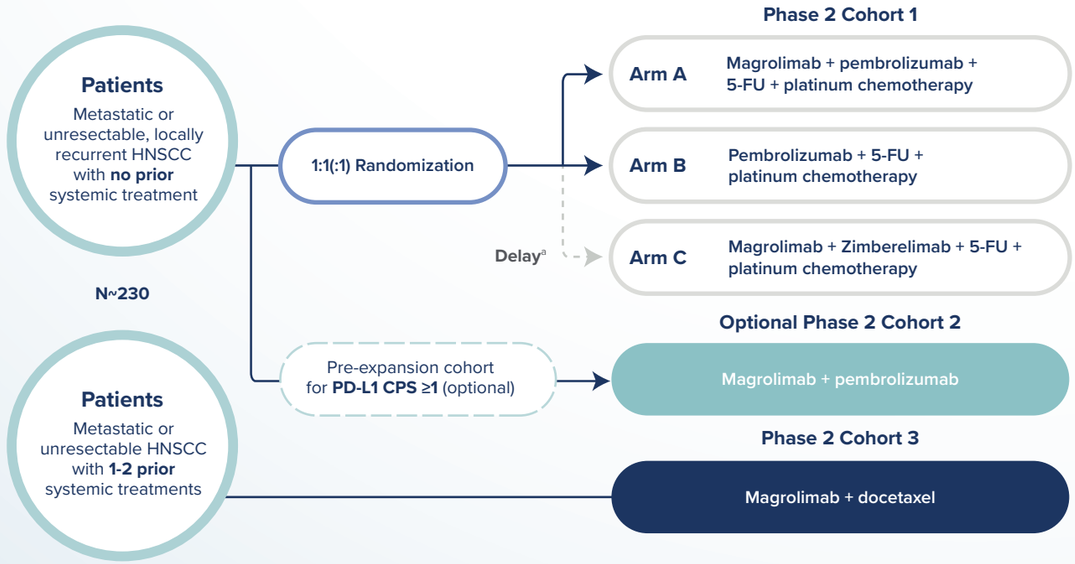
ClinicalTrials.gov Identifier: NCT04854499

ELEVATE Head and Neck Cancer: A Phase 2 Study of Magrolimab Combination Therapy in Patients With Head and Neck Squamous Cell Carcinoma

Study Design[1,2]



[a]Once the Phase 2 Cohort 1 enrolls 20 patients in each Arm A and Arm B, Arm C (n=46) will open. Randomization will continue 1:1:1 across all 3 arms.

5-FU, fluorouracil; CPS, combined positive score; HNSCC, head and neck squamous cell carcinoma; PD-L1, programmed death-ligand 1.

Key Eligibility Criteria[1,2]

Key Inclusion Criteria

All Patients

- Histologically or cytologically confirmed metastatic or locally recurrent HNSCC that is considered incurable by local therapies (except Phase 2 Cohort 3)
- ECOG PS of ≤1
- Measurable disease according to RECIST v1.1
- Hgb ≥9 g/dL prior to initial dose

Cohort-Specific Inclusion Criteria

- HNSCC regardless of PD-L1 status (Phase 2 Cohort 1)
- HNSCC with a PD-L1 CPS ≥1 (Pre-expansion Safety Run-in Cohort [if applicable] and Phase 2 Cohort 2)
- Histologically or cytologically confirmed locally advanced/mHNSCC regardless of PD-L1 status with at least 1 and no more than 2 lines of prior systemic anticancer therapy in the locally advanced/metastatic setting (Phase 2 Cohort 3)

Key Exclusion Criteria

All Patients

- Active CNS disease (individuals with asymptomatic and stable, treated CNS lesions who have been off corticosteroids, radiation, or other CNS-directed therapy for at least 4 weeks are not considered active)
- History of (noninfectious) pneumonitis that required steroids or current pneumonitis

Pre-expansion Safety Run-in Cohort (if Applicable), and Phase 2 Cohorts 1 and 2

- Progressive disease within 6 months of completion of curatively intended systemic treatment for locoregionally advanced HNSCC
- Prior treatment with any of the following: anti–PD-1 or anti–PD-L1 checkpoint inhibitors, anti–cytotoxic T-lymphocyte–associated protein 4 checkpoint inhibitors

Phase 2 Cohorts 3

- Progressive disease within 6 months of completion of curatively intended systemic treatment for locally advanced/mHNSCC
- Prior treatment with a taxane

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CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; Hgb, hemoglobin; mHNSCC, metastatic HNSCC; PD-1, programmed death 1; RECIST, Response Evaluation Criteria in Solid Tumors.

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: NCT04854499

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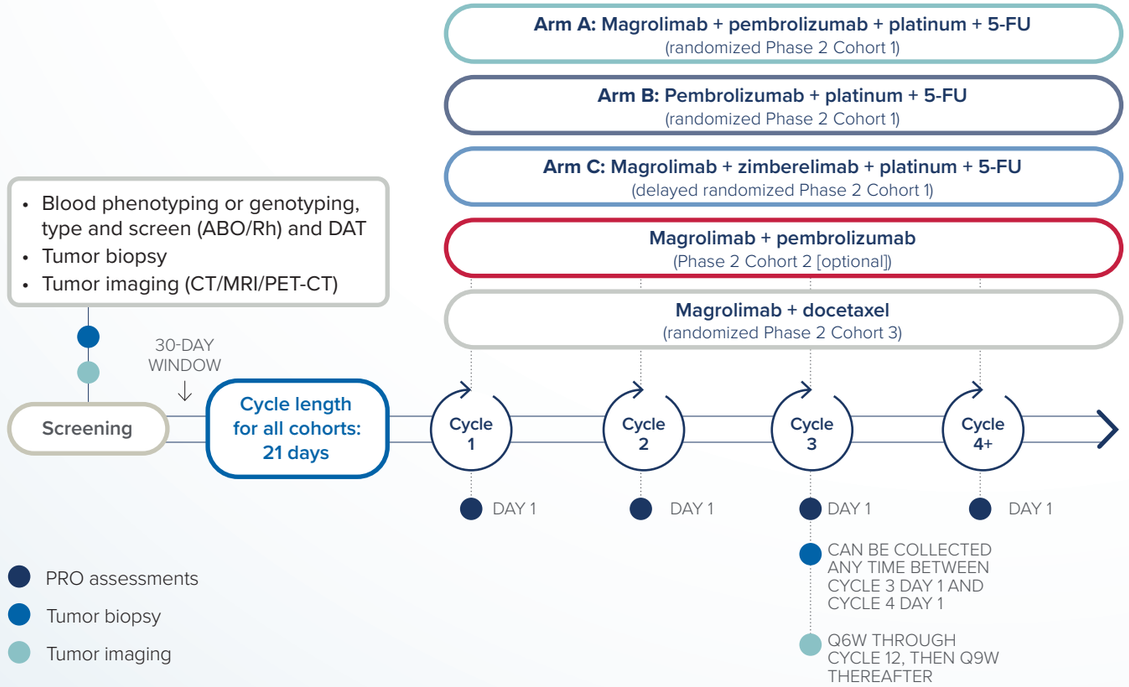
Timeline with Key Assessments[1,2]



ABO, any of the 4 blood groups A, B, AB, and O comprising the ABO system; CT, computed tomography; DAT, direct antiglobulin test; MRI, magnetic resonance imaging; PET, positron emission tomography; PRO, patient-reported outcome; Q6W, every 6 weeks; Q9W, every 9 weeks; Rh, Rhesus factor.

ELEVATE HEAD AND NECK CANCER

Endpoints[1,2]

Primary Endpoints

- PFS, independent central review (Phase 2 Cohort 1, Arm A vs Arm B)
- ORR, investigator assessed (Phase 2 Cohorts 2 and 3)

Secondary Endpoints Phase 2 Cohorts

- PFS, independent central review (Phase 2 Cohort 1, Arm C vs Arm B)
- ORR, independent central review
- PFS, investigator assessed
- DOR and OS
- PROs
- PK
- ADAs

ADA, antidrug antibody; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT04854499
2. Data on file. Gilead Sciences, Inc.; 2022.

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