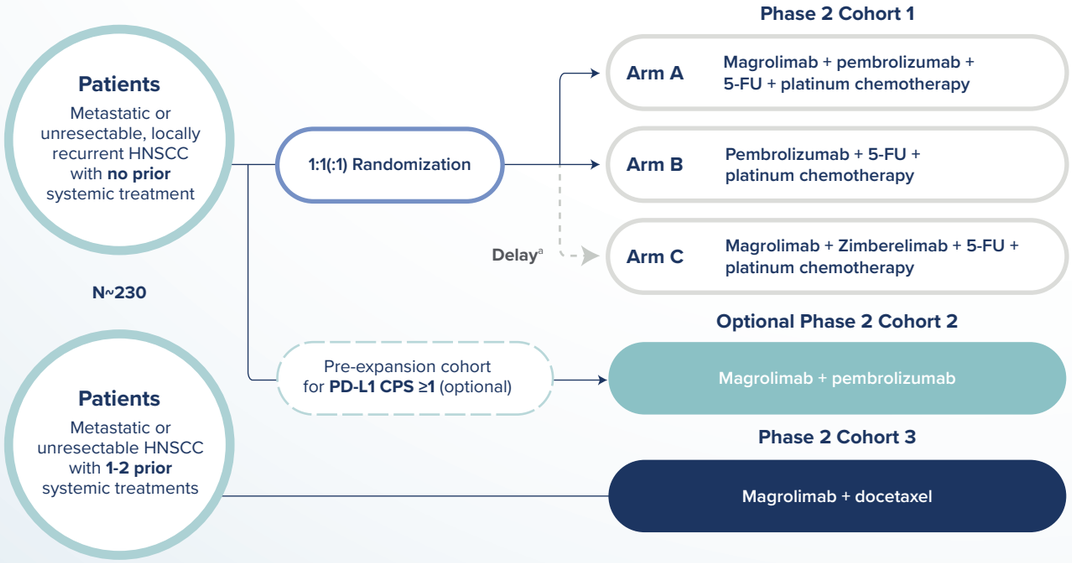
ClinicalTrials.gov Identifier: NCT04854499 • EudraCT Identifier: 2020-005708-20

ELEVATE HNSCC is active, not recruiting

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

Study Design[1-3]



[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[1-3]

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

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

- 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 Cohort 3

- 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 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.

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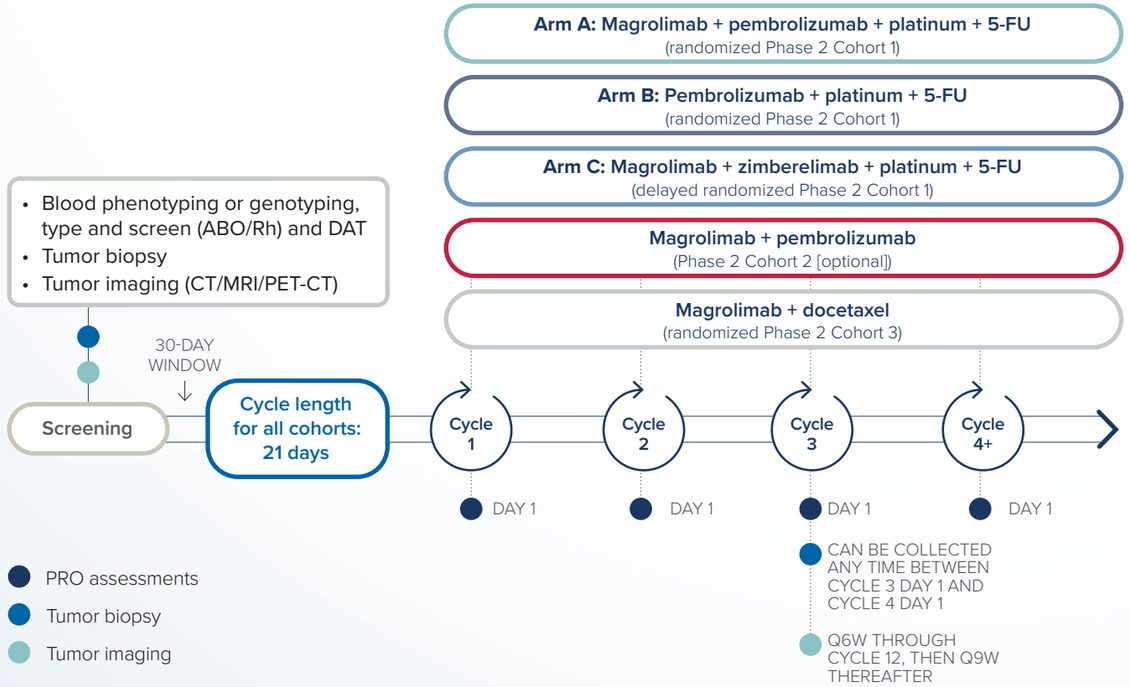
Timeline with Key Assessments[1-3]



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.

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Endpoints[1-3]

Primary Endpoints

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

Secondary Endpoints Phase 2 Cohorts

- PFS, investigator assessed
- ORR, 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 February 6, 2024. https://clinicaltrials.gov/ct2/show/NCT04854499
2. Data on file. Gilead Sciences, Inc.; 2022.
3. Clinicaltrialsregister.eu website

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