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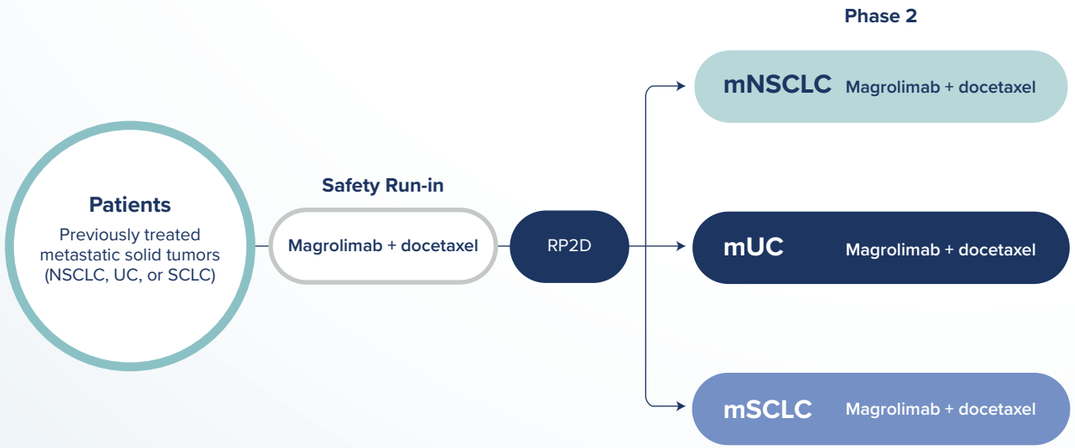
ELEVATE Lung and Urothelial Cancer: A Phase 2, Multi-Arm Study of Magrolimab in Patients With Solid Tumors

Study Design[1-3]



mNSCLC, metastatic NSCLC; mSCLC, metastatic SCLC; mUC, metastatic UC; NSCLC, non-small cell lung cancer; RP2D, recommended phase 2 dose; SCLC, small cell lung cancer; UC, urothelial carcinoma.

Key Eligibility Criteria[1-3,a]

Key Inclusion Criteria

- Age ≥18 years
- ECOG PS ≤2
- Adequate blood counts, renal function, and liver function
- Pretreatment blood cross-match completed
- Measurable disease according to RECIST version 1.1
- Males and females of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception

Key Exclusion Criteria

- Prior treatment with CD47- or SIRPα-targeting agents
- Active CNS disease. Individuals with asymptomatic, stable, treated CNS lesions (radiation and/or surgery and/or other CNS-directed therapy who have not yet received corticosteroids for at least 4 weeks) are allowed
- History of hemolytic anemia, autoimmune thrombocytopenia, or Evans syndrome in the last 3 months
- RBC transfusion dependence
- Known hypersensitivity to any of the study drugs, metabolites, or formulation excipients

Key Exclusion Criteria (cont'd)

- Known inherited or acquired bleeding disorders
- Known active or chronic hepatitis B or C infection or human immunodeficiency virus infection
- Positive serum pregnancy test or breastfeeding female
- Treatment with a taxane in the last 12 months or refractory to taxane (Phase 2 Cohorts)
- Significant disease or medical conditions, including but not limited to acute myocardial infarction within the past 6 months, unstable angina, uncontrolled diabetes mellitus, significant active infections, and congestive heart failure
- Second malignancy, except treated basal cell or localized squamous skin carcinomas, localized prostate cancer, or those for which patients are not on active anticancer therapy and have been in complete remission for >3 years
- Prior anticancer therapy, including but not limited to chemotherapy, immunotherapy, or investigational agents last administered ≤4 weeks prior to administration of magrolimab
  - Palliative, localized non-CNS radiotherapy, previous hormonal therapy with luteinizing hormone releasing hormone agonists for prostate or breast cancer, and treatment with bisphosphonates and RANKL inhibitors are not criteria for exclusion

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[a]Other protocol defined Inclusion/Exclusion criteria may apply.

CD, cluster of differentiation; CNS, central nervous system; PS, performance status; RANKL, receptor activator of nuclear factor kappaB ligand; RBC, red blood cell; RECIST, Response Evaluation Criteria in Solid Tumors; SIRPα, signal regulatory protein alpha.

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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Cohort-specific Inclusion Criteria[1-3]

Safety Run-in

- Patients with metastatic advanced solid tumors treated in a locally advanced/metastatic setting with ≥1 prior line (mNSCLC and mSCLC) or ≥2 prior lines (mUC) of systemic anticancer therapy, but not more than 3 prior lines in a locally advanced/metastatic setting

Phase 2 Cohort 1a (mNSCLC)

- Patients with mNSCLC treated with platinum-based chemotherapy and an immune checkpoint inhibitor in a locally advanced/metastatic setting, either in combination or sequentially (unless not eligible for one of these therapies) are eligible
  - — 1 or 2 prior lines of systemic therapy in a locally advanced/metastatic setting
  - — Individuals whose tumors have genomic alterations are excluded

Phase 2 Cohort 1b (mUC)

- Patients with mUC treated with systemic chemotherapy and/or an immune checkpoint inhibitor in a locally advanced/metastatic setting
  - — 2 or 3 prior lines of therapy in a locally advanced/metastatic setting

Phase 2 Cohort 1c (mSCLC)

- Patients with mSCLC treated with platinum-based chemotherapy and/or an immune checkpoint inhibitor
  - — 1 or 2 prior lines of systemic therapy in a locally advanced/metastatic setting

Note: maintenance therapies are not counted as separate lines of therapy.

Phase 2 Cohorts Endpoints[1-3]

Primary Endpoints

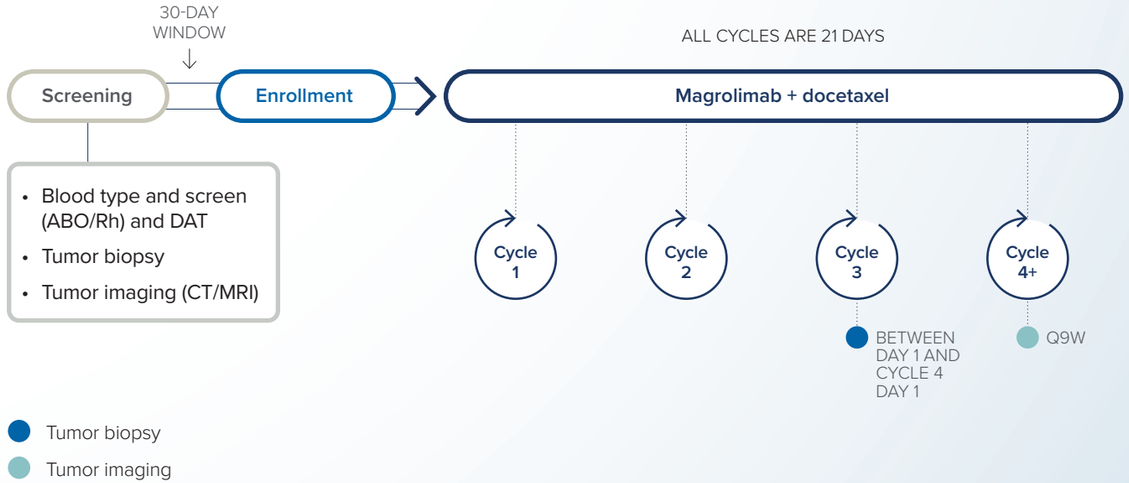
- Incidence of AEs and laboratory abnormalities
- ORR

Secondary Endpoints

- PFS
- DOR
- OS
- ADAs to magrolimab
- Serum concentration of magrolimab

ADA, antidrug antibody; AE, adverse event; ALK, anaplastic lymphoma kinase; DOR, duration of response; EGFR, epidermal growth factor receptor; MET, mesenchymal-epithelial transition; NTRK, neurotrophic tyrosine receptor kinase; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; ROS1, c-ros oncogene 1.

Phase 2 Cohorts: 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; Q9W, every 9 weeks; Rh, Rhesus factor.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT04827576
2. Subbiah, et al. Poster presentation at ASCO Annual Meeting 2023 (TPS9412).
3. Clinicaltrialsregister.eu website

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