A Phase 2, Multi-arm Study of Magrolimab in Patients With Solid Tumors

Schematic[1,2]

Primary Objectives: Cohorts 1a, 1b, and 1c

- Safety and tolerability of magrolimab with docetaxel
- Efficacy assessed by ORR (Phase 2 Cohorts)

Key Inclusion Criteria[1,2*]

- 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
- Willing to consent to providing baseline tumor tissue from a core or excisional biopsy
- Males and females of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception

Key Exclusion Criteria[1,2*]

- 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
- Known inherited or acquired bleeding disorders
- Known active or chronic hepatitis B or C infection or human immunodeficiency virus
- Positive serum pregnancy test or breastfeeding female
- Treatment with a taxane in the last 12 months or refractory to taxane (Phase 2 Cohorts)
- Significant medical diseases or 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
- Localized non-CNS radiotherapy, previous hormonal therapy with luteinizing hormone releasing hormone agonists for prostate or breast cancer, and treatment with bisphosphonates and receptor activator of nuclear factor kappaB ligand (RANKL) inhibitors are not criteria for exclusion

*Other protocol-defined Inclusion/Exclusion criteria may apply[1]. The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that the investigational therapies or uses will be approved for use. Visit clinicaltrials.gov for more information on trial inclusion and exclusion criteria. **Clinicaltrials.gov: NCT04827576**

Cohort-specific Inclusion Criteria[1,2]

Safety run-in

- 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):

- mNSCLC treated with platinum-based chemotherapy and/or an immune checkpoint inhibitor in a locally advanced/metastatic setting
  - 1 or 2 prior lines of therapy in a locally advanced/metastatic setting
  - mNSCLC treated for EGFR, ROS1, ALK, NTRK, or MET exon 14 genomic alterations are excluded

Phase 2 Cohort 1b (mUC):

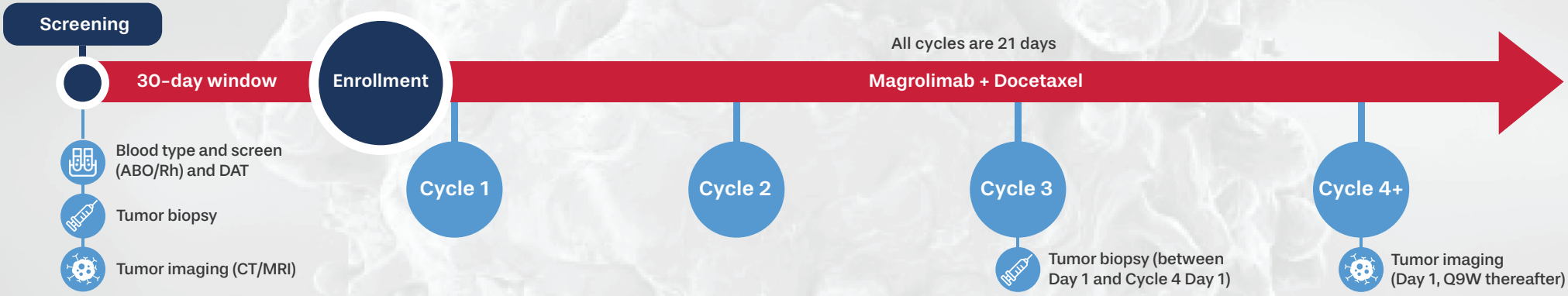
- mUC treated with systemic chemotherapy and/or an immune checkpoint inhibitor in a locally advanced/metastatic setting
  - 2 or 3 prior lines of therapy in a locally advanced/metastatic setting

Phase 2 Cohort 1c (mSCLC):

- 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

Timeline With Key Assessments for Phase 2 Cohorts



Primary Endpoints: Phase 2

- Incidence of AEs
- ORR

Secondary Endpoints: Phase 2

- PFS
- DOR
- OS
- ADA to magrolimab
- Serum concentration for magrolimab

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ABO, any of the 4 blood groups A, B, AB, and O comprising the ABO system; ADA, antidrug antibodies; AE, adverse event; ALK, anaplastic lymphoma kinase; CD, cluster of differentiation; CNS, central nervous system; CT, computed tomography; DAT, direct antiglobulin test; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; EGFR, epidermal growth factor receptor; MET, mesenchymal-epithelial transition; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer; NTRK, neurotrophic tyrosine receptor kinase; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PS, performance status; Q9W, every 9 weeks; RANKL, receptor activator of nuclear factor kappaB ligand; RBC, red blood cell; RECIST, response evaluation criteria in solid tumors; Rh, Rhesus factor; ROS1, c-ros oncogene 1; RP2D, recommended phase 2 dose; SCLC, small cell lung cancer; SIRPα, signal regulatory protein alpha; UC, urothelial carcinoma.

References

1. Clinicaltrials.gov website. Accessed October 11, 2021. https://clinicaltrials.gov/ct2/show/NCT04827576
2. Data on file. Gilead Sciences, Inc.; 2021.

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