LANDSCAPE 1011

Sub-Study B now enrolling patients with non-small cell lung cancer

A Phase 1b/2 Open Label Umbrella Study of Sasanlimab (a PD-1 antagonist monoclonal antibody) Combined with Anti-Cancer Therapies Targeting Multiple Molecular Mechanisms in Participants with Non-Small Cell Lung Cancer (NSCLC)

Now enrolling: North America, Europe, Asia, and Australia

Sub-Study B Key Inclusion/Exclusion Criteria*

Key Inclusion Criteria:

- Stage IIIB-IV NSCLC
- Men and women aged ≥18 years
- ≥1 measurable lesion(s)
- ECOG 0 - 1
- Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade ≤1
- Adequate bone marrow, renal, and liver function

Key Exclusion Criteria:

- Documentation of any tumor-driving molecular alteration (eg, BRAF, EGFR, ALK)
- Active or prior autoimmune disease that might deteriorate when receiving an immunostimulatory agent
- Active non-infectious pneumonitis, pulmonary fibrosis, or known history of immune-mediated pneumonitis
- Active infection requiring systemic therapy
- Clinically significant cardiovascular disease
- Symptomatic brain metastasis, with exceptions

Sub-Study B Treatments

Sasanlimab will be administered subcutaneously once weekly every three weeks. Axitinib will be administered orally twice daily. SEA-TGT will be administered intravenously once every three weeks. Treatments will be administered until progressive disease, unacceptable AE, participant withdraws, or study is terminated.

Sasanlimab	Axitinib	SEA-TGT±
— PD-1 antagonist monoclonal antibody	— VEGFR inhibitor	— A nonfucosylated anti-TIGIT monoclonal antibody

Summary of Endpoints

Primary

Phase 1b: dose-limiting toxicities (DLTs) during the first cycle (21 days)

Phase 2: objective response rate (ORR), defined as confirmed complete response (CR) or partial response (PR), using RECIST v1.1

Secondary

Phase 1b: adverse events and laboratory abnormalities, durable ORR, PK parameters of sasanlimab, axitinib, and SEA-TGT, anti-drug antibodies (ADA; NAbs)

Phase 2: overall survival (OS), CR and duration of CR, time to tumor response, progression-free survival, tumor sample biomarker status based on PD-L1 expression, health-related quality of life

Sasanlimab is an investigation compound. Its safety and efficacy have not been established. Axitinib is not approved for this investigational use. Its safety and efficacy have not been established in this use. SEA-TGT is not approved for this investigational use. Its safety and efficacy have not been established in this use.

*These are not the complete inclusion/exclusion criteria. For more information about this clinical research study, please visit **www.clinicaltrials.gov (NCT04585815)**.

±SEA-TGT is provided by Seagen.

This information is current as of July 2022.

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Pfizer Oncology