A PHASE 1B/2 UMBRELLA STUDY OF ANTI-PD-1 SASANLIMAB IN COMBINATION WITH OTHER THERAPIES FOR PATIENTS WITH STAGE IIIB/IV NON-SMALL CELL LUNG CANCER (NSCLC): THE LANDSCAPE 1011 TRIAL IN PROGRESS

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Background Programmed cell death protein 1 (PD-1) inhibitors as monotherapy or in combination with chemotherapy have become a standard of care first-line therapy for Stage IIIB/IV non-small cell lung cancer (NSCLC). However, many patients experience disease progression and require subsequent therapy within the first year of treatment.¹ For patients requiring salvage chemotherapy, prognosis is poor, with a median progression-free survival (PFS) and overall survival (OS) of 4.0 and 8.5 months, respectively.² Combinations of PD-1 blockade using sasanlimab (PF-06801591) and other immune and/or targeted therapies may be able to achieve clinical response in patients who have progressed on standard chemoimmunotherapy.

Methods LANDSCAPE 1011 (NCT04585815) is a prospective, open-label, multi-center, parallel group, phase 1b/2 umbrella study evaluating the safety, efficacy, pharmacokinetics, and pharmacodynamics of sasanlimab in combination with other therapies, in patients with Stage IIIB/IV NSCLC. The study is expected to enrol ~375 patients age 18 years or older diagnosed with stage IIIB/IV NSCLC. During phase 1b, the safety of each sub-study combination with subcutaneous sasanlimab will be assessed and the recommended phase 2 dose determined for each combination. Phase 2 will further evaluate safety and anti-tumor activity of each combination using the respective recommended phase 2 dose (figure 1). Up to 5 parallel sub-studies are planned. Currently, 2 sub-studies are ongoing. Sub-Study A will investigate sasanlimab, encorafenib (a BRAF inhibitor), and binimetinib (a MEK inhibitor) in patients with BRAF^{V600E} mutations (only including treatment-naïve patients in phase 2). Sub-Study B will investigate sasanlimab, axitinib (a vascular endothelial growth factor receptor inhibitor), and SEA-TGT (an anti-TIGIT antibody). In phase 2, this will involve treatment-naïve patients without oncogene drivers who have PD ligand 1-positive tumors or whose disease has progressed on prior immune checkpoint inhibitor-containing regimens. The primary phase 1b endpoint is the dose-limiting toxicity during the first cycle (28 days). The primary phase 2 endpoint in Sub-Study A is durable objective response (OR) defined as confirmed complete response or partial response lasting 10 or more months; and in Sub-Study B, OR defined as confirmed complete response or partial response, according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Secondary endpoints include adverse events and laboratory abnormalities, duration of response, time to tumor response, PFS, OS, OR by PD-L1

expression at baseline, pharmacokinetic parameters, incidence of anti-drug antibodies and neutralizing antibodies, and health-related quality of life. The first patient was enrolled in November 2020.

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Trial Registration ClinicalTrials.gov NCT04585815

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Ethics Approval The study is approved at each study site according to local regulations.

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