EDGE-Lung: A Phase 2 Open-Label Platform Study to Evaluate Immunotherapy-Based Combinations in Patients with Metastatic NSCLC

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**Study Objectives**
- The EDGE-Lung Study will investigate the safety and clinical activity of novel quinazolin-4(3H)-one and doxorubicin-based treatment combinations in patients with metastatic NSCLC.

**Study Design**
- EDGE-Lung (NCT07573531) is a global, multicenter, randomized, open-label, 2-stage phase II trial (Figure 3).
- Different NSCLC patient populations will be treated with novel regimens via separate study sub-studies. A minimum of approximately 160 patients, and up to approximately 320 patients, will be enrolled.
- Each sub-study will enrol 20 to 30 patients per treatment arm during the preliminary stage, then enrol 40 to 50 patients per treatment arm in the later phase, up to a total of 40 patients per treatment arm.

**Key Inclusion and exclusion criteria are shown in Table 1.**

**Methods**

**Patient Population**
- Eligible patients are adults with histologically confirmed metastatic squamous or non-squamous NSCLC.
- Eligible treatment-naïve and pretreated NSCLC patients with high PD-L1 expression may be enrolled in either sub-study A or sub-study B at the discretion of the investigator.

**Key inclusion and exclusion criteria are shown in Table 1.**

**Key Exclusion Criteria**
- Previous treatment failure with any anti-PD-1 or any other therapeutic antibody targeting the immunotherapy checkpoint

**Outcomes and Endpoints**
- Treatment will be continued until unacceptable toxicity, loss to follow-up, disease progression, study withdrawal, death, or study termination.

**Key study endpoints are listed in Table 2.**

**Statistical Considerations**
- Efficacy and safety will be analyzed for all enrolled patients who received any amount of study treatment.
- For quinazolin-4(3H)-one and doxorubicin-based arms that include a safety run-in, patients will be evaluable for the safety run-in phase if they have received at least one dose of treatment and completed follow-up safety assessments for at least 1 full 21-day treatment cycle.

**Status**
- The study is currently planned to enroll patients in Asia-Pacific, Europe, and North America.

**REFERENCES**

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