**Background**

- Lung cancer is the second most common cancer worldwide, with an estimated 2.2 million new cases and 1.8 million deaths in 2020. Approximately 80-85% of lung cancers are non-small cell lung cancer (NSCLC).

**Key eligibility criteria**

- **Stage II-III NSCLC**
- Histologically confirmed stage II-III NSCLC
- Aged ≥18 years
- ECOG PS 0 or 1

- This phase 2, randomized, open label, multicenter study aims to evaluate tislelizumab monotherapy and in multiple immunotherapy combinations +/- chemotherapy as neoadjuvant treatment in Chinese patients with resectable NSCLC.

**Methods**

- **Tumor assessment** (by investigator per National Comprehensive Cancer Network (NCCN)).

- **Study Design and Treatments**

  - This phase 2, randomized, open label, multicenter study aims to evaluate tislelizumab monotherapy and in multiple immunotherapy combinations +/- chemotherapy as neoadjuvant treatment in Chinese patients with resectable NSCLC. The phase 2 randomized, open label, multicenter study will include 60 patients randomized 1:1:1:1 into 4 arms divided among 4 treatment combinations.

  - **Arm 1A: Tislelizumab monotherapy**
  - **Arm 1B: Tislelizumab + ociperlimab**
  - **Arm 1C: Tislelizumab + LBL-007**
  - **Arm 2A: Tislelizumab + LBL-007 + histology-specific chemotherrapy**
  - **Arm 2B: Tislelizumab + LBL-007 + histology-specific chemotherrapy**
  - **Arm 2C: Tislelizumab + ociperlimab + chemotherapy**

- **Substudy 1** will include 60 patients

- **Substudy 2** will include 60 patients

- **Study Population**

  - **Key inclusion criteria:**
    - Aged ≥18 years
    - ECOG PS 0 or 1
    - Histologically confirmed stage II–IIIA NSCLC
    - Tumor assessment by investigator per National Comprehensive Cancer Network (NCCN)

  - **Key exclusion criteria:**
    - Prior therapy with an anti-PD-1, anti-PD-L1, or anti-LAG-3 antibody
    - Mixed small cell lung cancer
    - Large cell neuroendocrine carcinoma
    - Epithelial growth factor receptor sensitizing mutations or ALK-rearrangement

**Endpoints**

- **Primary endpoints**
  - OS
  - DFS

- **Secondary endpoints**
  - OS
  - DFS

**Assessments and Endpoints**

- **Tumor assessment (by investigator per RECIST v1.1)** will be performed during screening, after the neoadjuvant treatment phase, and after surgery (3 months post-surgery, then every 12 months for the first 2 years, then annually thereafter)

- **Key exclusion criteria:**
  - Any prior antitumor therapy for current NSCLC

- **Prior therapy with an anti-PD-1, anti-PD-L1, or anti-LAG-3 antibody**

- **Mixed small cell lung cancer**

- **Large cell neuroendocrine carcinoma**

- **Epithelial growth factor receptor sensitizing mutations or ALK-rearrangement**

- **OS**
- **DFS**
- **Response per blinded independent pathology review**
- **Quality of life**
- **Health-related quality of life**

**Figure 2. Study Design**

**Figure 1. Targeting Tumor Cell Antigens**

**Table 1. Study Endpoints**

<table>
<thead>
<tr>
<th>Primary endpoint</th>
<th>OS, DFS</th>
<th>DFS per RECIST v1.1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Secondary endpoint</strong></td>
<td>OS, DFS</td>
<td>DFS per RECIST v1.1</td>
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