Tislelizumab Combined With Chemotherapy as Neoadjuvant Therapy for Potentially Resectable Stage IIIA-IIIB (N2) Squamous Non-small-cell Lung Cancer (TACT)

Jianzhuan Shan*, 1 Zhen Liu, 2 Chengli Du, 2 Yanru Hu, 3 Lingxian Ruan, 4 Xiaodong Tang, 1 Lingjie Wang, 1 Miaoyan Du, 1 Tian Tian, 1 Danlu Jiang, 6 Zhongliang Tu*, 2

1Department of Medical Oncology, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China. 2Department of Thoracic Surgery, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China. 3Department of Medical Affairs, BeGene Beijing Co., Ltd., Beijing, China. 4Department of Radiology, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China. 5Department of Pathology, The First Affiliated Hospital, Zhejiang University School of Medicine, Hangzhou, China. 6Department of Medicine, Burning Rock Biotech, Beijing, China.

This is the first prospective study to test CT-IO in the neoadjuvant setting in potentially resectable stage IIIA-IIIB(N2) squamous non-small-cell lung cancer. Neoadjuvant tislelizumab plus platinum-based doublet chemotherapy could achieve a high MPR rate with manageable toxicity in stage IIIA-IIIB(N2) squamous NSCLC. Ongoing analysis of predictive biomarker on efficacy and safety will be available in the future meeting.

Background
Recently, multiple clinical trials demonstrated neoadjuvant chemotherapy is a promising treatment option for resectable non-small-cell lung cancer (NSCLC). However, there is still limited evidence for using chemomunotherapy as neoadjuvant treatment in potentially resectable stage IIIA-IIIB(N2) squamous NSCLC. TACT(NCT05024263) is a phase II, open label, single arm trial evaluating the efficacy and safety of tislelizumab(Ts) plus chemotherapy(CT) as neoadjuvant treatment for potentially resectable stage IIIA-IIIB(N2) squamous NSCLC.

Methods
Squamous NSCLC Potentially resectable: Stage IIA-IIIB(N2) (8th edition) ECOG 0-1
Neoadjuvant treatment Tislelizumab 200mg N1, Q3W (9-12 cycles) + Alumain paclitaxel 260mg/m²+ Carboplatin AUC 4 IV, Q3W (2-6 cycles)
Adjuvant treatment Tislelizumab 200mg N2, Q3W (2-6 cycles)

Results
• Between September 13, 2021 and May 17, 2022, a total of 35 patients were enrolled at The First Affiliated Hospital, Zhejiang University School of Medicine.
• All patients received neoadjuvant treatment. Patients baseline characteristics were shown in Table 1. Among 35 patients, 32 (91.4%) met surgical criteria and 3 did not meet surgical criteria. R0 resection was achieved in all 32 patients who underwent surgery.

Table 1. Baseline demographics (N=35)

| Age | Median Min. Max. |
| --- | ---: ---: |
| 65 | 46-78 |

EBCG performance status
0 | 30(84.3%) |
1 | 5(15.7%) |

Clinical stage
IA | 19 |
IB | 11 |
IIA | 6 |
IIIB | 8 |

Smoking status
Current or former | 30(85.7%) |
Never | 5(14.3%) |

Duration of operation, minutes, median
Intraoperative blood loss (mL), median
Intraoperative blood loss (mL), median

Table 2. Response Rate

<table>
<thead>
<tr>
<th>Patients (N=32)</th>
<th align="right">Resected N=32</th>
</tr>
</thead>
<tbody>
<tr>
<td>pCR</td>
<td align="right">11(34.4%)</td>
</tr>
<tr>
<td>Complete response</td>
<td align="right">10(31.3%)</td>
</tr>
<tr>
<td>Partial response</td>
<td align="right">10(31.3%)</td>
</tr>
<tr>
<td>Stable disease</td>
<td align="right">3(9.4%)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td align="right">5(15.7%)</td>
</tr>
</tbody>
</table>

Table 3. Surgical detail

<table>
<thead>
<tr>
<th>Nodal downstaging</th>
<th align="right">N3 to N0</th>
<th align="right">N2 to N0</th>
<th align="right">N1 to N0</th>
</tr>
</thead>
<tbody>
<tr>
<td>N3 to N0</td>
<td align="right">12(36.4%)</td>
<td align="right"></td>
<td align="right"></td>
</tr>
<tr>
<td>N2 to N0</td>
<td align="right">15(46.4%)</td>
<td align="right"></td>
<td align="right"></td>
</tr>
<tr>
<td>N1 to N0</td>
<td align="right">17(53.1%)</td>
<td align="right"></td>
<td align="right"></td>
</tr>
</tbody>
</table>

Table 1. Baseline demographics (N=35)

<table>
<thead>
<tr>
<th>Patients (N=32)</th>
<th align="right">Resected N=32</th>
</tr>
</thead>
<tbody>
<tr>
<td>R0 resection, n (%)</td>
<td align="right">32(100%)</td>
</tr>
</tbody>
</table>

Nodal downstaging
N3 to N0 | 12(36.4%) |
N2 to N0 | 15(46.4%) |
N1 to N0 | 17(53.1%) |

Thoracotomy | 7(21.9%) |
Lobectomy | 21(65.6%) |
Bilateral | 26(3.3%) |
Pneumonectomy | 26(3.3%) |

Resection type
Wedge resection | 7(21.9%) |
Lobectomy | 21(65.6%) |
Bilateral | 26(3.3%) |
Pneumonectomy | 26(3.3%) |