A Single-Arm Phase Ib Study of Autologous Cytokine-Induced Killer (CIK) Cell Immunotherapy in Combination with Sintilimab plus Chemotherapy in Patients with Advanced Non-Small-Cell Lung Cancer

Xiubao Ren, Liang Liu, Xinxwei Zhang, Baizhu Ren, Li Zhou, Wanhong Zhang, Runmei Li, Ying Han, Yan Wang, Shuzhan Li, Meng Shen, Jiali Zhang, Weijiao Du.
Tianjin Medical University Cancer Institute and Hospital

BACKGROUND
- Immune checkpoint inhibitors plus chemotherapy has demonstrated significant survival benefits for advanced non-small-cell lung cancer (NSCLC) patients without targetable mutations.
- Autologous cytokine-induced killer (CIK) cell therapy can restore the antitumor immunity to improve the patient outcomes.
- Therefore, a single-center, open-label, phase I/II trial was conducted to explore the efficacy and safety of autologous CIK cell therapy combined with sintilimab (anti-PD-1) plus chemotherapy as 1L treatment in advanced NSCLC patients.

METHOD
Eligible patients would receive platinum-based doublet chemotherapy, sintilimab (200mg) on Day 1, plus intravenous autologous CIK cells (10^6) on Day 14 every 3 weeks (Q3W) for 4 cycles, followed by sintilimab and autologous CIK maintenance until disease progression or unacceptable toxicity.

RESULTS
- From May 2019 to Jun 2020, 16 patients were enrolled.
- Among 13 evaluable patients, the ORR and DOR were 84.6% and 100%, respectively.
- Of the 11 PR patients, 3 (23.1%) were demonstrated CMR (Complete Metabolic Response) by PET-CT.
- Median follow-up was 5.55m (range: 0.63-12.3).
- Median DOR was not reached.

Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>(n=16)</th>
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<tbody>
<tr>
<td>Median age (range), year</td>
<td>62 (40-72)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 14, Female 2</td>
</tr>
<tr>
<td>ECOG performance status</td>
<td>0 3, 1 12</td>
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<tr>
<td>Smoking history</td>
<td>Current/former 12, Never 4</td>
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<tr>
<td>Histology</td>
<td>Squamous cells carcinoma 7, Adenocarcinoma 9</td>
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<tr>
<td>Stage at diagnosis</td>
<td>IIIIC 2, IV 14</td>
</tr>
<tr>
<td>Brain metastases</td>
<td>No 14, Yes 2</td>
</tr>
<tr>
<td>Liver metastases</td>
<td>No 13, Yes 3</td>
</tr>
</tbody>
</table>

Figures
- Figure 1: Study design
- Figure 2: Best of response: Sintilimab + Chemo + CIK (n=13)
- Figure 3: Time to response and duration
- Figure 4: Time to Progression

RESULTS -- Safety
- Adverse events (AEs) occurred in 15 (63.75%) patients, including 4 Grade 3 AEs (12.5%).
- The most common AEs were nausea (12, 75%), anemia (11, 68.75%), and leukopenia (10, 62.5%).
- Immune-related AEs were cardiomyopathy (1, 6.25%) and pneumonia (2, 12.5%); 1 patient had immune-related grade 5 pneumonia.

CONCLUSION
- Autologous CIK cell therapy in combination with sintilimab plus chemotherapy were well tolerated and showed encouraging efficacy.
- Further studies are warranted to confirm these preliminary results.

Disclosure and Acknowledgements
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References

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Corresponding author and E-mail: Xiubao Ren, Ph.D. renxiubao@gmail.com