Efficacy, Safety and Immune Activation with PEGylated human IL-10 (AM0010) in Combination with an anti-PD1 in Advanced NSCLC

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Study Design and Eligibility

AM0010 - Mechanism of Action (Background)

- IL-10 is anti-inflammatory and inhibits the activation of antigen-presenting cells (APC) in the tumor microenvironment.
- PD-L1 expression is induced in NSCLC by IL-10.
- Tumor-antigen specific CD8+ T lymphocytes can be boosted with AM0010 and Pembrolizumab.

Results

- Combination of AM0010 and anti-PD1 was well-tolerated in NSCLC patients.
- No increase or exacerbation of autoimmune toxicities was observed.

Summary of Results

- AM0010 + anti-PD1 was well-tolerated in NSCLC patients.
- No increase or exacerbation of autoimmune toxicities was observed.

Side Effects

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>AM0010 + Pembrolizumab</th>
<th>Pembrolizumab</th>
<th>AM0010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site reaction</td>
<td>1/10 (9.1%)</td>
<td>0/10 (0%</td>
<td>0/10 (0%)</td>
</tr>
<tr>
<td>Hypoalbuminaemia</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
</tr>
<tr>
<td>Increased transaminases</td>
<td>0/10 (0%)</td>
<td>1/10 (10%)</td>
<td>0/10 (0%)</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>4/10 (40%)</td>
<td>2/10 (20%)</td>
<td>1/10 (10%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1/10 (10%)</td>
<td>0/10 (0%)</td>
<td>0/10 (0%)</td>
</tr>
</tbody>
</table>

Contraindicated: Luminex, Activated ≥2 fold; Decreased ≥2 fold; Th17 cytokines (IL-6, IL-17, IL-22).

In this Phase 1b trial, antitumor activity was confirmed by a durable partial response (PR) in a patient with NSCLC expressing PD-L1.

In conclusion, PEGylated human IL-10 (AM0010) in combination with pembrolizumab is well-tolerated and demonstrates a durable antitumor effect in patients with advanced NSCLC. This finding provides a new immunotherapeutic approach for patients with this disease.

References


Contact Information