A Phase II study (TACTI-002) of etnilagimod alpha (a soluble LAG-3 protein) with pembrolizumab in PD-L1 unselected patients with metastatic non-small cell lung (NSCLC) or head and neck carcinoma (HNSCC)

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BACKGROUND

Differential alpha (α) is a soluble LAG-3 protein (does not bind interlukin-10 receptor α) that binds to LAG-3 in the tumor microenvironment (TME) that inhibits T cell response in the TME (TACTI-002 study) in indications for NSCLC (iUPD/iCPD) and OSE (Ovarian) test populations. The stimulation of the dendritic cell network and subsequent T cell response is impaired in NSCLC (82), iUPD/iCPD. Anti-tumor response in combination with pembrolizumab was improved in NSCLC with pretreated pembrolizumab. We therefore evaluated the TACTI-002 study (NCT01635323).

Non-randomized, uncontrolled. Two study phases consisting of three parts:

**Participant Characteristics and Efficacy Results**

<table>
<thead>
<tr>
<th>Stage</th>
<th>N (%): Median age, years</th>
<th>Best response</th>
<th>Tumor control rate</th>
<th>Progression free survival</th>
<th>Adverse events</th>
<th><em>Best responder± (ORR) (G3-4) pembrolizumab infusions.</em></th>
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<tr>
<td><strong>Stage 1</strong></td>
<td>22 (79)</td>
<td>Partial Response (44%)</td>
<td>Stable Disease (30%)</td>
<td>16 (73%)</td>
<td>24 (61%)</td>
<td>15%</td>
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<tr>
<td><strong>Stage 2</strong></td>
<td>21 (78)</td>
<td>Stable Disease (38%)</td>
<td>Progressive (59%)</td>
<td>17 (85%)</td>
<td>21 (67%)</td>
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**Tumor control rate**

- **Stage 1 (N=22):** 79%
- **Stage 2 (N=21):** 78%

**Progression free survival**

- **Stage 1 (N=22):** 163.6 weeks
- **Stage 2 (N=21):** 162.9 weeks

**Adverse events**

- **Stage 1 (N=22):** 15%
- **Stage 2 (N=21):** 14%

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**Part C** - 2nd line HNSCC Stage 1 & 2

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EULAR standard therapy, placebo

**BEST LINE: TACTI-O02**

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