**IMscin001: Phase Ib Dose-Finding Study of Subcutaneous Atezolizumab in Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)**

**Methods**

**Study Design**

Atezolizumab (TECENTRIQ, F. Hoffman-La Roche Ltd.) is a programmed death-ligand 1 (PD-L1) immune checkpoint inhibitor. The cycle 1 Ctrough values in Cohort 2 (1200 mg atezolizumab SC q2w) were consistent with those in the IMpassion130 trial (NCT0242589119; 840 mg atezolizumab IV q2w). The median cycle 1 AUC in Cohort 1 was 1914 µg • d/mL compared with previous IV data.

**Safety**

None of the patients had a cycle 1 Ctrough concentration below the target concentration of 6 µg/mL, which is the predicted target concentration assumed to provide 95% efficiency (particularly in the context of disruption during a pandemic), the potential for fewer adverse events, and the potential for fewer adverse events and decreased costs of medical use.

**Results**

**Study Population**

In Part 1 of this study, none of the 67 patients had a cycle 1 Ctrough concentration below the target concentration of 6 µg/mL, which is the predicted target concentration assumed to provide 95% efficiency (particularly in the context of disruption during a pandemic), the potential for fewer adverse events, and the potential for fewer adverse events and decreased costs of medical use. Safety was comparable across cohorts, and no clinically significant difference in the safety profile was observed.

**Atezolizumab SC PK**

- Atezolizumab SC PK parameters, following a single SC dose, are shown in Table 1.

**Comparison with previous IV data**

Comparison with previous IV data

Table 4: Safety Summary

- In Cohort 1, the most common AEs were rash, fatigue, nausea, and pruritus.

**Conclusions**

- These results support further development of atezolizumab SC for Part 3 of IMscin01, in combination with chemotherapy.

**Acknowledgments**

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**References**

- Mauricio Burotto, Enriqueta Felip, Zanete Zvirbule, Luis A. Herraez-Baranda, Pascal Chanu, Smita Kshirsagar, Vidya Maiya, Emanuela Pozzi, Eleonora Respiciu

**Image**

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**Table 1: Baseline demographics**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male</th>
<th>Female</th>
<th>N</th>
<th>Ref, IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-61</td>
<td>32</td>
<td>35</td>
<td>67</td>
<td>39</td>
</tr>
<tr>
<td>62-75</td>
<td>15</td>
<td>12</td>
<td>27</td>
<td>17</td>
</tr>
<tr>
<td>≥ 76</td>
<td>10</td>
<td>4</td>
<td>14</td>
<td>4</td>
</tr>
</tbody>
</table>

**Table 2: Summary statistics for area under the concentration-time curve (AUC) and maximum serum concentration (Cmax) following a single SC dose of atezolizumab**

<table>
<thead>
<tr>
<th>Cohort</th>
<th>AUC0-14 (µg • d/mL)</th>
<th>Cmax (µg/mL)</th>
<th>Tmax (day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>128,000 (63.0)</td>
<td>246</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>246,000 (661)</td>
<td>246</td>
<td>0.0</td>
</tr>
<tr>
<td>3</td>
<td>410,000 (621)</td>
<td>410</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Figure 1: Atezolizumab Part 1 Study Design**

- Cycle 1 Ctrough values in Cohort 2 (1200 mg atezolizumab SC q2w) were consistent with those in the IMpassion130 trial (NCT0242589119; 840 mg atezolizumab IV q2w).

**Figure 2: Cycle 1 atezolizumab SC mean concentration (µg/mL)**

- Atezolizumab SC PK parameters, following a single SC dose, are shown in Table 1.

**Figure 3: Cycle 1 AUC0-14 and Cmax values for atezolizumab SC compared with previous IV data**

- In Part 1 of this study, none of the 67 patients had a cycle 1 Ctrough concentration below the target concentration of 6 µg/mL, which is the predicted target concentration assumed to provide 95% efficiency (particularly in the context of disruption during a pandemic), the potential for fewer adverse events, and the potential for fewer adverse events and decreased costs of medical use. Safety was comparable across cohorts, and no clinically significant difference in the safety profile was observed.