### Development of a highly sensitive assay to quantitate circulating thymic stromal lymphopoietin (TSLP) levels in blood

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#### Introduction

- Thymic stromal lymphopoietin (TSLP) is an epithelial cytokine, released in response to cellular damage or inflammation, which activates multiple cell types and downstream inflammatory pathways associated with asthma and other allergic diseases.
- TSLP is a human monoclonal antibody that specifically blocks TSLP from interacting with its receptor complex and is in clinical trials for the treatment of asthma.

#### Methods

- An electrochemiluminescence immunoassay (ECLIA) was developed to quantify circulating TSLP levels.

#### Results

**Novel S-PLEX assay parameters**
- The novel S-PLEX assay was able to detect TSLP in all samples.
- Serum levels of TSLP were higher in patients with atopic dermatitis (AD) than in healthy individuals.
- The S-PLEX assay was able to detect lower levels of TSLP than the commercially available assays.

#### Conclusions

- The S-PLEX assay had a higher sensitivity and a better LLOD than commercially available assays.
- The novel S-PLEX assay was able to detect TSLP in all samples tested, which was lower than those detected using commercially available assays.
- Serum levels of TSLP were higher in patients with severe AD than in healthy individuals.
- These findings suggest that S. aureus colonization has been correlated with greater AD severity. It is not excluded that S. aureus colonization may contribute to the elevated serum levels of TSLP observed in patients with AD.

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*Table 1. Development and characterization of a highly sensitive assay to quantify circulating thymic stromal lymphopoietin (TSLP)*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>S-PLEX assay (n = 35)</th>
<th>U-PLEX assay (n = 38)</th>
<th>Quantikine assay (n = 35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOD, pg/mL</td>
<td>13.2</td>
<td>60.0</td>
<td>Not provided</td>
</tr>
<tr>
<td>LLOD, pg/mL</td>
<td>1.3</td>
<td>8.6</td>
<td>Not provided</td>
</tr>
<tr>
<td>Range of detection, pg/mL</td>
<td>19–2,392,968</td>
<td>60–30,000</td>
<td>300–200,000–1,500,000–5,000,000</td>
</tr>
<tr>
<td>LOD, lower bound of detection, pg/mL</td>
<td>0.36</td>
<td>0.26</td>
<td>Not provided</td>
</tr>
<tr>
<td>LLOD, lower bound of detection, pg/mL</td>
<td>0.09</td>
<td>0.06</td>
<td>Not provided</td>
</tr>
</tbody>
</table>

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*Figure 1. Serum levels of TSLP in healthy individuals without atopic skin disease and patients with AD.

Figure 2. Serum levels of TSLP in healthy individuals without atopic skin disease and patients with mild-to-moderate AD or severe-to-very-severe AD.

Figure 3. Serum levels of TSLP in healthy individuals without atopic skin disease and patients with AD who were negative or positive for S. aureus colonization.*