HIGHLIGHTS FROM ULTIMMA-1 AND ULTIMMA-2

-- PIVOTAL STUDIES AS PUBLISHED IN THE LANCET ASSESSING THE --

EFFICACY & SAFETY OF RISANKIZUMAB

IN ADULTS WITH MODERATE TO SEVERE PLACe PSORIASIS VS USTEKINUMAB & PLACEBO

Active Comparator: The ustekinumab used as a biologic active control in ultIMMa-1 and ultIMMa-2 was sourced from the European Union. Comparability between non-US-approved ustekinumab and US-approved ustekinumab has not been established.

INDICATION
SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

SAFETY CONSIDERATIONS
- SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Avoid use of live vaccines in SKYRIZI patients.

Please see additional Important Safety Information on last page.
Please see full Prescribing Information.
ULTIMMA-1 & 2 STUDY DESIGNS¹

**BASELINE CHARACTERISTICS**

<table>
<thead>
<tr>
<th></th>
<th>SKYRIZI (n=294)</th>
<th>UST (n=100)</th>
<th>PBO (n=102)</th>
<th>SKYRIZI (n=294)</th>
<th>UST (n=99)</th>
<th>PBO (n=88)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age, years</td>
<td>48</td>
<td>47</td>
<td>49</td>
<td>46</td>
<td>49</td>
<td>46</td>
</tr>
<tr>
<td>Mean weight, kg</td>
<td>88</td>
<td>89</td>
<td>89</td>
<td>89</td>
<td>89</td>
<td>89</td>
</tr>
<tr>
<td><strong>Disease Severity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean BSA involvement</td>
<td>26</td>
<td>25</td>
<td>28</td>
<td>26</td>
<td>21</td>
<td>24</td>
</tr>
<tr>
<td>Mean PASI</td>
<td>21</td>
<td>20</td>
<td>21</td>
<td>21</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td><strong>Biologic Experience</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Prior biologic use, %</td>
<td>34</td>
<td>30</td>
<td>39</td>
<td>40</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>Prior TNFi, %</td>
<td>22</td>
<td>19</td>
<td>22</td>
<td>23</td>
<td>24</td>
<td>27</td>
</tr>
<tr>
<td>Prior non-TNFi, %</td>
<td>18</td>
<td>17</td>
<td>24</td>
<td>26</td>
<td>31</td>
<td>26</td>
</tr>
</tbody>
</table>

**ACTIVE COMPARATOR**

The ustekinumab used as a biologic active control in ultIMMa-1 and ultIMMa-2 was sourced from the European Union. Comparability between non–US-approved ustekinumab and US-approved ustekinumab has not been established.

**CO-PRIMARY ENDPOINTS¹,²**

- **PASI 90 at Week 16¹**
  - SKYRIZI: 75% (229/304)
  - UST: 75% (220/294)
  - PLACEBO: 5% (14/282)

- **sPGA 0/1 at Week 16¹**
  - SKYRIZI: 88% (267/304)
  - UST: 84% (246/294)
  - PLACEBO: 8% (18/212)

**SAFETY CONSIDERATIONS³**

- SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Avoid use of live vaccines in SKYRIZI patients.

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**Efficacy in ultIMMa-1 & 2¹**

**PASI 90 achieved by 81% of patients at 1 year in ultIMMa-2¹**

**PASI 100 achieved by 60% of patients at 1 year in ultIMMa-2¹**

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**ULTIMMA-1 PASI 90 RESULTS¹:**

- WEEK 16: SKYRIZI 75%, ustekinumab 42%, placebo 5% (P=0.0001); WEEK 52: SKYRIZI 82%, ustekinumab 44% (P=0.0001)

**ULTIMMA-1 PASI 100 RESULTS¹:**

- WEEK 16: SKYRIZI 36%, ustekinumab 12%, placebo 0% (P=0.001); WEEK 52: SKYRIZI 58%, ustekinumab 21% (P=0.001)
### WELL-STUDIED SAFETY PROFILE

#### ADVERSE EVENTS AT WEEK 16<sup>2-4</sup> (occurring at ≥1%)

<table>
<thead>
<tr>
<th></th>
<th>ANY SERIOUS ADVERSE EVENT</th>
<th>UPPER RESPIRATORY INFECTIONS&lt;sup&gt;1&lt;/sup&gt;</th>
<th>HEADACHE&lt;sup&gt;1&lt;/sup&gt;</th>
<th>FATIGUE&lt;sup&gt;1&lt;/sup&gt;</th>
<th>INJECTION SITE REACTIONS&lt;sup&gt;1&lt;/sup&gt;</th>
<th>TINEA INFECTIONS&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>SKYRIZI&lt;sup&gt;a&lt;/sup&gt; (risankizumab)&lt;sup&gt;a&lt;/sup&gt; (n=1306)</td>
<td>2.4%</td>
<td>13.0%</td>
<td>3.5%</td>
<td>2.5%</td>
<td>1.5%</td>
<td>1.1%</td>
</tr>
<tr>
<td>USTEKINUMAB&lt;sup&gt;b&lt;/sup&gt; (n=239)</td>
<td>5.0%</td>
<td>11.7%</td>
<td>3.8%</td>
<td>2.9%</td>
<td>3.8%</td>
<td>0.4%</td>
</tr>
<tr>
<td>PLACEBO&lt;sup&gt;c&lt;/sup&gt; (n=300)</td>
<td>4.0%</td>
<td>9.7%</td>
<td>2.0%</td>
<td>1.0%</td>
<td>1.0%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

*SafETY THROUGH 52 WEEKS:*

Frequency of adverse reactions was similar to the safety profile observed during the first 16 weeks.<sup>2</sup>

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### IMPORTANT SAFETY INFORMATION AND INDICATION<sup>2</sup>

#### INDICATION

SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

#### INFECTION

- **SKYRIZI<sup>a</sup>** (risankizumab-rzza) may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it resolves or is adequately treated.
- In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

#### PRE-TREATMENT EVALUATION FOR TUBERCULOSIS (TB)

- Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

#### IMMUNIZATIONS

- Prior to initiating SKYRIZI, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with SKYRIZI.

#### ADVERSE REACTIONS

- Most common (≥1%) adverse reactions associated with SKYRIZI include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

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Please see full Prescribing Information.

### References:

2. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc.