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 PLAQUE 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.
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Please see additional Important Safety Information on last page. Please see full Prescribing Information.
WELL-STUDIED SAFETY PROFILE

ADVERSE EVENTS AT WEEK 16

(occurring at ≥1%)

<table>
<thead>
<tr>
<th></th>
<th>ANY SERIOUS ADVERSE EVENT</th>
<th>UPPER RESPIRATORY INFECTIONS</th>
<th>HEADACHE</th>
<th>FATIGUE</th>
<th>INJECTION SITE REACTIONS</th>
<th>TINEA INFECTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SKYRIZI (risankizumab)*</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>(n=1306)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>USTEKINUMAB b</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>(n=239)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLACEBO c</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>
<tr>
<td>(n=300)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Includes data from ultIMMa-1, ultIMMa-2, IMMhance, and IMMvent studies; bIncludes data from ultIMMa-1, ultIMMa-2, and one phase 2 study; Includes data from ultIMMa-1, ultIMMa-2, and IMMhance studies; dIncludes: respiratory tract infection (viral, bacterial or unspecified), sinusitis (including acute), rhinitis, nasopharyngitis, pharyngitis (including viral), tonsillitis; eIncludes: headache, tension headache, sinus headache, cervicogenic headache; fIncludes: fatigue, asthenia; gIncludes: injection site bruising, erythema, extravasation, hematoma, hemorrhage, infection, inflammation, irritation, pain, pruritus, reaction, swelling, warmth; hIncludes: tinea pedis, tinea cruris, body tinea, tinea versicolor, tinea manuum, tinea infection, onychomycosis.

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IMPORTANT SAFETY INFORMATION AND INDICATION

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® (risankizumab-rzaa) 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.

Please see full Prescribing Information.

References: