Deucravacitinib long-term efficacy in Week 16 placebo crossovers: 3-year results from the POETYK Pso program

Mark Lebowohl, 1 Richard B. Warren, 1-3 Shinichi Imafuku, 1 Jerry Bagel, 1 April W. Armstrong, 1 Thierry Passeron, 1 Subhashis Banerjee, 2 Renata M. Kisa, 2 Eleni Vritzali, 1 Matthew J. Colombo, 1 Thomas Schramm, 1 Kim Hoyt, 1 Diamant Thaci, 1 and Andrew Blauvelt 1,4

1 Icahn School of Medicine at Mount Sinai, New York, NY, USA; 2 Dermatology Centre, North Shore University Hospital, Manhasset, NY, USA; 3 Department of Medicine, Icahn School of Medicine, Mount Sinai, New York, NY, USA; 4 Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; 5 Oregon Medical Research Center, Portland, OR, USA

Synopsis

Deucravacitinib is a first-in-class oral, selective, allosteric TYK2 inhibitor, approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are intolerant or inappropriate for systemic therapy. Deucravacitinib is selective for TYK2 versus JAK2 and other JAKs, with ≥2000-fold greater selectivity for TYK2 vs JAK2.

• Deucravacitinib reduces inflammation in the epidermis of human skin in vitro and in vivo.
• Deucravacitinib significantly reduces disease activity in comparison to placebo in patients with moderate-to-severe plaque psoriasis.

Objective

To examine the long-term clinical efficacy of deucravacitinib in patients who crossed over from placebo to deucravacitinib at Week 14 in both POETYK Pso-1 and Pso-2 and went on to enroll in the POETYK LTE study.

Methods

Study designs

• In POETYK Pso-1 (NCT02617417) and POETYK Pso-2 (NCT02811781), eligible patients were randomized 1:1 to oral placebo, deucravacitinib 1 mg once daily (QD1), or 3 mg once daily (QD3) (Figure 2).
• Patients randomized to placebo at baseline crossed over to deucravacitinib 1 mg QD at Week 14 in both trials.
• At Week 24, patients could enter the POETYK LTE (NCT03345549) trial and receive open-label deucravacitinib 1 mg QD.

Results

Patients

• Baseline demographics and disease characteristics of patients who crossed over from placebo to deucravacitinib at Week 14 in both POETYK Pso-1 and Pso-2 and went on to enroll in the POETYK LTE study are shown in Table 1.

Table 1. Baseline patient demographics and disease characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>POETYK Pso-1</th>
<th>POETYK Pso-2</th>
<th>POETYK LTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>47 (11.8)</td>
<td>48 (11.3)</td>
<td>49 (11.6)</td>
</tr>
<tr>
<td>Weight, mean (SD), kg</td>
<td>80 (15.9)</td>
<td>80 (15.9)</td>
<td>80 (15.9)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>61 (15.5)</td>
<td>61 (15.5)</td>
<td>61 (15.5)</td>
</tr>
<tr>
<td>Body mass index, mean (SD)</td>
<td>25 (6.3)</td>
<td>25 (6.3)</td>
<td>25 (6.3)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td>100 (25.0)</td>
<td>100 (25.0)</td>
<td>100 (25.0)</td>
</tr>
<tr>
<td>Age at disease onset, mean (SD), y</td>
<td>49 (11.3)</td>
<td>49 (11.3)</td>
<td>49 (11.3)</td>
</tr>
<tr>
<td>Disease duration, mean (SD), y</td>
<td>19 (6.0)</td>
<td>19 (6.0)</td>
<td>19 (6.0)</td>
</tr>
<tr>
<td>PASI score, mean (SD)</td>
<td>25 (0.8)</td>
<td>25 (0.8)</td>
<td>25 (0.8)</td>
</tr>
<tr>
<td>PGA score, mean (SD)</td>
<td>81 (15.4)</td>
<td>81 (15.4)</td>
<td>81 (15.4)</td>
</tr>
<tr>
<td>DLQI score, mean (SD)</td>
<td>12 (6.8)</td>
<td>12 (6.8)</td>
<td>12 (6.8)</td>
</tr>
<tr>
<td>BSA involvement, mean, %</td>
<td>9.0 (10.0)</td>
<td>9.0 (10.0)</td>
<td>9.0 (10.0)</td>
</tr>
<tr>
<td>Prior systemic therapy, n (%)</td>
<td>15 (6.3)</td>
<td>15 (6.3)</td>
<td>15 (6.3)</td>
</tr>
<tr>
<td>Previous treatment, n (%)</td>
<td>15 (6.3)</td>
<td>15 (6.3)</td>
<td>15 (6.3)</td>
</tr>
</tbody>
</table>

Conclusions

• Once-daily oral deucravacitinib is effective in patients who have previously received placebo or have been unable to tolerate systemic therapies.
• Deucravacitinib is well tolerated in patients with moderate-to-severe plaque psoriasis for up to 3 years.
• Deucravacitinib maintains disease remission and improvement for up to 3 years in patients who crossed over from placebo to deucravacitinib at Week 14 in both POETYK Pso-1 and Pso-2.

References