Deucravacitinib long-term safety in plaque psoriasis: 2-year results from the phase 3 POETYK PSO program

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Background

- Tyro3, Kit, and Fms-like tyrosine kinase 3 (TYK3) are intracellular mediators that regulate cytokine signaling in regulatory T cells and in psoriasis pathogenesis
- Deucravacitinib is a novel oral agent that selectively inhibits TYK2 via an allosteric mechanism, uniquely binding to the regulatory domain rather than to the more conserved catalytic domain where Janus kinase (JAK) 1/2/3 inhibition binds

Methods

- Study design: The study design for POETYK PSO-1, PSO-2, and the LTE is summarized in Figure 2
- Patients meeting the following key criteria were eligible to enroll in one of the parent studies:
  - Age ≥18 years
  - Diagnosis of moderate to severe plaque psoriasis
  - Baseline BSA ≥ 10% (PSO-1, PSO-2) or ≥ 5% (LTE)
- Deucravacitinib 6 mg once daily
- Patients completing the PSO-1 and PSO-2 trials could enroll in the POETYK long-term extension (LTE) trial and receive open-label deucravacitinib 6 mg once daily

Objective

- To characterize the safety and tolerability of long-term use of deucravacitinib in patients with moderate to severe plaque psoriasis

Results

Patients

- A total of 1519 patients received ≥1 dose of deucravacitinib during the parent trials and the LTE, including 1346 patients in PSO-1/PSO-2 and 121 patients in the LTE
- Deucravacitinib was long-term used in the peak of the COVID-19 pandemic
- Baseline patient demographics and disease characteristics for the overall population are presented in Table 1

Exposure

- Exposure data at 1 year and 2 years are presented in Table 2
- The median exposure to deucravacitinib was 892 days
- Exposure during Weeks 0–52 of PSO-1/PSO-2 was 96.0 patient-years (PY), with an additional 1515.0 PY of exposure during the LTE
- There were 179 patients with ≥1 year (52 weeks) of continuous exposure and 54 patients with ≥2 years (104 weeks) of continuous exposure

Table 1. Baseline patient demographics and disease characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
<th>N (%)</th>
</tr>
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<tbody>
<tr>
<td>Age (years), median (IQR)</td>
<td>47 (42, 52)</td>
<td>47 (42, 52)</td>
</tr>
<tr>
<td>Gender, male/female</td>
<td>970 (64.0)</td>
<td>1077 (79.9)</td>
</tr>
<tr>
<td>Race, non-Hispanic/Hispanic</td>
<td>1314 (86.4)</td>
<td>1514 (11.8)</td>
</tr>
<tr>
<td>Body mass index (BMI), kg/m²</td>
<td>30.8 (27.3, 34.5)</td>
<td>30.1 (27.0, 33.6)</td>
</tr>
<tr>
<td>Prior treatment duration, months</td>
<td>20.8 (18.1, 23.0)</td>
<td>20.8 (18.1, 23.0)</td>
</tr>
<tr>
<td>Prior treatment (n = 121)</td>
<td>221 (79.7)</td>
<td>221 (79.7)</td>
</tr>
<tr>
<td>Prior treatment exposure (n = 121)</td>
<td>221 (79.7)</td>
<td>221 (79.7)</td>
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Table 2. Extent of exposure to deucravacitinib

<table>
<thead>
<tr>
<th>Year</th>
<th>1 year (%)</th>
<th>2 years (%)</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>N = 1519</td>
<td>N = 1519</td>
</tr>
<tr>
<td>N of patients exposed</td>
<td>1519 (100)</td>
<td>1519 (100)</td>
</tr>
<tr>
<td>N of patient-years of exposure</td>
<td>1,201 (100)</td>
<td>1,201 (100)</td>
</tr>
<tr>
<td>N of patient-months of exposure</td>
<td>5,496 (100)</td>
<td>5,496 (100)</td>
</tr>
<tr>
<td>N of patient-weeks of exposure</td>
<td>40,776 (100)</td>
<td>40,776 (100)</td>
</tr>
</tbody>
</table>

Conclusions

Overall, the 2-year safety profile of deucravacitinib was consistent with Weeks 0–52 of the POETYK PSO-1 and PSO-2 trials, and there were no emerging safety signals

- The severity of AEs continued to be predominantly mild or moderate, and the incidence of SAEs and AEs leading to discontinuation remained low-up to 2 years
- The most common AEs (≥5% of patients) continued to be nausea, upper respiratory tract infections, diarrhea, arthralgia, headache, and COVID-19
- Utilize most other previous phase 3 trials, the POETYK studies were conducted in the context of the global COVID-19 pandemic, and COVID-19 was therefore one of the most common AEs
- The overall incidence rates of COVID-19 infection and COVID-19-related hospitalization and death were consistent with background epidemiological rates
- AEs were predominantly mild or moderate in severity
- An additional 8 deaths were reported in the LTE up to 2 years
- AEs were predominantly mild or moderate in severity
- The overall malignancy incidence rate was largely in line with POETYK PSO-1 and PSO-2 and background rates
- There was a low incidence of melphalan and YTEs

References

- RBW: 1

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Disclosures

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