# Deucravacitinib in moderate to severe plaque psoriasis: liver transaminase results from the phase 3 POETYK PSO program


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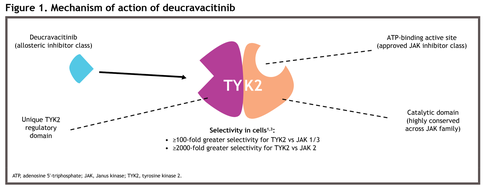
## Synopsis

- Tyrosine kinase 2 (TYK2) is essential to intracellular signaling of cytokines (interleukin-23 and Type I interferons) involved in psoriasis pathogenesis[1] (**Figure 1**)
- Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy[2]

**Figure 1. Mechanism of action of deucravacitinib**




ATP, adenosine 5′-triphosphate; JAK, Janus kinase; TYK2, tyrosine kinase 2.

- In two phase 3 pivotal trials in patients with moderate to severe plaque psoriasis, deucravacitinib demonstrated a robust safety and efficacy profile, including superiority to placebo and apremilast[4,5]
- Deucravacitinib treatment did not result in clinically relevant mean changes over time across multiple laboratory parameters, including in measures of liver transaminases[6]
  - Mean alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels remained unchanged and within normal limits over Weeks 0-16[1]
  - Increases in liver transaminases have been observed with Janus kinase 1/2/3 inhibitors in patients with autoimmune diseases, including plaque psoriasis[7]
- However, increases ≥3× the upper limit of normal (ULN) in ALT and AST were observed over 16 weeks in individual patients[2]
  - ALT elevations ≥3× ULN were reported in 9 patients (3.6/100 person-years [PY]) treated with deucravacitinib and in 2 patients (1.6/100 PY) receiving placebo who did not have ALT elevation at baseline
  - AST elevations ≥3× ULN were reported in 13 patients (5.2/100 PY) treated with deucravacitinib and in 2 patients (1.6/100 PY) receiving placebo

## Objective

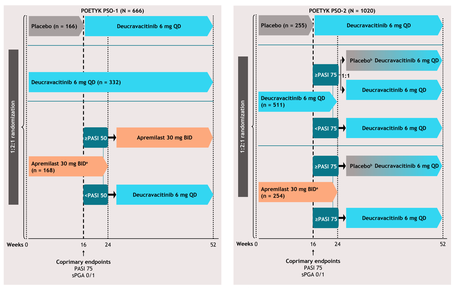
- To assess laboratory measures of liver function in the POETYK PSO-1 and PSO-2 trials, including changes over 52 weeks in patients who experienced an elevation ≥3× ULN for ALT or AST in the first 16 weeks of treatment

## Methods

### Study designs

- POETYK PSO-1 and PSO-2 were 52-week, multinational, phase 3, double-blind, randomized, placebo- and active comparator-controlled trials (**Figure 2**)
- Patients with moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] ≥12, static Physician's Global Assessment [sPGA] ≥3, body surface area involvement ≥10%) were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily during Weeks 0-16
  - Patients receiving placebo crossed over to deucravacitinib at Week 16

**Figure 2. POETYK PSO-1 and PSO-2 study designs**




From Armstrong AW, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trial. *J Am Acad Dermatol*. 2023;88:29-39.This work is licensed under a Creative Commons Attribution License (CC BY-NC-ND 4.0). https://creativecommons.org/licenses/by-nc-nd/4.0/.




From Strober B, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, phase 3 POETYK PSO-2 trial. *J Am Acad Dermatol*. 2023;88:40-51. This work is licensed under a Creative Commons Attribution License (CC BY-NC-ND 4.0). https://creativecommons.org/licenses/by-nc-nd/4.0/.

[a]Apremilast was titrated from 10 mg QD to 30 mg BID over the first 5 days of dosing.
[b]Upon relapse (≥50% loss of Week 24 PASI percentage improvement from baseline), patients were to be switched to deucravacitinib 6 mg QD.
BID, twice daily; PASI, Psoriasis Area and Severity Index; PASI 50, ≥50% reduction from baseline in PASI; PASI 75, ≥75% reduction from baseline in PASI; QD, once daily; sPGA 0/1, static Physician's Global Assessment of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline.

### Post hoc analysis of changes in liver function

- POETYK PSO-1 and PSO-2 data were pooled by treatment group
- ALT and AST elevations are presented as:
  - Events classified as adverse events (AEs) and AEs leading to treatment discontinuation
  - Shifts from baseline to maximum grade (based on the Common Terminology Criteria for Adverse Events [CTCAE] version 5) over Weeks 0-16
  - Maximum elevations over Weeks 0-16 and Weeks 0-52
  - Patient-level data for patients who experienced an elevation ≥3× ULN during Weeks 0-16

## Results

### Patient population

- This analysis included 666 and 1020 patients randomized in POETYK PSO-1 and PSO-2, respectively

### AEs related to liver abnormalities

- The frequencies and exposure-adjusted incidence rates for "ALT elevation" and "AST elevation" reported as AEs were higher in placebo patients vs patients treated with deucravacitinib or apremilast (**Table 1**)
- There was also 1 event of "hepatic function abnormal" (including ALT and AST elevations ≥3× ULN) in a deucravacitinib-treated patient and 1 event of "liver function test abnormal" (including ALT elevation ≥3× ULN) in a placebo patient
- One patient in each treatment group discontinued in the first 16 weeks because of an ALT- or AST-related AE, including the events of "hepatic function abnormal" and "liver function test abnormal"
- There were no cases of drug-induced liver injury

**Table 1. Liver abnormalities reported as AEs, Weeks 0-16 and Weeks 0-52**

| Preferred term | POETYK PSO-1 + PSO-2, Weeks 0-16 | | | POETYK PSO-1 + PSO-2, Weeks 0-52 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Placebo (n = 419) | Deucravacitinib (n = 842) | Apremilast (n = 422) | Placebo (n = 666) | | | Deucravacitinib (n = 1364) | | | Apremilast (n = 422) | | |
| | n (%) | n (%) | n (%) | n (%) | Total PY | IR/ 100 PY | n (%) | Total PY | IR/ 100 PY | n (%) | Total PY | IR/ 100 PY |
| ALT increased | 3 (0.7) | 2 (0.2) | 0 | 7 (1.1) | 247.8 | 2.8 | 10 (0.7) | 982.0 | 1.0 | 2 (0.5) | 225.9 | 0.9 |
| AST increased | 2 (0.5) | 3 (0.4) | 1 (0.2)[a] | 3 (0.5) | 249.2 | 1.2 | 7 (0.5) | 982.3 | 0.7 | 1 (0.2)[a] | 226.4 | 0.4 |
| Hepatic function abnormal | 0 | 1 (0.1)[b] | 0 | 0 | 0 | – | 1 (0.1)[b] | 986.6 | 0.1 | 0 | 0 | – |
| Liver function test abnormal | 1 (0.2)[c] | 0 | 0 | 1 (0.2)[c] | 249.9 | 0.4 | 0 | – | – | 0 | – | – |

Shading indicates events that led to treatment discontinuation.
[a]Patient with no reported medical history and baseline ALT 58 U/L (>1× ULN) and AST 33 U/L discontinued treatment on Day 18 due to increased CPK and increased AST. Values at the time of discontinuation were CPK 11,878 U/L (grade 4; reference range, 39-308 U/L), ALT 117 U/L (>2× ULN), and AST 226 U/L (>5× ULN). All values returned to within baseline range on Day 53.
[b]Patient with a relevant history of fatty liver and baseline ALT 110 U/L (>2× ULN), AST 80 U/L (>2× ULN), and bilirubin 0.9 mg/dL discontinued treatment on Day 59 due to "hepatic function abnormal." Bilirubin levels ranged from 0.9-2.0 mg/dL (reference range, 0-1.2 mg/dL) prior to the reported AE. Values on Day 58 were: ALT 119 U/L (>2× ULN), AST 119 U/L (>3× ULN), and bilirubin 4.2 mg/dL (>3× ULN). The event resolved on Day 91.
[c]Patient with a relevant history of fatty liver, increased liver function tests, and screening ALT 73 U/L (>1× ULN) and AST 44 U/L (>1× ULN) discontinued treatment on Day 2 due to "liver function test abnormal." Values on Day 1 were: ALT 387 U/L (>5× ULN) and AST 177 U/L (>3× ULN). Values returned to within screening range on Day 36.
AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CPK, creatine phosphokinase; IR, incidence rate; PY, person-years; ULN, upper limit of normal.

### Shifts in CTCAE grade

- Definitions of CTCAE grades for increased ALT and increased AST are defined in **Table 2**
- Across treatment arms, maximum increases from baseline in ALT and AST rarely exceeded 1 CTCAE grade during Weeks 0-16 (**Table 3**)
  - Shifts of 1 grade from baseline:
    - ALT: placebo, 11.4%; deucravacitinib, 11.3%; apremilast, 14.6%
    - AST: placebo, 9.4%; deucravacitinib, 8.6%; apremilast, 6.7%
  - Shifts of ≥2 grades from baseline:
    - ALT: placebo, 0%; deucravacitinib, 0.4%; apremilast, 0.5%
    - AST: placebo, 0%; deucravacitinib, 0.5%; apremilast, 0.5%

**Table 2. Definitions of CTCAE grades for ALT and AST elevations**

| Laboratory parameter | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|---|---|---|---|
| ALT | • ULN-3× ULN if baseline normal<br>• 1.5×-3× baseline if baseline abnormal | • >3×-5× ULN if baseline normal<br>• >3×-5× baseline if baseline abnormal | • >5×-20× ULN if baseline normal<br>• >5×-20× baseline if baseline abnormal | • >20× ULN if baseline normal<br>• >20× baseline if baseline abnormal |
| AST | • ULN-3× ULN if baseline normal<br>• 1.5×-3× baseline if baseline abnormal | • >3×-5× ULN if baseline normal<br>• >3×-5× baseline if baseline abnormal | • >5×-20× ULN if baseline normal<br>• >5×-20× baseline if baseline abnormal | • >20× ULN if baseline normal<br>• >20× baseline if baseline abnormal |

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CTCAE, Common Terminology Criteria for Adverse Events; ULN, upper limit of normal.

**Table 3. Shifts in transaminase elevations from baseline during Weeks 0-16 by CTCAE grade**

| CTCAE term, n (%) | BL grade | POETYK PSO-1 and PSO-2 | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Placebo | | | | | Deucravacitinib 6 mg QD | | | | | Apremilast 30 mg BID | | | | |
| | | Maximum grade (Weeks 0-16) | | | | | Maximum grade (Weeks 0-16) | | | | | Maximum grade (Weeks 0-16) | | | | |
| | | 0 | 1 | 2 | 3 | 4 | 0 | 1 | 2 | 3 | 4 | 0 | 1 | 2 | 3 | 4 |
| ALT Increased | | n = 413 | | | | | n = 833 | | | | | n = 419 | | | | |
| | 0 | 297 (86.3) | 47 (13.7) | 0 | 0 | 0 | 579 (85.0) | 92 (13.6) | 3 (0.4) | 0 | 0 | 287 (82.0) | 61 (17.4) | 2 (0.6) | 0 | 0 |
| | 1 | 55 (87.3) | 8 (12.7) | 0 | 0 | 0 | 143 (89.9) | 14 (8.8) | 2 (1.3) | 0 | 0 | 64 (94.1) | 4 (5.9) | 0 | 0 | 0 |
| | 2 | 3 (75.0) | 1 (25.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (100) | 0 | 0 | 0 | 0 |
| | 3 | 2 (100) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| AST Increased | | n = 413 | | | | | n = 833 | | | | | n = 419 | | | | |
| | 0 | 342 (90.0) | 38 (10.0) | 0 | 0 | 0 | 687 (90.4) | 69 (9.1) | 3 (0.4) | 1 (0.1) | 0 | 344 (92.0) | 28 (7.5) | 1 (0.3) | 1 (0.3) | 0 |
| | 1 | 27 (90.0) | 2 (6.7) | 1 (3.3) | 0 | 0 | 60 (82.2) | 10 (13.7) | 3 (4.1) | 0 | 0 | 64 (97.8) | 1 (2.2) | 0 | 0 | 0 |
| | 2 | 2 (100) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 1 (100) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Light pink shading indicates shifts of 1 grade from baseline; dark pink shading indicates shifts of ≥2 grades from baseline.
Values sum to 100% across rows for each treatment group.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; BID, twice daily; BL, baseline; CTCAE, Common Terminology Criteria for Adverse Events; QD, once daily.

### Maximum elevations over time

- Postbaseline incidences of ALT >3× ULN during Weeks 0-16 were low (<2%) and comparable in all 3 treatment arms (**Table 4**)
  - Similar findings were observed for the Weeks 0-52 period (**Table 5**)
- Postbaseline incidences of AST >3× ULN and AST >5× ULN during Weeks 0-16 were low across treatment groups (<2% and <0.5%, respectively) but greater with deucravacitinib vs placebo or apremilast (**Table 4**)
  - Similar findings were observed for the Weeks 0-52 period (**Table 5**)

**Table 4. Maximum elevations in ALT and AST, Weeks 0-16**

| Abnormality | Placebo (n = 413) | | Deucravacitinib (n = 833) | | Apremilast (n = 419) | |
|---|---|---|---|---|---|---|
| | Baseline | Weeks 0-16 | Baseline | Weeks 0-16 | Baseline | Weeks 0-16 |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| ALT | | | | | | |
| >3×-≤20× ULN | 6 (1.5) | 5 (1.2) | 0 | 9 (1.1) | 1 (0.2) | 2 (0.5) |
| >5×-≤20× ULN | 2 (0.5) | 3 (0.7) | 0 | 0 | 0 | 0 |
| >10×-≤20× ULN | 0 | 0 | 0 | 0 | 0 | 0 |
| >20× ULN | 0 | 0 | 0 | 0 | 0 | 0 |
| AST | | | | | | |
| >3×-≤20× ULN | 3 (0.7) | 2 (0.5) | 0 | 13 (1.6) | 0 | 3 (0.7) |
| >5×-≤20× ULN | 1 (0.2) | 1 (0.2) | 0 | 3 (0.4) | 0 | 1 (0.2) |
| >10×-≤20× ULN | 0 | 0 | 0 | 0 | 0 | 0 |
| >20× ULN | 0 | 0 | 0 | 0 | 0 | 0 |

Patients are counted once in each relevant category. Includes data from POETYK PSO-1 and PSO-2. For ALT, the ULN was defined as 33 U/L for women and 41 U/L for men. For AST, the ULN was defined as 31 U/L for women and 37 U/L for men.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal.

**Table 5. Maximum elevations in ALT and AST, Weeks 0-52**

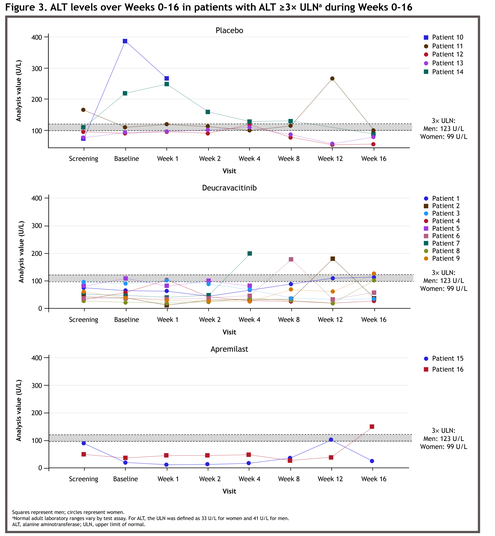
| Abnormality | Placebo (n = 658) | | | Deucravacitinib (n = 1351) | | | Apremilast (n = 419) | | |
|---|---|---|---|---|---|---|---|---|---|
| | n (%) | PY | IR/100 PY | n (%) | PY | IR/100 PY | n (%) | PY | IR/100 PY |
| ALT | | | | | | | | | |
| >3×-≤20× ULN | 11 (1.7) | 247.0 | 4.5 | 21 (1.6) | 977.0 | 2.1 | 4 (1.0) | 225.8 | 1.8 |
| >5×-≤20× ULN | 2 (0.3)[a] | 249.9 | 0.8 | 6 (0.4) | 983.8 | 0.6 | 0 | – | – |
| >10×-≤20× ULN | 0 | – | – | 1 (0.1) | 984.7 | 0.1 | 0 | – | – |
| >20× ULN | 0 | – | – | 0 | – | – | 0 | – | – |
| AST | | | | | | | | | |
| >3×-≤20× ULN | 5 (0.8) | 249.1 | 2.0 | 25 (1.9) | 973.3 | 2.6 | 3 (0.7) | 226.4 | 1.3 |
| >5×-≤20× ULN | 1 (0.2) | 250.2 | 0.4 | 7 (0.5) | 981.9 | 0.7 | 1 (0.2) | 226.8 | 0.4 |
| >10×-≤20× ULN | 0 | – | – | 2 (0.1) | 984.4 | 0.2 | 0 | – | – |
| >20× ULN | 0 | – | – | 0 | – | – | 0 | – | – |

[a]One patient who had an ALT elevation during Weeks 0-16 had a higher elevation after switching to deucravacitinib treatment and is counted with the deucravacitinib patients for the Weeks 0-52 treatment period.
Patients are counted once in each relevant category. Includes data from POETYK PSO-1 and PSO-2. For ALT, the ULN was defined as 33 U/L for women and 41 U/L for men. For AST, the ULN was defined as 31 U/L for women and 37 U/L for men.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; IR, incidence rate; PY, person-years; ULN, upper limit of normal.

### Patient-level data in patients who experienced an elevation ≥3× ULN during Weeks 0-16

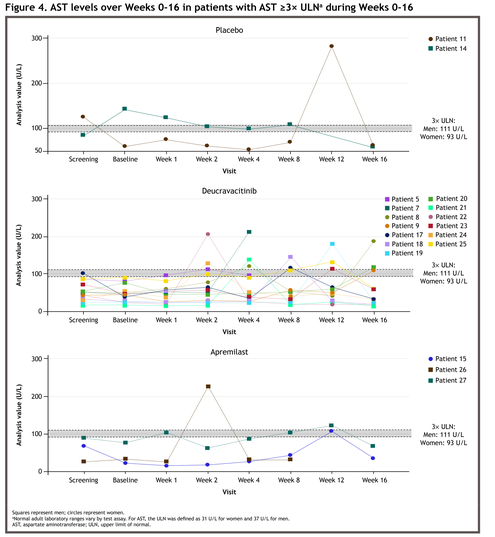
- Most ALT elevations ≥3× ULN were transient and were often related to underlying liver conditions or concomitant medications (**Figure 3**; **Table 6**)
- Most AST elevations ≥3× ULN were transient and were often related to underlying liver conditions or concomitant medications (**Figure 4**; **Table 6**)

**Figure 3. ALT levels over Weeks 0-16 in patients with ALT ≥3× ULN[a] during Weeks 0-16**




Squares represent men; circles represent women.
[a]Normal adult laboratory ranges vary by test assay. For ALT, the ULN was defined as 33 U/L for women and 41 U/L for men.
ALT, alanine aminotransferase; ULN, upper limit of normal.

**Figure 4. AST levels over Weeks 0-16 in patients with AST ≥3× ULN[a] during Weeks 0-16**




Squares represent men; circles represent women.
[a]Normal adult laboratory ranges vary by test assay. For AST, the ULN was defined as 31 U/L for women and 37 U/L for men.
AST, aspartate aminotransferase; ULN, upper limit of normal.

**Table 6. Summary of relevant medical history and prior and concomitant medications in patients with ALT or AST elevations ≥3× ULN through Week 16**

| Patient ID | Treatment | Timing of ≥3× ULN ALT increase, weeks | Timing of ≥3× ULN AST increase, weeks | Relevant medical history and prior and concomitant medications through Week 16 |
|---|---|---|---|---|
| Patient 1 | Deucravacitinib | 12-16 | – | • History of liver disease, including fatty liver disease, jaundice, possible hepatitis A, previous elevated ALT, and obesity (BMI 32.3 kg/m²)<br>• Prior use of infliximab, etanercept, and methotrexate |
| Patient 2 | Deucravacitinib | 12 | – | • Patient BMI 32.7 kg/m², no other relevant medical history or medications available |
| Patient 3 | Deucravacitinib | Screening, 1 | – | • History of coronary artery disease, myocardial infarction, hypertriglyceridemia, Type 2 diabetes, hypertension, BMI 33.4 kg/m², and previous left nephrectomy<br>• Previous treatment with etanercept, clobetasol, and betamethasone dipropionate; previous and continuing treatment with metformin, aspirin, losartan, lorazepam |
| Patient 4 | Deucravacitinib | 1 | – | • History of hepatic steatosis and obesity (BMI 38.6 kg/m²)<br>• No relevant medications taken before or during the event at Week 1 |
| Patient 5 | Deucravacitinib | Baseline | 2 | • History of fatty liver disease and alcohol use, BMI 30.8 kg/m²<br>• Prior treatment with clopidogrel and betamethasone butyrate propionate; prior and continuing treatment with triazolam, zolpidem tartrate |
| Patient 6 | Deucravacitinib | 8 | – | • History of adipositas, BMI 37.0 kg/m²<br>• Previous treatment with Fumaderm |
| Patient 7 | Deucravacitinib | 4 | 4 | • BMI 29.5 kg/m²<br>• Previous and continuing treatment with sildenafil, beclomethasone dipropionate inhaler |
| Patient 8 | Deucravacitinib | 16 | 16 | • History of Kawasaki's disease and hypertension, BMI 17.0 kg/m²<br>• Alcohol use was not reported in the parent study, but during the long-term extension study the investigator reported an AE of alcohol dependence syndrome<br>• An abdominal CT done for AE of acute abdomen on Day 74 revealed hepatic steatosis<br>• History of clobetasol propionate, betamethasone butyrate propionate, prednisolone valerate acetate, metronidazolamine hydrochloride, Soluyzen, acetaminophen, lohexol, esomeprazole magnesium hydrate |
| Patient 9 | Deucravacitinib | 16 | 16 | • BMI 37.4 kg/m²<br>• Previous treatment with acetic acid, dexamethasone, neomycin sulfate, Otomize ear spray; previous and continuing treatment with Depo-Provera |
| Patient 10 | Placebo | Baseline, 1 | – | • History of fatty liver disease, latent tuberculosis, tinea vericolor, liver function elevations, prediabetes mellitus, gout, and hypertriglyceridemia, BMI 26.0 kg/m²<br>• Previous treatment with methotrexate, cyclosporine, neotigason; previous and continuing treatment with Legalon, tinopramide hydrochloride, febuxostat, clostazol, crovelin, trimebutine maleate, buspirone hydrochloride, pyridoxine, isoniazid |
| Patient 11 | Placebo | Screening, 12 | 12 | • History of transaminitis, BMI 37.6 kg/m²<br>• Previous and ongoing use of intrauterine contraception device |
| Patient 12 | Placebo | Screening, 1, 4 | – | • History of elevated ALT and AST, hypertension, BMI 35.8 kg/m²<br>• Previous treatment with secukinumab; previous and ongoing treatment with nedal, karnidin, Jaydess, Hepa-Merz 3000, and furaginum |
| Patient 13 | Placebo | Baseline, 1, 2, 4 | – | • History of hepatic steatosis, latent tuberculosis, intermittent elevated liver function tests, HAIR-AN syndrome, and obesity (BMI 37.0 kg/m²)<br>• Previous treatment with rifampin; previous and continuing treatment with ibuprofen |
| Patient 14 | Placebo | Screening, baseline, 1, 2, 4, 8 | Baseline, 1, 2, 4, 8 | • History of elevated ALT and AST, and benign prostatic hyperplasia, BMI 26.6 kg/m²<br>• Previous treatment with isekizumab, guselkumab, amitriptyline, ciprofloxacin; treatment with sulfamethoxazole and trimethoprim (Days 11-16 and Days 29-39) |
| Patient 15 | Apremilast | Screening, 12 | 12 | • BMI 33.0 kg/m², no other relevant medical history or medications available |
| Patient 16 | Apremilast | 16 | – | • BMI 28.1 kg/m²<br>• Prior treatment with levocetirizine dihydrochloride |
| Patient 17 | Deucravacitinib | – | Screening, 8 | • History of *Helicobacter pylori*-positive serum antibody, Type 2 diabetes, and hypertension, BMI 32.6 kg/m²<br>• Previous treatment with tepilamide fumarate or placebo (as part of a clinical trial), omeprazole, clarithromycin, amoxicillin; previous and continuing treatment with Ancef, lisinopril, amitriptyline, metformin |
| Patient 18 | Deucravacitinib | – | 8 | • BMI 33.0 kg/m²<br>• Previous treatment with adalimumab and ustekinumab |
| Patient 19 | Deucravacitinib | – | 12 | • BMI 50.7 kg/m², no other relevant medical history or medications available |
| Patient 20 | Deucravacitinib | – | 16 | • BMI 43.4 kg/m², no other relevant medical history or medications available |
| Patient 21 | Deucravacitinib | – | 4 | • BMI 27.2 kg/m²<br>• Previous treatment with methotrexate |
| Patient 22 | Deucravacitinib | – | 2 | • BMI 26.4 kg/m²<br>• Previous and continuing treatment with ethinyl-estradiol/etonogestrel |
| Patient 23 | Deucravacitinib | – | 12 | • History of penicillin allergy, hypercholesterolemia, occasional heavy alcohol consumption, and hypertension, BMI 25.7 kg/m²<br>• Previous treatment with guselkumab, doxycycline (taken from Day 72 to Day 81); previous and continuing treatment with aspirin, amlodipine/benazepril, rosuvastatin |
| Patient 24 | Deucravacitinib | – | 2 | • History of coronary artery disease, smoking, stent insertion (3 stents total), and arterial hypertension, BMI 27.6 kg/m²<br>• Previous and continuing treatment with Coversyl, bisoprolol, Lipitor, and acetylsalicylic acid |
| Patient 25 | Deucravacitinib | – | 8, 12 | • BMI 28.9 kg/m²<br>• Previous and ongoing treatment with lisinopril, patient-reported excessive alcohol intake while in the long-term extension study |
| Patient 26 | Apremilast | – | 2 | • BMI 31.2 kg/m²<br>• Previous treatment with brodalumab |
| Patient 27 | Apremilast | – | 1, 8, 12 | • History of hepatic steatosis, high liver function tests, hypertlipidemia, hypertension, BMI 35.3 kg/m², and renal cyst (left)<br>• Previous treatment with neotigason; previous and continuing treatment with perindopril and indapamide |

Squares represent men; circles represent women.
AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; CT, computed tomography; ULN, upper limit of normal.

## Conclusions

- In the POETYK PSO-1 and PSO-2 trials in patients with moderate to severe plaque psoriasis, shifts >1 CTCAE grade from baseline in ALT and AST were infrequent over Weeks 0-16 with deucravacitinib treatment
  - There were no shifts to grade 4 and only 2 shifts to grade 3 (1 each with deucravacitinib and apremilast treatment)
- In patients treated with deucravacitinib, increases in ALT and AST >3× ULN were observed in <2% of patients over 52 weeks
- ALT and AST increases to >3× ULN were mainly transient, and most were related to underlying liver conditions or concomitant medications
- There were no cases of drug-induced liver injury

### References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