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

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Synopsis

- Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (interleukin [IL]-23 and Type I interferons) involved in psoriasis pathogenesis[1]
- Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved by the US Food and Drug Administration for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy[2]
  - Uniquely binds to the regulatory domain rather than to the more conserved catalytic domain where Janus kinase (JAK) 1/2/3 inhibitors bind (**Supplemental Material**)[1]
- Findings from the phase 3 POETYK PSO-1 and PSO-2 trials in patients with moderate to severe plaque psoriasis showed that deucravacitinib was significantly more efficacious than placebo and apremilast based on the coprimary endpoints of ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) and achievement of a static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline (sPGA 0/1) at Week 16 and was well tolerated[3,4]
- Clinical responses were maintained through 52 weeks in patients who received continuous deucravacitinib treatment and were improved in patients who switched from placebo to deucravacitinib at Week 16[5]
- Patients completing the POETYK 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

Objectives

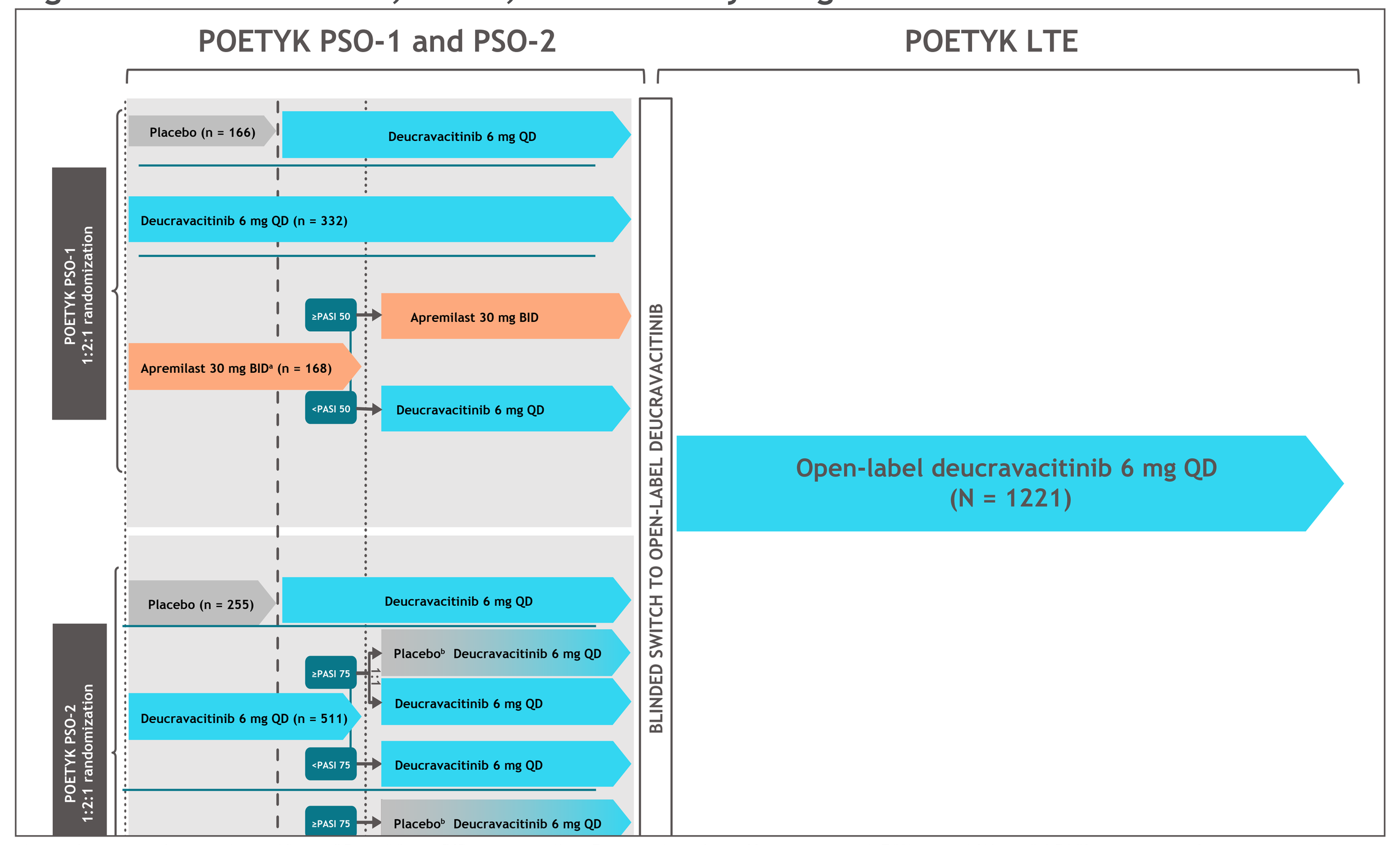
- The primary objective of this analysis was to characterize the safety and tolerability of long-term deucravacitinib use in patients with moderate to severe plaque psoriasis
- The secondary objective was to characterize the maintenance of efficacy responses

Methods

Study designs

- The study designs for POETYK PSO-1, PSO-2, and the LTE are summarized in **Figure 1**
- 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 PASI ≥12, sPGA ≥3, and body surface area (BSA) involvement ≥10%
- Patient randomization in POETYK PSO-1 and PSO-2 was stratified by geographic region, body weight, and prior biologic use
- All patients were eligible to enter the POETYK LTE after 52 weeks

Figure 1. POETYK PSO-1, PSO-2, and LTE study designs



[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; due to a programming error, however, these patients continued on placebo until Week 52. [c]Data were reported through the cutoff date of October 1, 2021.
BID, twice daily; LTE, long-term extension; 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.

Outcome measures

- Safety outcomes included total adverse events (AEs) and select AEs of interest, including infections, herpes zoster, major adverse cardiovascular events (MACE), venous thromboembolism (VTE) events, and malignancies through the cutoff date of October 1, 2021
  - To account for variable periods of treatment exposure, safety events are reported both as frequencies and as exposure-adjusted incidence rates (EAIRs) per 100 person-years (PY)
- Efficacy endpoints included PASI 75, ≥90% reduction from baseline in PASI (PASI 90), and sPGA 0/1 responses through the cutoff date of October 1, 2021
- Consistent with methodologies for assessing long-term outcomes in clinical trials of psoriasis therapies, 2 methods of imputation were used for sensitivity analyses[6]
  - **Treatment failure rule (TFR):** Patients who discontinued treatment or the study due to worsening of psoriasis or lack of efficacy were imputed as nonresponders
  - **Modified nonresponder imputation (mNRI):** Multiple imputation was used for patients with missing data, and patients who discontinued due to worsening of psoriasis were imputed as nonresponders; only patients who discontinued or reached Week 60 by October 1, 2021, were included

Results

Patients

- A total of 1519 patients received ≥1 dose of deucravacitinib across the parent trials and the POETYK LTE, including 1364 patients in POETYK PSO-1/PSO-2 and 1221 patients in the POETYK LTE
- Enrollment in the POETYK LTE coincided with the peak of the COVID-19 pandemic
- Baseline patient demographics and disease characteristics for the overall population are presented in **Table 1**

Exposure

- The median exposure to deucravacitinib was 682 days
- Exposure data at 1 year and 2 years are presented in **Table 2**
  - Exposure during Weeks 0—52 of POETYK PSO-1/PSO-2 was 969.0 PY, with an additional 1513.0 PY of exposure during the POETYK LTE
  - 1179 patients had ≥1 year (52 weeks) of continuous exposure and 584 had ≥2 years (104 weeks) of continuous exposure

Table 1. Baseline patient demographics and disease characteristics in the parent trials

Parameter	Total (N = 1519)
Age, mean (SD), y	46.6 (13.4)
Weight, mean (SD), kg	90.6 (21.6)
Female, n (%)	493 (32.5)
Race, n (%)	
White	1325 (87.2)
Asian	153 (10.1)
Black or African American	23 (1.5)
Other	18 (1.2)
Age at disease onset, mean (SD), y	28.8 (14.9)
Disease duration, mean (SD), y	18.7 (12.7)
PASI, mean (SD)	21.1 (8.1)
sPGA, n (%)	
3 (moderate)	1211 (79.7)
4 (severe)	308 (20.3)
BSA involvement, mean (SD), %	26.2 (15.8)

BSA, body surface area; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Table 2. Extent of exposure to deucravacitinib

	At 1 year[a]	At 2 years[b]
Continuous exposure, n (%)	Deucravacitinib 6 mg QD (N = 1364) Total PY = 969.0	Deucravacitinib 6 mg QD (N = 1519) Total PY = 2482.0
≥52 weeks	503 (36.9)	1179 (77.6)
≥104 weeks	—	584 (38.4)
Total exposure, n (%)		
≥52 weeks	—	1200 (79.0)
≥104 weeks	—	606 (39.9)

[a]This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0—52). Not all patients were receiving deucravacitinib 6 mg QD continuously throughout this period. [b]This represents the pooled POETYK PSO-1 and PSO-2 population enrolled in the POETYK LTE through the 120-day cutoff date of October 1, 2021.
LTE, long-term extension; PY, person-years; QD, once daily.

Overall safety

- A summary of overall safety with deucravacitinib, including the most common AEs at 1 year and 2 years, is presented in **Table 3**
  - 2-year safety outcomes should be considered in the context of COVID-19, as the timing of the POETYK LTE coincided with the peak of the pandemic
- A consistent AE profile was observed across POETYK PSO-1, PSO-2, and the LTE, aside from COVID-19 (**Table 3**)
- AEs were predominantly mild or moderate in severity
- An additional 8 deaths were reported in the POETYK LTE up to the cutoff date
  - 6 of these deaths were due to COVID-19, 1 was attributed to a ruptured thoracic aortic aneurysm (not drug related), and 1 was due to an unknown cause
  - Mortality due to COVID-19 was not higher than expected since the mortality rate was comparable to rates in the general population and a reference population (placebo arm of the Johnson & Johnson/Janssen COVID-19 vaccine trial) during the pandemic[7]

Table 3. Overall safety summary at 1 year vs at 2 years (as-treated population)

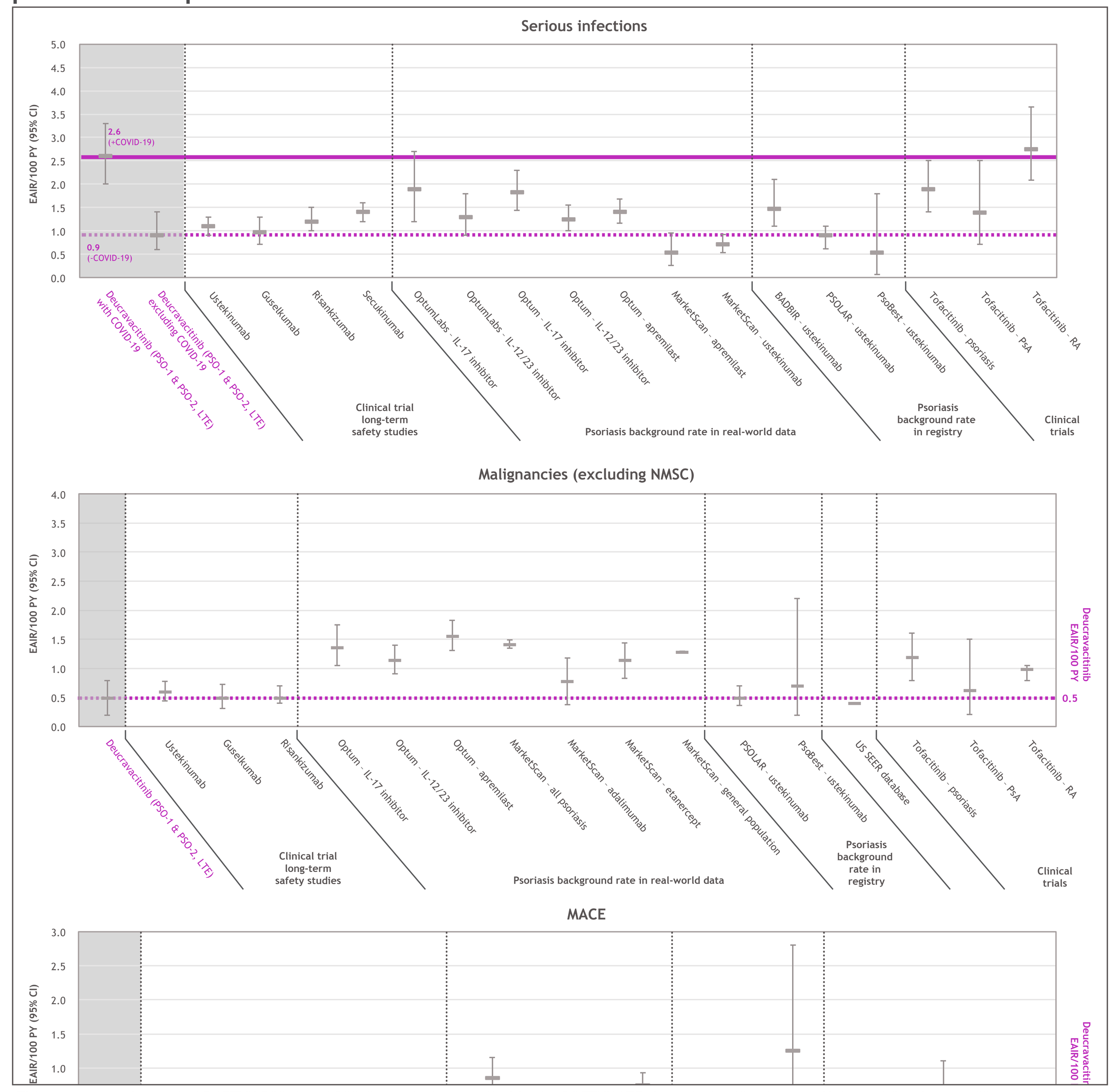
	At 1 year[a] (POETYK PSO-1 + PSO-2)		At 2 years[b] (POETYK PSO-1 + PSO-2 + LTE)	
	Deucravacitinib 6 mg QD (N = 1364) Total PY = 969.0		Deucravacitinib 6 mg QD (N = 1519) Total PY = 2482.0	
AE category	n (%)	EAIR/100 PY	n (%)	EAIR/100 PY
AEs	995 (72.9)	229.2	1214 (79.9)	154.4
SAEs	55 (4.0)	5.7	145 (9.5)	6.1
Discontinued treatment due to AEs	43 (3.2)	4.4	69 (4.5)	2.8
Deaths	2 (0.1)	0.2	10 (0.7)	0.4
Most common AEs (≥5% of patients)	n (%)	EAIR/100 PY	n (%)	EAIR/100 PY
Nasopharyngitis	229 (16.8)	26.1	271 (17.8)	12.9
Upper respiratory tract infection	124 (9.1)	13.4	150 (9.9)	6.5
COVID-19	5 (0.4)	0.5	124 (8.2)	5.1
Headache	80 (5.9)	8.5	99 (6.5)	4.2
Arthralgia	55 (4.0)	5.7	85 (5.6)	3.5
Diarrhea	69 (5.1)	7.3	84 (5.5)	3.5

[a]This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0—52). Not all patients were receiving deucravacitinib 6 mg QD continuously throughout this period. [b]This represents the pooled POETYK PSO-1 and PSO-2 population enrolled in the POETYK LTE through the 120-day cutoff date of October 1, 2021.
AE, adverse event; EAIR, exposure-adjusted incidence rate; LTE, long-term extension; PY, person-years; QD, once daily; SAEs, serious adverse events.

AEs of interest

- The incidence rates for AEs of interest were generally consistent with findings from clinical trials of other agents targeting similar pathways in patients with moderate to severe plaque psoriasis, after accounting for the different methodologies and time frames of those studies; rates were also comparable to real-world registry data (**Figure 2**)[8-23]
- The incidence rates were similar at 1 year and 2 years, except for events related to COVID-19 infection (**Table 4**)
- Most COVID-19 cases were not severe or serious and did not lead to treatment discontinuation
  - A total of 6 COVID-19—related deaths were reported at 2 years, corresponding to an EAIR of 0.2/100 PY (**Table 4**)
    - This is comparable to the incidence of deaths in the placebo group (N = 19,544) of the Johnson & Johnson/Janssen global vaccine study (0.23/100 PY)[7]
  - The majority of patients who experienced a COVID-19—related serious AE (SAE) had known or potential risk factors for severe illness from COVID-19 (eg, diabetes mellitus, obesity, cardiovascular disease, lung disease, smoking)
- The incidence rates for MACE, VTEs, and malignancies were low and in line with observations in POETYK PSO-1 and PSO-2 (**Table 4**)
- Descriptions of VTE events occurring during the study period are included in the **Supplemental Material**
  - None of these events were considered drug related
- The ratio of basal cell cancer to squamous cell cancer remained close to 2:1
- The incidence rates for non-nonmelanoma skin cancers (non-NMSCs) were not higher than expected in the psoriasis population or clinical trial safety data with approved agents[24]
  - Descriptions of the lymphoma cases are included in the **Supplemental Material**; all 3 patients with lymphoma had multiple confounding factors that made it difficult to attribute these events to treatment[24]
  - Other non-NMSCs occurring at 2 years were not clustered to any particular malignancy type[24]

Figure 2. EAIRs for serious infections, malignancies (excluding NMSC), and MACE at 2 years[a] compared with long-term safety data, real-world data, or registry studies of other systemic psoriasis therapies



[a]This represents the pooled POETYK PSO-1 and PSO-2 population enrolled in the POETYK LTE through the 120-day cutoff date of October 1, 2021.
BADBIR, British Association of Dermatologists Biologic and Immunomodulators Register; EAIR, exposure-adjusted incidence rate; IL, interleukin; LTE, long-term extension; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer; PsA, psoriatic arthritis; PsoBest, German Psoriasis Registry; PSOLAR, PSOriasis Longitudinal Assessment and Registry; PY, person-years; RA, rheumatoid arthritis; SEER, Surveillance, Epidemiology, and End Results Program.

Table 4. AEs of interest at 1 year vs at 2 years (as-treated population)

	At 1 year[a] (POETYK PSO-1 + PSO-2)		At 2 years[b] (POETYK PSO-1 + PSO-2 + LTE)	
	Deucravacitinib 6 mg QD (N = 1364) Total PY = 969.0		Deucravacitinib 6 mg QD (N = 1519) Total PY = 2482.0	
AE category	n (%)	EAIR/100 PY	n (%)	EAIR/100 PY
Serious infections	17 (1.2)	1.7	64 (4.2)	2.6
Herpes zoster infection	9 (0.7)	0.9	18 (1.2)	0.7
Total COVID-19 infection	5 (0.4)	0.5	124 (8.2)	5.1
Serious COVID-19 infection	2 (0.1)	0.2	30 (2.0)	1.2
COVID-19 pneumonia	0 (0)	0.0	13 (0.9)	0.5
COVID-19—related deaths	0 (0)	0.0	6 (0.4)	0.2
MACE[c]	3 (0.2)	0.3	9 (0.6)	0.4
VTE[d]	2 (0.1)	0.2	3 (0.2)	0.1
Total malignancies	10 (0.7)	1.0	22 (1.4)	0.9
NMSC	7 (0.5)	0.7	11 (0.7)	0.4
Malignancies excluding NMSC	3 (0.2)	0.3	12 (0.8)	0.5
Lymphoma	1 (0.1)	0.1	3 (0.2)	0.1

[a]This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0—52). Not all patients were on deucravacitinib 6 mg QD continuously throughout this period. [b]This represents the pooled POETYK PSO-1 and PSO-2 population enrolled in the POETYK LTE through the 120-day cutoff date of October 1, 2021. [c]MACE is defined as cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. [d]VTE is defined as pulmonary embolism and deep vein thrombosis.
AE, adverse event; EAIR, exposure-adjusted incidence rate; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer; PY, person-years; QD, once daily; VTE, venous thromboembolism.

Table 5. Efficacy results at Week 60 by imputation analysis

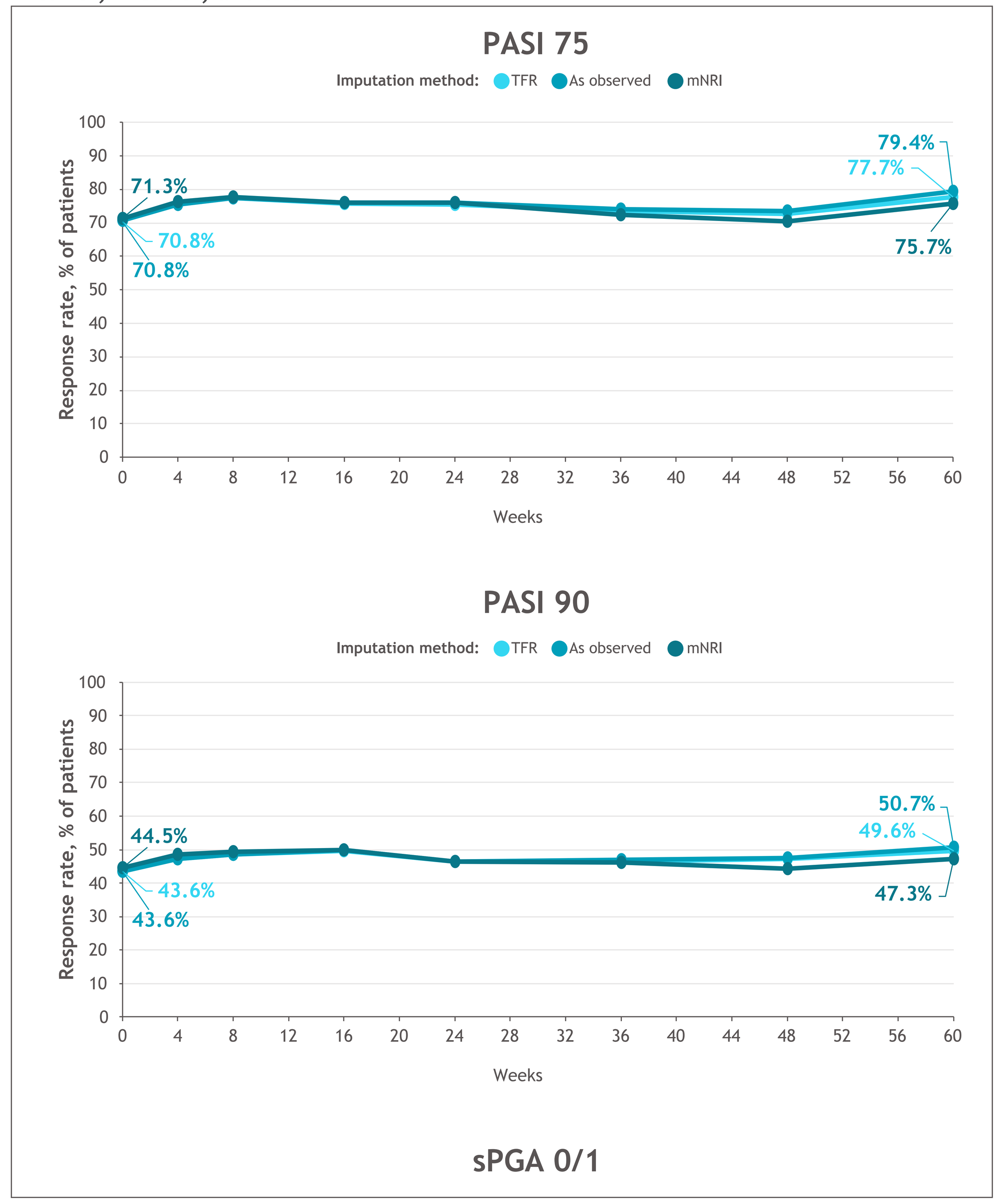
Type of sensitivity analysis	Deucravacitinib — deucravacitinib				Placebo — deucravacitinib				Apremilast — deucravacitinib				Total			
	Week 0		Week 60		Week 0		Week 60		Week 0		Week 60		Week 0		Week 60	
	n	Mean response rate (%)	n	Mean response rate (%)	n	Mean response rate (%)	n	Mean response rate (%)	n	Mean response rate (%)	n	Mean response rate (%)	n	Mean response rate (%)	n	Mean response rate (%)
PASI 75																
TFR	944	70.8	705	77.7	197	34.5	127	87.4	80	73.8	70	87.1	1221	65.1	902	79.8
mNRI	805	71.3	805	75.7	138	37.0	138	87.4	79	74.7	79	84.8	1022	66.9	1022	78.1
As observed	944	70.8	690	79.4	197	34.5	124	89.5	80	73.8	70	87.1	1221	65.1	884	81.4
PASI 90																
TFR	944	43.6	705	49.6	197	15.7	127	53.5	80	40.0	70	62.9	1221	38.9	902	51.2
mNRI	805	44.5	805	47.3	138	17.4	138	54.2	79	40.5	79	60.1	1022	40.5	1022	49.3
As observed	944	43.6	690	50.7	197	15.7	124	54.8	80	40.0	70	62.9	1221	38.9	884	52.3
sPGA 0/1																
TFR	944	56.0	705	58.7	197	25.4	126	65.1	80	53.8	70	72.9	1221	50.9	901	60.7
mNRI	805	56.3	805	57.1	138	27.5	138	65.0	79	54.4	79	70.7	1022	52.3	1022	59.2
As observed	944	56.0	690	60.0	197	25.4	123	66.7	80	53.8	70	72.9	1221	50.9	883	61.9

TFR: NRI was implemented for patients who discontinued treatment or study due to worsening of psoriasis or lack of efficacy. mNRI: Multiple imputation was used for patients with missing data, and patients who discontinued due to worsening of psoriasis only were imputed as nonresponders; includes patients who reached Week 60 or discontinued by October 1, 2021.
mNRI, modified nonresponder imputation; PASI 75, ≥75% reduction from baseline in Psoriasis Area and Severity Index; PASI 90, ≥90% reduction from baseline in PASI; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2% improvement from baseline; TFR, treatment failure rule.

Efficacy

- Over 60 weeks of follow-up in the POETYK LTE, the proportions of patients who achieved PASI 75, PASI 90, and sPGA 0/1 were similar regardless of which treatment they were receiving at Week 52 in the parent study (**Table 5**)
- Sensitivity analyses demonstrated the robustness of these results, with comparable response rates observed using the TFR, as-observed, or mNRI method (**Table 5**; **Figure 3**)

Figure 3. Clinical efficacy responses during POETYK LTE Weeks 0—60 in patients who were receiving deucravacitinib at Week 52 in the parent study (sensitivity analysis): PASI 75[a], PASI 90[b], and sPGA 0/1[c]



[a]PASI 75 responder defined as at least a 75% improvement from the parent study baseline in the PASI score. [b]PASI 90 responder defined as at least a 90% improvement from the parent study baseline in the PASI score. [c]sPGA 0/1 responder defined as an sPGA score of 0 or 1 with at least a 2-point improvement from parent study baseline. mNRI: Multiple imputation was used for patients with missing data, and patients who discontinued due to worsening of psoriasis only were imputed as nonresponders; includes patients who reached Week 60 or discontinued by October 1, 2021. TFR: NRI was implemented for patients who discontinued treatment or study due to worsening of psoriasis or lack of efficacy.
mNRI, modified nonresponder imputation; PASI 75, ≥75% reduction from baseline in Psoriasis Area and Severity Index; PASI 90, ≥90% reduction from baseline in PASI; sPGA 0/1, static Physician's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline; TFR, treatment failure rule.

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
  - The most common AEs (≥5% of patients) included nasopharyngitis, upper respiratory tract infection, diarrhea, arthralgia, and headache
  - An increase in serious infections was observed, which is attributable to COVID-19 infections due to the ongoing pandemic
  - No cases of herpes zoster were disseminated, serious, or led to treatment discontinuation
  - The overall malignancy incidence rate was largely in line with POETYK PSO-1 and PSO-2 and rates seen in other clinical trials and real-world populations
  - There was a low incidence rate of cardiovascular events (eg, MACE) that was comparable to long-term safety data from clinical trials with anti-IL-12/23 or anti-IL-23 agents and in real-world populations
- Unlike most other previous phase 3 trials, the POETYK studies were conducted in the context of the global COVID-19 pandemic, and COVID-19 rates increased from Year 1 to Year 2
  - The overall incidence rates for COVID-19 infection and COVID-19—related hospitalization and death were consistent with background epidemiologic rates
- Clinical efficacy was maintained for up to 2 years with deucravacitinib treatment, regardless of which treatment was received at Week 52 in the parent study
  - Response rates at the start of the LTE for PASI 75, PASI 90, and sPGA 0/1 were maintained at LTE Week 60
  - Consistent results were observed across tested imputation methods, including TFR, mNRI, and as-observed data
- These findings further support the use of deucravacitinib, a once-daily oral drug, as an effective and well-tolerated treatment for moderate to severe plaque psoriasis

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References and Supplemental Material

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