

# Deucravacitinib in moderate to severe plaque psoriasis: 5-year, long-term safety and efficacy results from the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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## Synopsis

- Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of select inflammatory cytokines (eg, interleukin [IL]-23, IL-12, Type I interferons [IFNs])
  - IL-23 and Type I IFNs are involved in psoriasis pathogenesis<sup>1</sup>
- Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy<sup>4</sup>
- Deucravacitinib uniquely binds to the TYK2 regulatory domain rather than to the catalytic domain where Janus kinase 1, 2, 3 inhibitors bind,<sup>1,7</sup> driving its selectivity for TYK2 and representing the first in a new class of oral drugs
- The global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) trials demonstrated that deucravacitinib 6 mg once daily (QD) was significantly more efficacious than placebo and apremilast at Week 16 and was well tolerated in patients with moderate to severe plaque psoriasis<sup>8,9</sup>
- Patients who completed the POETYK PSO-1 and PSO-2 parent trials could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial and receive open-label deucravacitinib
- Clinical efficacy was previously reported to be well maintained through 4 years, with no new safety signals compared with Year 3, in deucravacitinib-treated patients in the ongoing POETYK LTE trial<sup>11</sup>

## Objective

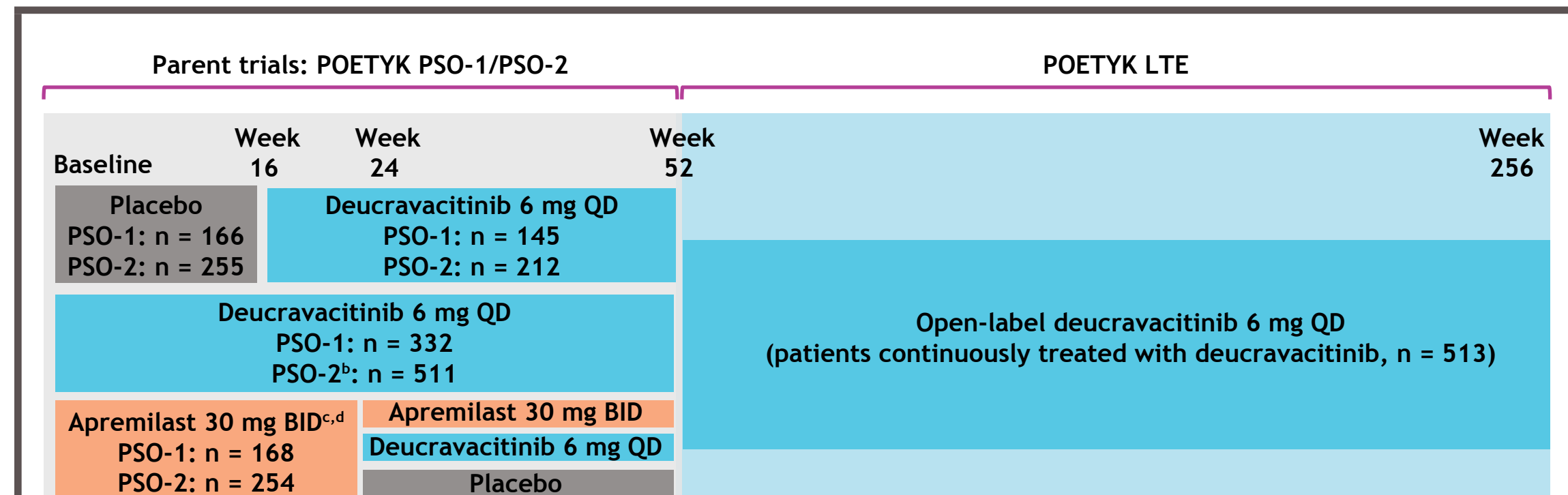
- To report the safety and efficacy of deucravacitinib treatment through 5 years (Week 256; data cutoff, September 2, 2024) in patients with moderate to severe plaque psoriasis who participated in the POETYK PSO-1, PSO-2, and LTE trials

## Methods

### Study designs

- In the POETYK PSO-1 and PSO-2 trials, adults with moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI]  $\geq 12$ , static Physician Global Assessment [sPGA]  $\geq 3$ , and body surface area [BSA] involvement  $\geq 10\%$  at baseline) were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg QD, or apremilast 30 mg twice daily (BID) (Figure 1)
- At Week 52, eligible patients were allowed to enroll in the POETYK LTE trial and receive open-label deucravacitinib 6 mg QD

Figure 1. POETYK PSO-1, PSO-2, and LTE analysis populations\*



- Key eligibility criteria in the parent studies:
- Age  $\geq 18$  years
  - Moderate to severe plaque psoriasis:
  - PASI  $\geq 12$
  - sPGA  $\geq 3$
  - BSA involvement  $\geq 10\%$

\*Includes patients with  $\geq 1$  dose of deucravacitinib 6 mg QD, n = 1519. <sup>†</sup>In POETYK PSO-2, patients randomized to deucravacitinib on Day 1 who achieved R75 at Week 24 were randomized to placebo or deucravacitinib; for patients who were randomized to placebo, upon release ( $\geq 50\%$  loss of Week 24 PASI percent improvement from baseline), they were to cross over to deucravacitinib; however, due to a programming error, these patients continued to receive placebo until Week 52. <sup>‡</sup>In POETYK PSO-1, patients who responded to apremilast remained on apremilast. In POETYK PSO-2, patients who responded to apremilast crossed over to placebo and were to cross over to deucravacitinib upon release; however, due to a programming error, these patients continued to receive placebo until Week 52. <sup>§</sup>Apremilast was titrated from 10 mg QD to 30 mg BID over the first 5 days of dosing. <sup>||</sup>Week 16 only. BSA, body surface area; LTE, long-term extension; PASI, Psoriasis Area and Severity Index; R75,  $\geq 75\%$  reduction from baseline in PASI; QD, once daily; sPGA, static Physician Global Assessment.

### Analysis populations

- Safety population:** patients receiving  $\geq 1$  dose of deucravacitinib at any time in the pooled parent (POETYK PSO-1 and PSO-2) and POETYK LTE trials over 5 years in the as-treated population
- Efficacy population:** patients from the pooled parent trials (POETYK PSO-1 and PSO-2) who received continuous deucravacitinib treatment from Day 1 of the parent trials through 5 years (Week 256)

### Outcomes

- Safety outcomes:**
  - Adverse events (AEs), serious AEs, deaths, AEs of interest, and AEs leading to treatment discontinuation through the last data cutoff (September 2, 2024)
  - Comparison of AEs of interest to those reported for other psoriasis medications and real-world datasets
- Efficacy outcomes:**
  - Achievement of  $\geq 75\%$   $\geq 90\%$  reduction from baseline in PASI (PASI 75/90)
  - An sPGA score of 0 (clear) or 1 (almost clear) (sPGA 0/1)

### Statistical analysis

- Safety and efficacy were analyzed through the data cutoff (September 2, 2024; Week 256, 5 years)
- AEs were ascribed to the assigned treatment at the time of the event
  - When a patient had multiple events of the same type, the patient was counted only once
- Safety data were reported as exposure-adjusted incidence rate (EAIR)/100 person-years (PY) and calculated as 100  $\times$  (number of patients with an AE) / (total exposure time for all patients at risk [time to initial AE occurrence for patients with AE + total exposure time for patients without AE])
- In addition to observed values, two additional methods of imputation for missing data were used as sensitivity analyses for efficacy
  - Treatment failure rules (TFR)**<sup>12</sup>: patients who discontinued treatment due to lack of efficacy or worsening of psoriasis were imputed as nonresponders; all other missing data were not imputed
  - Modified nonresponder imputation (mNRI)**<sup>13</sup>: patients who either discontinued prior to Week 256 or reached Week 256 were included; patients with missing data who discontinued treatment due to worsening of psoriasis were imputed as nonresponders; all other missing data were imputed by multiple imputation

## Results

### Patients

- Baseline patient demographics and clinical characteristics for the safety and efficacy populations are presented in Table 1

Table 1. Baseline patient demographics and clinical characteristics

Parameter	Patients who received $\geq 1$ dose of deucravacitinib (safety population, n = 1519)	Patients who received continuous deucravacitinib (efficacy population, n = 513)
Age, mean (SD), y	46.6 (13.4)	46.9 (13.3)
Weight, mean (SD), kg	90.6 (21.6)	89.9 (22.2)
Body mass index, mean (SD), kg/m <sup>2</sup>	30.5 (6.8)	30.3 (7.0)
Female, n (%)	493 (32.5)	159 (31.0)
Race, n (%)		
White	1325 (87.2)	440 (85.8)
Asian	153 (10.1)	64 (12.5)
Black or African American	23 (1.5)	5 (1.0)
Other	18 (1.2)	4 (0.8)
Disease duration, mean (SD), y	18.7 (12.7)	18.8 (12.6)
PASI, mean (SD)	21.1 (8.1)	21.1 (7.9)
sPGA score, n (%)		
3 (moderate)	1211 (79.7)	401 (78.2)
4 (severe)	308 (20.3)	112 (21.8)
BSA involvement, mean (SD), %	26.2 (15.8)	26.9 (15.8)
PSDD total score, mean (SD)	-	52.9 (23.5)
DLQI, mean (SD)	-	11.8 (6.6)

BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; PSDD, Psoriasis Symptoms and Signs Diary; SD, standard deviation; sPGA, static Physician Global Assessment.

### Deucravacitinib exposure: safety population

- Exposure data through 5 years are shown in Table 2
- Median duration of exposure was 4.2 years
  - Approximately 30% of patients had more than 5 years of exposure

Table 2. Deucravacitinib exposure of the safety population through 5 years

Exposure	Deucravacitinib (n = 1519)
Total exposure, PY	5046.7
Median (min, max) exposure, days	1539.0 (1, 2150)
$\geq 4$ months of exposure, n (%)	1407 (92.6)
$\geq 12$ months of exposure, n (%)	1206 (79.4)
$\geq 24$ months of exposure, n (%)	1051 (69.2)
$\geq 36$ months of exposure, n (%)	911 (60.0)
$\geq 48$ months of exposure, n (%)	813 (53.5)
$\geq 60$ months of exposure, n (%)	449 (29.6)

This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0-52). \*This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the data cutoff (September 2, 2024). LTE, long-term extension; max, maximum; min, minimum; PY, person-years.

### Overall safety

- A cumulative safety summary is presented in Table 3
- Incidence rates of AEs (EAIR = n/100 PY) decreased from 1 year to 5 years
  - The most common AEs continued to be nasopharyngitis and upper respiratory tract infections
  - The data cutoffs for Year 1 of the POETYK PSO-1 and PSO-2 trials were October 15, 2020, and December 22, 2020, respectively; the peak of the global COVID-19 pandemic occurred during the first 2 years of the POETYK LTE trial, contributing to the higher COVID-19 rate seen through Year 5 compared with Year 1

Table 3. Cumulative safety summary through 1 year and 5 years (as-treated population)

AE category	Cumulative through 1 year* (POETYK PSO-1 + PSO-2)		Cumulative through 5 years* (POETYK PSO-1 + PSO-2 + LTE)	
	1-Year cumulative n (%)	EAIR/100 PY (95% CI)	5-Year cumulative n (%)	EAIR/100 PY (95% CI)
<b>AEs</b>	995 (72.9)	229.2 (215.4-243.9)	1315 (86.6)	127.4 (120.6-134.5)
<b>Serious AEs</b>	55 (4.0)	5.7 (4.4-7.4)	235 (15.5)	5.1 (4.4-5.8)
<b>Discontinued treatment due to AEs</b>	43 (3.2)	4.4 (3.3-5.9)	106 (7.0)	2.1 (1.7-2.5)
<b>Deaths</b>	2 (0.1) <sup>†</sup>	0.2 (0.1-0.8)	11 (0.7) <sup>†</sup>	0.2 (0.1-0.4)
<b>Most common AEs (EAIR <math>\geq 5/100</math> PY)</b>				
Nasopharyngitis	229 (16.8)	26.1 (23.0-29.8)	363 (23.9)	9.1 (8.2-10.1)
Upper respiratory tract infection	124 (9.1)	13.4 (11.3-16.0)	258 (17.0)	5.8 (5.1-6.6)
Headache	80 (5.9)	8.5 (6.8-10.5)	124 (8.2)	2.6 (2.2-3.1)
Diarrhea	69 (5.1)	7.3 (5.7-9.2)	102 (6.7)	2.1 (1.7-2.6)
Arthralgia	55 (4.0)	5.7 (4.4-7.4)	126 (8.3)	2.7 (2.2-3.2)
COVID-19 <sup>‡</sup>	5 (0.4)	0.5 (0.2-1.2)	352 (23.2)	8.2 (7.4-9.1)

Not all patients were receiving deucravacitinib 6 mg QD continuously throughout this period. Total PY corresponds to the total exposure time to deucravacitinib during the indicated time period. \*This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0-52). <sup>†</sup>This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the data cutoff (September 2, 2024). <sup>‡</sup>In POETYK PSO-1 and PSO-2 through 1 year, 1 patient discontinued deucravacitinib after 4 days of treatment due to prohibited medication (fluorenone) and died 9 days later reportedly due to heart failure and sepsis, with no medical records available. Another death occurred between Weeks 16 and 52 and was due to hepatocellular carcinoma in a patient with a history of hepatitis C virus infection and liver cirrhosis. Both deaths were considered unrelated to treatment by the investigator. <sup>§</sup>After Week 52, 7 deaths were due to COVID-19 (all in patients with risk factors for severe disease; 2 deaths were considered related to treatment and the other 5 deaths were considered unrelated to treatment by the investigator). One patient with cardiovascular risk factors died due to a ruptured aortic aneurysm which was considered related to treatment by the investigator. One patient with a history of type 2 diabetes mellitus with neutropathy, hypertension, and hypercholesterolemia died due to sudden death of unknown cause, which was not considered related to treatment by the investigator. <sup>||</sup>In PSO-1, PSO-2, and LTE trials were conducted during the COVID-19 pandemic. <sup>¶</sup>AE, adverse event; CI, confidence interval; EAIR, exposure-adjusted incidence rate; LTE, long-term extension; PY, person-years; QD, once daily.

### AEs of interest

- AEs of interest are presented in Table 4
- The rate of serious infections was higher through 5 years than through 1 year due to the concurrent global COVID-19 pandemic
  - When COVID-19 was excluded from the 5-year analysis, the rate of serious infections was lower at 5 years (EAIR/100 PY [95% confidence interval (CI)], 0.94 [0.69-1.25])
- Incidence rates for adjudicated major adverse cardiovascular events (MACE) and malignancies were low and comparable through 1 year and 5 years
- Incidence rates for malignancies decreased from 1 year through 5 years
  - One new case of lymphoma (B-cell lymphoma) was reported from Year 4 to Year 5<sup>11</sup>
- No venous thromboembolic (VTE) events were observed in Year 4 or Year 5<sup>11</sup>
- Other AEs of interest related to the known safety profile of deucravacitinib decreased in frequency from the 1-year to 5-year cumulative period, respectively, including acne (2.88 and 0.95), folliculitis (2.77 and 0.72), and oral ulcer (1.84 and 0.81)

Table 4. Cumulative AEs of interest through 1 year and 5 years (as-treated population)

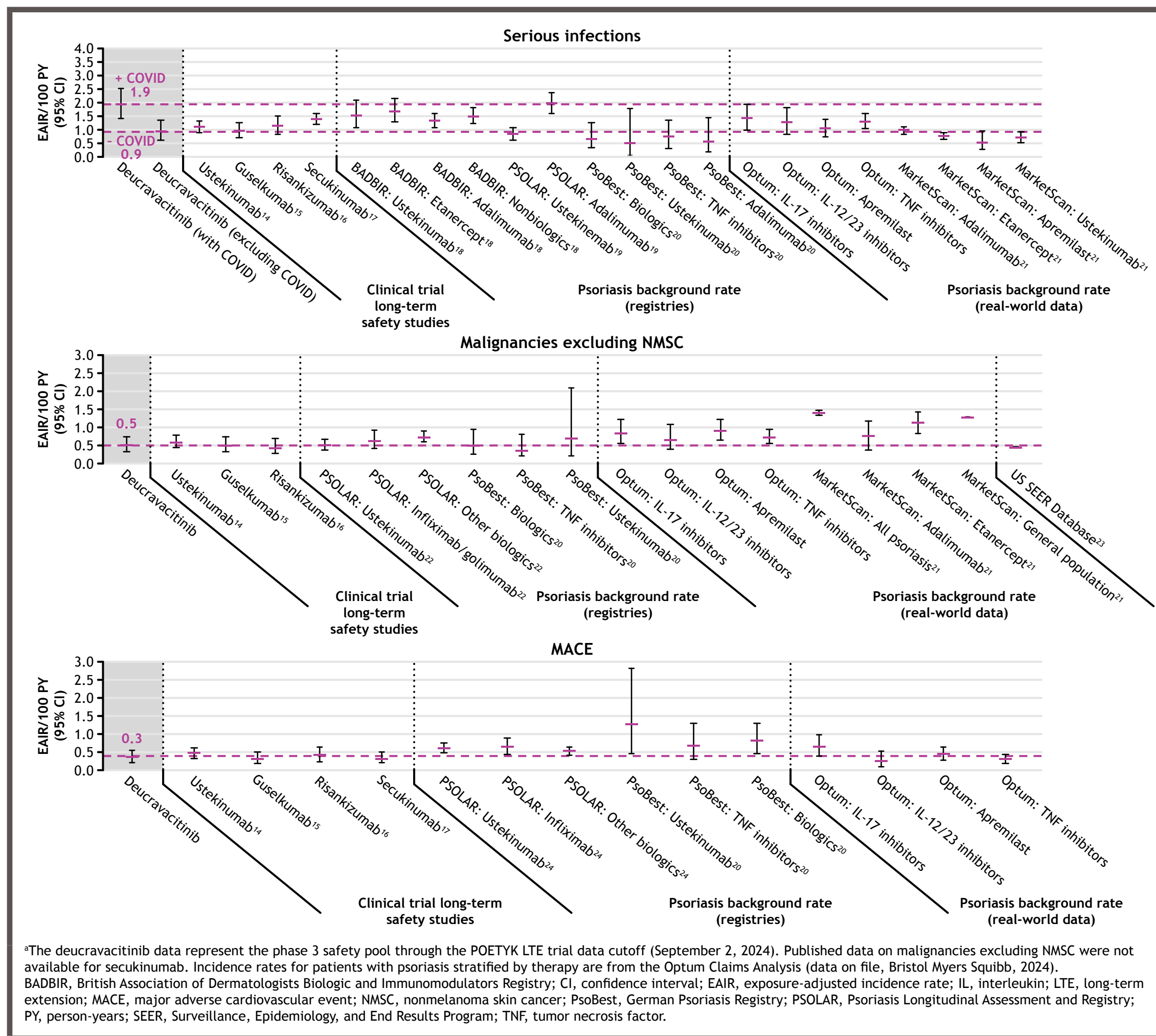
AE category	Cumulative through 1 year* (POETYK PSO-1 + PSO-2)		Cumulative through 5 years* (POETYK PSO-1 + PSO-2 + LTE)	
	1-Year cumulative n (%)	EAIR/100 PY (95% CI)	5-Year cumulative n (%)	EAIR/100 PY (95% CI)
<b>Serious infections</b>	17 (1.3)	1.73 (1.08-2.79)	94 (6.2)	1.93 (1.56-2.36)
Serious infections excluding COVID-19	15 (1.1)	1.53 (0.86-2.52)	47 (3.1)	0.94 (0.69-1.25)
<b>Herpes zoster</b>				
Herpes zoster <sup>†</sup>	8 (0.6)	0.81 (0.41-1.63)	29 (1.9)	0.58 (0.39-0.83)
Ophthalmic herpes zoster <sup>‡</sup>	1 (0.1)	0.10 (0.01-0.72)	1 (0.1)	0.02 (0.00-0.11)
<b>MACE*</b>	3 (0.2)	0.30 (0.10-0.94)	17 (1.1)	0.34 (0.20-0.54)
<b>VTE<sup>§</sup></b>	2 (0.1)	0.20 (0.05-0.81)	3 (0.2)	0.06 (0.01-0.17)
<b>Malignancies</b>	10 (0.7)	1.02 (0.55-1.89)	46 (3.0)	0.92 (0.67-1.22)
NMSC	7 (0.5)	0.71 (0.34-1.49)	21 (1.4)	0.42 (0.26-0.64)
Basal cell carcinoma	4 (0.3)	0.41 (0.15-1.08)	14 (0.9)	0.28 (0.15-0.47)
Squamous cell carcinoma <sup>¶</sup>	2 (0.1)	0.20 (0.05-0.81)	7 (0.5)	0.14 (0.06-0.28)
Malignancies excluding NMSC <sup>**</sup>	3 (0.2)	0.30 (0.10-0.94)	26 (1.7)	0.51 (0.33-0.75)
Lymphoma	1 (0.1)	0.10 (0.01-0.72)	4 (0.3)	0.08 (0.02-0.20)
Hodgkin's disease	1 (0.1)	0.10 (0.01-0.72)	1 (0.1)	0.02 (0.00-0.11)
Leukemia	0	0	1 (0.1)	0.02 (0.00-0.11)

Not all patients were receiving deucravacitinib 6 mg QD continuously throughout this period. Total PY corresponds to the total exposure time to deucravacitinib during the indicated time period. \*This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0-52). <sup>†</sup>This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the data cutoff (September 2, 2024). <sup>‡</sup>One patient who was coded as having herpes zoster had herpetic keratitis related to herpes virus infection diagnosed by an ophthalmologist with a positive qualitative chlamydia virus antigen epithelial cells. The patient who was coded as having ophthalmic herpes zoster with swelling of eyelids was referred for ophthalmology consultation, which was noted as normal; there was no corneal/ocular disease related to herpes virus infection. <sup>§</sup>MACE were adjudicated and were defined as nonfatal stroke, nonfatal myocardial infarction, or cardiovascular death. MACE in deucravacitinib-treated patients through 1 year: cardiac failure leading to death; cerebrovascular accident; myocardial infarction. Through Year 5: acute myocardial infarction; n = 8; cerebrovascular accident; n = 2; myocardial infarction; n = 2; and aortic aneurysm rupture, cardiac arrest, cardiac failure leading to death, cerebral hemorrhage, ischemic stroke, sudden death; n = 1 each. <sup>¶</sup>VTE was defined as deep vein thrombosis and pulmonary embolism. VTE events in deucravacitinib-treated patients through 1 year: deep vein thrombosis; pulmonary embolism. Through Year 5: deep vein thrombosis; n = 2; pulmonary embolism; n = 1. <sup>\*\*</sup>Includes preferred terms of squamous cell carcinoma, squamous cell carcinoma of skin, and Bowen's disease. <sup>††</sup>Includes events of breast cancer, colon cancer, lung adenocarcinoma, malignant melanoma, prostate cancer (n = 2 each), acute promyelocytic leukemia, adenocarcinoma of colon, B-cell lymphoma, bladder cancer, colorectal cancer, diffuse large B-cell lymphoma, esophageal carcinoma, hepatocellular carcinoma, Hodgkin's disease, intraductal proliferative breast lesion, intraductal breast carcinoma, metastatic colon cancer, metastatic melanoma, mucosal marginal zone B-cell lymphoma, pancreatic carcinoma, rectal adenocarcinoma, squamous cell carcinoma of the oral cavity, and squamous cell carcinoma of the tongue (n = 1 each). <sup>‡‡</sup>AE, adverse event; CI, confidence interval; EAIR, exposure-adjusted incidence rate; LTE, long-term extension; MACE, major adverse cardiovascular event; NMSC, non-melanoma skin cancer; PY, person-years; QD, once daily; VTE, venous thromboembolism.

### Comparison of deucravacitinib safety with other psoriasis treatments

- EAIRs from the 5-year period remained consistent with findings from long-term clinical trial safety studies, disease registry, and real-world claims data of other approved psoriasis treatments for AEs of interest, including serious infections, MACE, and malignancies excluding nonmelanoma skin cancers (NMSC) (Figure 2)

Figure 2. EAIRs of serious infections, MACE, and malignancies (excluding NMSC) in the phase 3 safety pool at Year 5<sup>a</sup> compared with other psoriasis medications and real-world datasets



### Patient population: efficacy

- Of the 513 patients in the efficacy population who received deucravacitinib from Day 1 and entered the POETYK LTE trial, 207 (40.4%) discontinued before Week 256:
  - 16 (3.1%) due to lack of efficacy
  - 25 (4.9%) due to AEs
  - Other common reasons: 60 (11.7%) due to withdrawal by patient; 46 (9.0%) due to "other" miscellaneous causes as described by the patient; and 23 (4.5%) due to the study being terminated by the sponsor
- As of the data cutoff date, 28 (5.5%) patients were receiving deucravacitinib in the POETYK LTE trial but had not yet reached Week 256

### Efficacy

- PASI 75 (Figure 3), PASI 90 (Figure 4), and sPGA 0/1 (Figure 5) response rates were sustained from Week 52 (beginning of the POETYK LTE trial) through 5 years

Figure 3. PASI 75 response rates in the efficacy population

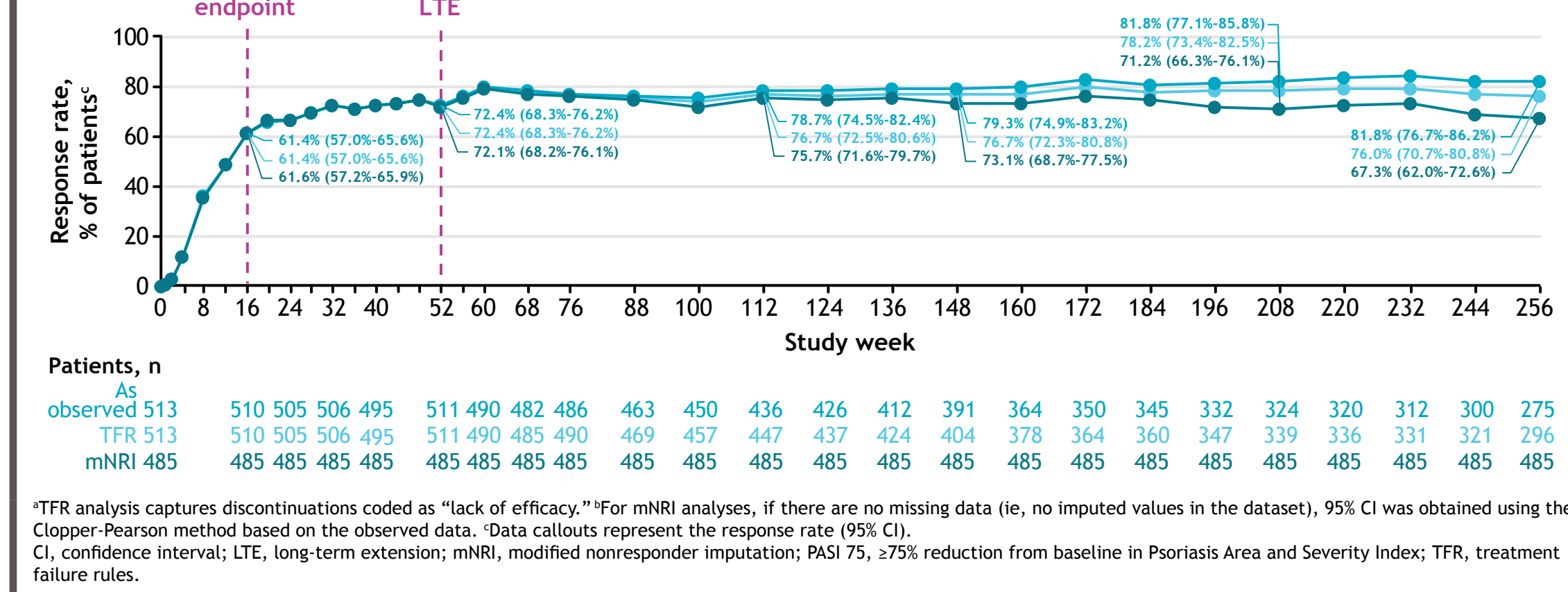


Figure 4. PASI 90 response rates in the efficacy population

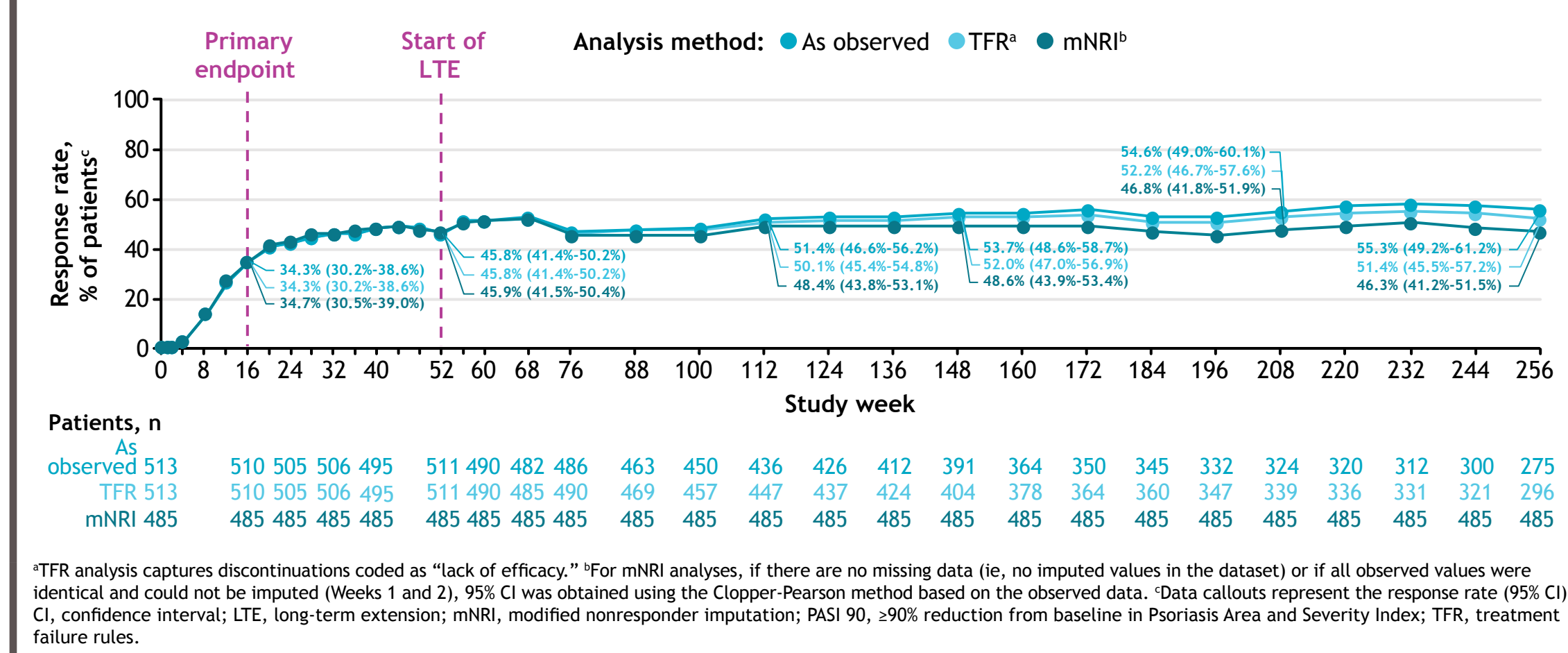
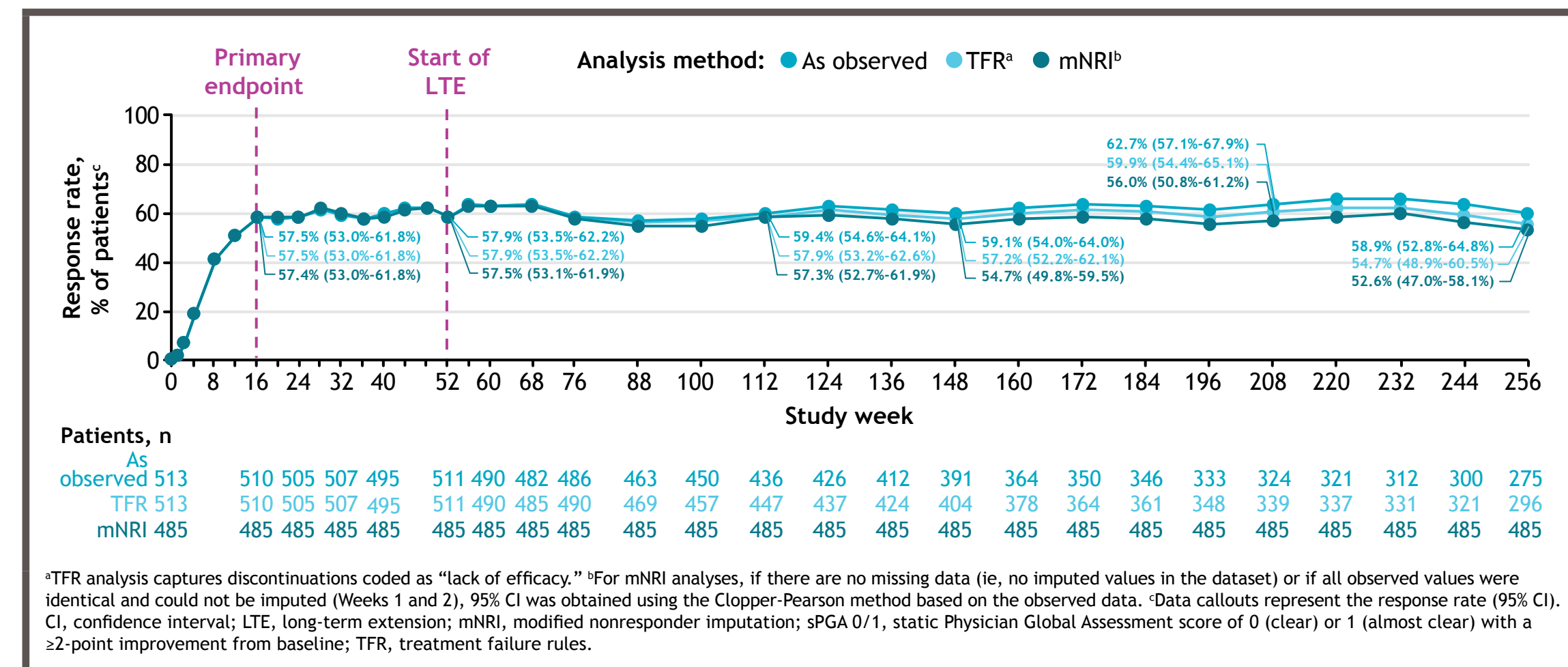


Figure 5. sPGA 0/1 response rates in the efficacy population



## Conclusions

- Deucravacitinib demonstrated a consistent safety profile through 5 years with  $\sim 5000$  PY of exposure and no increases in AE or serious AE rates over time or emergence of any new safety signals
  - Rates of serious infections (minus COVID-19), malignancies, and MACE through 5 years were low and comparable with what has been observed with approved psoriasis treatments in clinical trials and real-world databases
- PASI 75, PASI 90, and sPGA 0/1 responses were sustained through 5 years in over 500 patients treated continuously with deucravacitinib from Day 1 in the parent trials
  - Efficacy results were consistent regardless of imputation method, indicating the robustness of the results
- These data support the long-term safety and durable efficacy profile through 5 years of treatment with deucravacitinib, the first-in-class, allosteric TYK2 inhibitor treatment for psoriasis

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- BS: Consultant (with honoraria): AbbVie, Acelyrin, Alamar, Almirall, Alumis, Amgen, Arcutis, Arana, Aristea, Asano, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas Psoriasis Registry, Dermavant, Eli Lilly, Imagene, Janssen/J&J Innovative Medicine, Kangsu Biopharmaceuticals, Leo Pharma, Maruho, Meiji Seika Pharma, Monte Rosa Therapeutics, Novartis, Pfizer, Protogen, RAPT Therapeutics, Regeneron, Sanofi, Sun Pharma, Takeda, TD Cowen, Union Therapeutics, Ventyx Biosciences, and VTX Therapeutics; Speaker: AbbVie, Arcutis, Dermavant, Eli Lilly, Incyte, Janssen/J&J Innovative Medicine, Regeneron, and Sanofi; Co-scientific director (consulting fee) and investigator: CorEvitas Psoriasis Registry; Editor-in-chief (with honorarium): *Journal of Psoriasis and Psoriatic Arthritis*; Stock options: Connect Biopharma and Minda Health
- AB: Speaker (with honoraria): Lilly and UCB; Scientific adviser (with honoraria): AbbVie, Abcentra, Aclaris, Affibio, Allergan, Almirall, Alumis, Amgen, AnaptyBio, Apogee, Arcutis, Arana, Aslan, Athenex, Bluebird BioMedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Celldex, CTI Biopharma, Dermavant, Ecor1, Eli Lilly, Euflexin, Evolio Biosciences, Evomune, Forte Biosciences, Galderma, HighLight Pharma, Incyte, InovoneBio, Janssen, Landos, Leo Pharma, Lipidion, Microbion, Merck, Monte Rosa Therapeutics, Nektar, Novartis, Overton Therapeutics, Paragon, Pfizer, Q32 Bio, Rami, Rapt, Regeneron, Sanofi Genzyme, Spherix Global Insights Sun Pharma, Takeda, TLL Pharmaceutical, TrialSpark, UCB, Union Therapeutics, Ventyx Biosciences, Viblyme, and Xencor; Clinical study investigator (institution received clinical study funds): AbbVie, Acelyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, DermBiont, Eli Lilly, Evolio Biosciences, Evomune, Galderma, Incyte, Janssen, Leo Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, UCB Pharma, and Ventyx Biosciences; Stock owner: Lipidion and Onkva
- YS: Research grants: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, Jimro, Kyowa Kirin, Leo Pharma, Maruho, Sun Pharma, Taiho Pharmaceutical, Tanabe-Mitsubishi, Torii, and UCB; Honoraria: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eisai, Eli Lilly, Janssen, Jimro, Kyowa Kirin, Leo Pharma, Maruho, Novartis, Pfizer, Sun Pharma, Taiho, Tanabe-Mitsubishi, Torii, and UCB; Consulting fees: AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, Maruho, Novartis, Pfizer, Sanofi, and UCB
- TP: Advisory board and consulting fees: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma