Deucravacitinib in plaque psoriasis: 4-year safety and efficacy results from the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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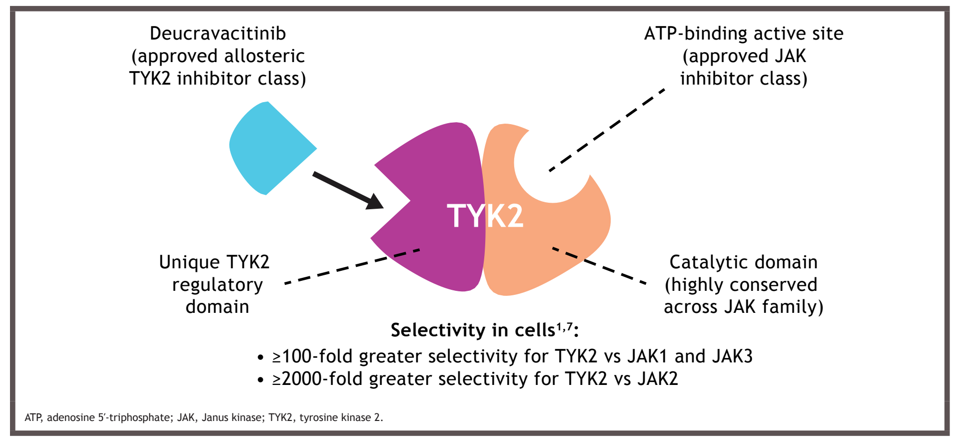
Synopsis

- 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])[1]
  - IL-23 and Type I IFNs are involved in psoriasis pathogenesis[1]
- 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[2-6]
- Deucravacitinib uniquely binds to the TYK2 regulatory domain rather than to the catalytic domain where Janus kinase (JAK) 1,2,3 inhibitors bind[1,7] (**Figure 1**), driving its selectivity for TYK2 and representing the first in a new class of oral drugs

Figure 1. Mechanism of action of deucravacitinib



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

- Two global, 52-week, phase 3 trials, POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751), in patients with moderate to severe plaque psoriasis showed that deucravacitinib 6 mg once daily (QD) was well tolerated and was significantly more efficacious than placebo and apremilast at Week 16 based on achievement of the key endpoints[8,9]:
  - PASI 75 (≥75% reduction from baseline in Psoriasis Area and Severity Index)
  - sPGA 0/1 (static Physician Global Assessment score of 0 [clear] or 1 [almost clear])
- Patients who completed the POETYK PSO-1 and PSO-2 parent trials could enroll in the ongoing POETYK long-term extension (LTE) trial (NCT04036435) and receive open-label deucravacitinib
- Clinical efficacy was previously reported to be maintained well through 3 years, with no new safety signals compared with Year 2, in deucravacitinib-treated patients who entered the POETYK LTE trial[10,11]

Objective

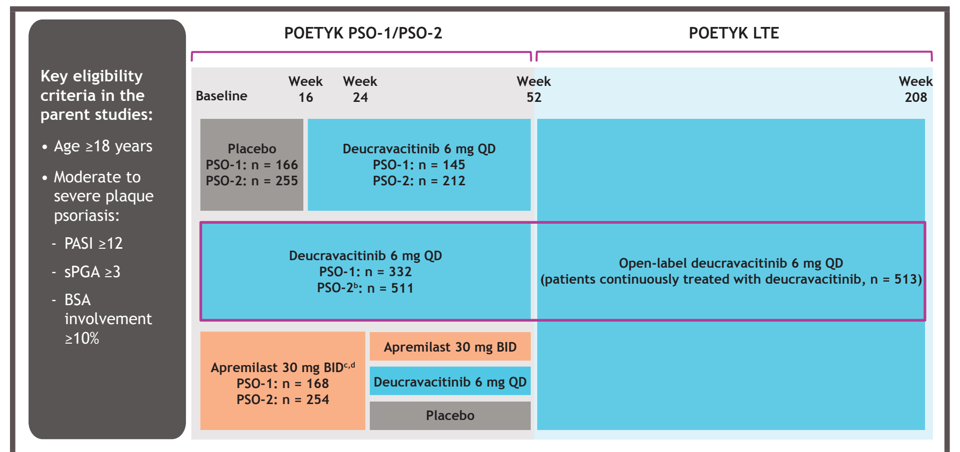
- To report the safety and efficacy of deucravacitinib for an additional year through 4 years (Week 208; cutoff date, November 1, 2023) in patients with moderate to severe plaque psoriasis who participated in the POETYK PSO-1, PSO-2, and LTE trials

Methods

Study designs

- In the POETYK PSO-1 and PSO-2 trials, adults with moderate to severe plaque psoriasis (PASI ≥12, sPGA ≥3, and body surface area involvement ≥10% at baseline) were randomized 1:2:1 to oral placebo, deucravacitinib 6 mg QD, or apremilast 30 mg twice daily (BID) (**Figure 2**)
- At Week 52, eligible patients were allowed to enroll in the POETYK LTE trial and receive open-label deucravacitinib 6 mg QD

Figure 2. POETYK PSO-1, PSO-2, and LTE study designs and analysis populations[a]



[a]Data reported through the POETYK LTE trial cutoff date of November 1, 2023. [b]In POETYK PSO-2, patients randomized to deucravacitinib on Day 1 who achieved PASI 75 at Week 24 were rerandomized to placebo or deucravacitinib; for patients who were rerandomized to placebo, upon relapse (≥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. [c]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 relapse; however, due to a programming error, these patients continued to receive placebo until Week 52. [d]Apremilast was titrated from 10 mg QD to 30 mg BID over the first 5 days of dosing.
BID, twice daily; BSA, body surface area; LTE, long-term extension; PASI, Psoriasis Area and Severity Index; PASI 75, ≥75% reduction from baseline in PASI; QD, once daily; sPGA, static Physician Global Assessment.

Analysis populations

- Safety population: patients receiving ≥1 dose of deucravacitinib at any time in the pooled parent (POETYK PSO-1 and PSO-2) and POETYK LTE trials over 4 years in the as-treated population
  - Adverse events (AEs) were ascribed to the assigned treatment when the event first occurred
- 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 Week 208

Outcomes

- Safety outcomes: AEs, serious AEs (SAEs), deaths, AEs leading to treatment discontinuation, and AEs of interest through the last data cutoff date of November 1, 2023
- Efficacy outcomes: achievement of PASI 75, ≥90% reduction from baseline in PASI (PASI 90), 100% reduction from baseline in PASI (PASI 100), sPGA 0/1, and sPGA 0

Statistical analysis

- Efficacy and safety were analyzed through the data cutoff date of November 1, 2023 (Week 208, 4 years)
- Safety data were reported as exposure-adjusted incidence rate (EAIR)/100 person-years (PY) and calculated as 100 * (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 methods of imputation for missing data were used as sensitivity analyses for efficacy
  - **Treatment failure rules (TFR)**[12]: 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)**[13]: patients who either discontinued prior to Week 208 or reached Week 208 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 demographics and disease characteristics for patients who received continuous deucravacitinib from Day 1 (n = 513) are presented in **Table 1**

Table 1. Baseline patient demographics and disease characteristics for the efficacy population

Parameter	Patients receiving continuous deucravacitinib[a] (n = 513)
Age, mean (SD), y	46.9 (13.3)
Weight, mean (SD), kg	89.9 (22.2)
Body mass index, mean (SD), kg/m^2	30.3 (7.0)
Female, n (%)	159 (31.0)
Race, n (%)	
White	440 (85.8)
Asian	64 (12.5)
Black or African American	5 (1.0)
Other	4 (0.8)
Disease duration, mean (SD), y	18.8 (12.6)
Prior systemic therapy, n (%)	300 (58.5)
Prior systemic biologic	191 (37.2)
Prior systemic non-biologic	206 (40.2)
Systemic therapy naive, n (%)	213 (41.5)
PASI score, mean (SD)	21.1 (7.9)
sPGA score, n (%)	
3 (moderate)	401 (78.2)
4 (severe)	112 (21.8)
BSA involvement, mean (SD), %	26.9 (15.8)

[a]Randomized to deucravacitinib in the parent trials and entering the POETYK LTE trial.
BSA, body surface area; PASI, Psoriasis Area and Severity Index; SD, standard deviation; sPGA, static Physician Global Assessment.

Deucravacitinib exposure

- Exposure data through 4 years are shown in **Table 2**

Table 2. Deucravacitinib exposure of the safety population through Week 208 (4 years)

Exposure	Deucravacitinib 6 mg QD (n = 1519)
Total exposure, PY	**4392.8**
Median (min, max) exposure, days	1298.0 (1, 1893)
≥4 months of exposure, n (%)	1407 (92.6)
≥12 months of exposure, n (%)	1203 (79.2)
≥24 months of exposure, n (%)	1050 (69.1)
≥36 months of exposure, n (%)	906 (59.6)
≥48 months of exposure, n (%)	542 (35.7)

This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of November 1, 2023.
LTE, long-term extension; max, maximum; min, minimum; PY, person-years; QD, once daily.

Overall safety

- A cumulative safety summary is presented in **Table 3**
- Aside from higher rates of COVID-19 due to the concurrent global pandemic, incidence rates of AEs (EAIR = n/100 PY) decreased from 1 year to 4 years

Table 3. Cumulative safety summary through 1 year and 4 years (as-treated population)

AE category	Cumulative through 1 year[a] (POETYK PSO-1 + PSO-2) Deucravacitinib (n = 1364) Total PY = 969.0: 1-Year cumulative n (%)	EAIR/100 PY (95% CI)	Cumulative through 4 years[b] (POETYK PSO-1 + PSO-2 + LTE) Deucravacitinib (n = 1519) Total PY = 4392.8: 4-Year cumulative n (%)	EAIR/100 PY (95% CI)
AEs	995 (72.9)	**229.2 (215.4-243.9)**	1301 (85.6)	**131.7 (124.6-139.0)**
SAEs	55 (4.0)	**5.7 (4.4-7.4)**	205 (13.5)	**5.0 (4.4-5.8)**
Discontinued treatment due to AEs	43 (3.2)	**4.4 (3.3-5.9)**	97 (6.4)	**2.2 (1.8-2.7)**
Deaths	2 (0.1)[c]	**0.2 (0.1-0.8)**	11 (0.7)[d]	**0.3 (0.1-0.4)**
Most common AEs (EAIR ≥5/100 PY)				
Nasopharyngitis	229 (16.8)	**26.1 (23.0-29.8)**	343 (22.6)	**9.7 (8.7-10.8)**
Upper respiratory tract infection	124 (9.1)	**13.4 (11.3-16.0)**	240 (15.8)	**6.1 (5.4-6.9)**
Headache	80 (5.9)	**8.5 (6.8-10.5)**	117 (7.7)	**2.8 (2.3-3.4)**
Diarrhea	69 (5.1)	**7.3 (5.7-9.2)**	99 (6.5)	**2.4 (1.9-2.9)**
Arthralgia	55 (4.0)	**5.7 (4.4-7.4)**	117 (7.7)	**2.8 (2.3-3.4)**
COVID-19[e]	5 (0.4)	**0.5 (0.1-1.2)**	321 (21.1)	**8.3 (7.4-9.3)**

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. [a]This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0-52). [b]This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of November 1, 2023. [c]In POETYK PSO-1 and PSO-2 through 1 year, 1 patient discontinued deucravacitinib after 4 days of treatment due to prohibited medication (leflunomide) 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. [d]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 by the investigator 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 unrelated to treatment by the investigator. One patient died due to sudden death, which was considered not related to treatment by the investigator. [e]POETYK PSO-1, PSO-2, and LTE trials were conducted during the COVID-19 pandemic.
AE, adverse event; CI, confidence interval; EAIR, exposure-adjusted incidence rate; LTE, long-term extension; PY, person-years; QD, once daily; SAE, serious adverse event.

AEs of interest

- The EAIRs of AEs of interest from the 4-year cumulative period (**Table 4**) remained comparable to findings from long-term clinical safety studies, disease registries, and real-world claims data of other approved psoriasis treatments
- The rate of serious infections was higher at 4 years than at 1 year; the peak of the global COVID-19 pandemic occurred during Years 2 and 3 of the POETYK LTE trial
  - When COVID-19 was excluded from the 4-year analysis, the rate of serious infections was lower at 4 years (EAIR/100 PY [95% confidence interval (CI)], 0.8 [0.6-1.1])
  - The rate of serious infections with COVID-19 excluded was comparable to long-term clinical safety studies of other psoriasis treatments (0.97-1.1/100 PY)
- The rate of herpes zoster decreased from Year 1 to Year 4
- Incidence rates for adjudicated major adverse cardiovascular events (MACE) were low and comparable through 1 year and 4 years
  - Rates of MACE with deucravacitinib treatment through 4 years were comparable to long-term clinical safety studies of other psoriasis treatments (0.3-0.4/100 PY)
- Incidence rates for malignancies were low and comparable through 1 year and 4 years
  - The rate of malignancy (excluding nonmelanoma skin cancer [NMSC]) with deucravacitinib through 4 years was consistent with other trials (0.4-0.6/100 PY)
  - The rate of NMSC in patients treated with deucravacitinib was consistent with other trials (0.3-0.5/100 PY), and the ratio of basal cell to squamous cell carcinoma remained at least 2:1
- No venous thromboembolism (VTE) or lymphoma events were observed in Year 3 or Year 4

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

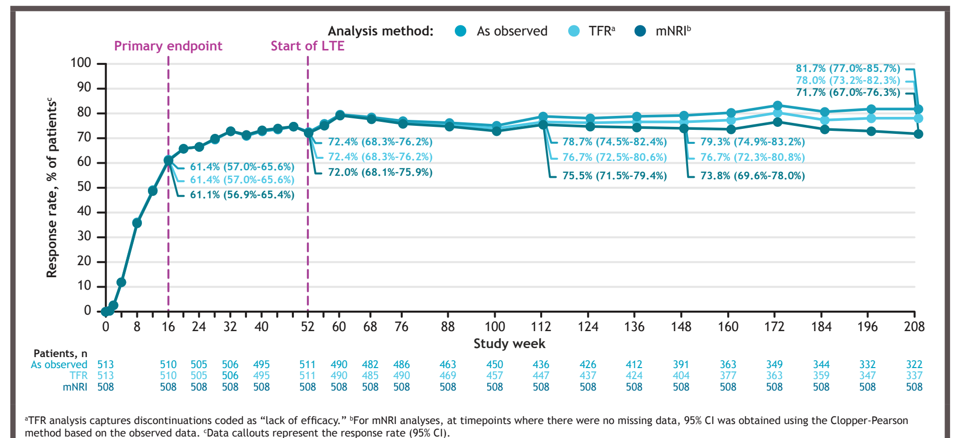
AE category	Cumulative through 1 year[a] (POETYK PSO-1 + PSO-2) Deucravacitinib (n = 1364) Total PY = 969.0: 1-Year cumulative n (%)	EAIR/100 PY (95% CI)	Cumulative through 4 years[b] (POETYK PSO-1 + PSO-2 + LTE) Deucravacitinib (n = 1519) Total PY = 4392.8: 4-Year cumulative n (%)	EAIR/100 PY (95% CI)
Serious infections	17 (1.2)	**1.7 (1.1-2.8)**	85 (5.6)	**2.0 (1.6-2.5)**
Serious COVID-19 infections				
Serious COVID-19	2 (0.1)	**0.2 (0.1-0.8)**	38 (2.5)	**0.9 (0.6-1.2)**
Serious COVID-19 pneumonia	0	**0**	16 (1.1)	**0.4 (0.2-0.6)**
Herpes zoster (non-serious)				
Herpes zoster[c]	8 (0.6)	**0.8 (0.4-1.6)**	24 (1.6)	**0.6 (0.4-0.8)**
Ophthalmic herpes zoster[d]	1 (0.1)	**0.1 (0.0-0.7)**	1 (0.1)	**0.0 (0.0-0.1)**
MACE[e]	3 (0.2)	**0.3 (0.1-0.9)**	14 (0.9)	**0.3 (0.2-0.5)**
VTE[f]	2 (0.1)	**0.2 (0.1-0.8)**	3 (0.2)	**0.1 (0.0-0.2)**
Malignancies	10 (0.7)	**1.0 (0.5-1.9)**	39 (2.6)	**0.9 (0.6-1.2)**
NMSC	7 (0.5)	**0.7 (0.3-1.5)**	18 (1.2)	**0.4 (0.2-0.7)**
Basal cell carcinoma	4 (0.3)	**0.4 (0.2-1.1)**	13 (0.9)	**0.3 (0.2-0.5)**
Squamous cell carcinoma[g]	2 (0.1)	**0.2 (0.1-0.8)**	5 (0.3)	**0.1 (0.0-0.3)**
Malignancies excluding NMSC	3 (0.2)	**0.3 (0.1-0.9)**	22 (1.4)[h]	**0.5 (0.3-0.8)**
Lymphoma	1 (0.1)	**0.1 (0.0-0.7)**	3 (0.2)	**0.1 (0.0-0.2)**
Hodgkin's disease	1 (0.1)	**0.1 (0.0-0.7)**	1 (0.1)	**0.0 (0.0-0.1)**
Leukemia	0	**0**	1 (0.1)	**0.0 (0.0-0.1)**

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. [a]This represents the pooled patient population of POETYK PSO-1 and PSO-2 (Weeks 0-52). [b]This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of November 1, 2023. [c]One patient who was coded as having herpes zoster had corneal/ocular disease related to herpes virus infection diagnosed by an ophthalmologist with a positive qualitative chickenpox virus antigen (epithelial cells). [d]One 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. [e]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 4 years: acute myocardial infarction (n = 5), cerebrovascular accident (n = 2), myocardial infarction (n = 2), aortic aneurysm rupture, cardiac arrest, cardiac failure leading to death, cerebral hemorrhage, ischemic stroke, sudden death. [f]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 4 years: deep vein thrombosis (n = 2), pulmonary embolism. The second deep vein thrombosis event occurred in Year 2. [g]Includes preferred terms of squamous cell carcinoma, squamous cell carcinoma of skin, and Bowen's disease. [h]Includes events of breast cancer (n = 2), invasive ductal breast carcinoma, intraductal proliferative breast lesion, lung adenocarcinoma (n = 2), colon cancer (n = 2), metastatic colon cancer, adenocarcinoma of colon, colorectal cancer, pancreatic carcinoma, hepatocellular carcinoma, B-cell lymphoma, nodal marginal zone B-cell lymphoma, Hodgkin's disease, acute promyelocytic leukemia, malignant melanoma (n = 2), esophageal carcinoma, prostate cancer, squamous cell carcinoma of the tongue, and squamous cell carcinoma of the oral cavity.
AE, adverse event; CI, confidence interval; EAIR, exposure-adjusted incidence rate; LTE, long-term extension; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer; PY, person-years; QD, once daily; VTE, venous thromboembolism.

Efficacy

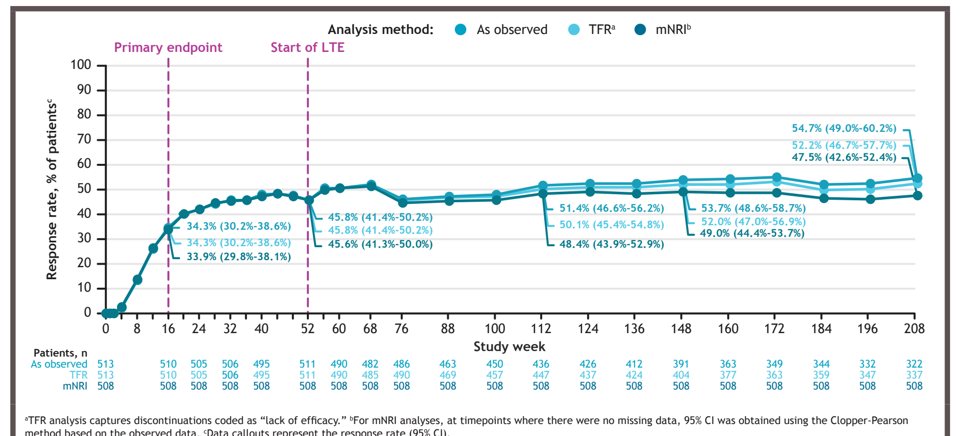
- PASI 75 (**Figure 3**), PASI 90 (**Figure 4**), and PASI 100 (**Figure 5**) response rates were sustained well from Week 52 (beginning of the POETYK LTE trial) through 4 years
- sPGA 0/1 (**Figure 6**) and sPGA 0 (**Figure 7**) response rates were sustained well from Week 52 (beginning of the POETYK LTE trial) through 4 years

Figure 3. PASI 75 response rates in the efficacy population



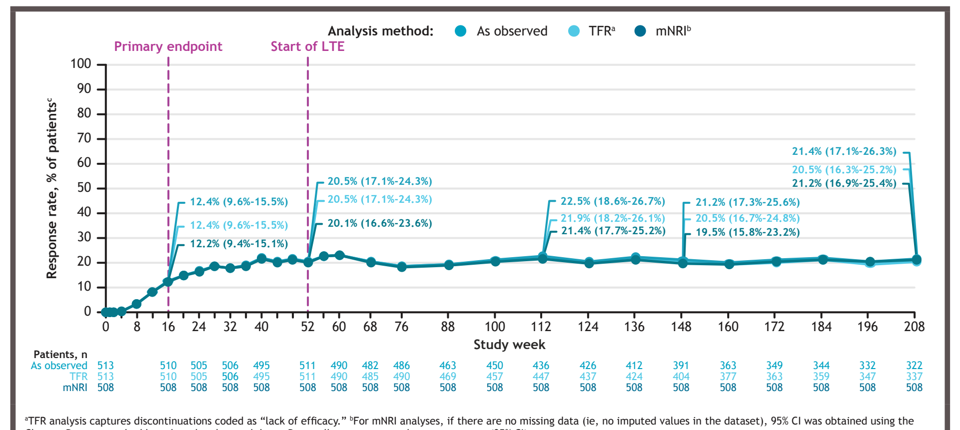
[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, at timepoints where there were no missing data, 95% CI was obtained using the Clopper-Pearson method based on the observed data. [c]Data callouts represent the response rate (95% CI).
CI, confidence interval; LTE, long-term extension; mNRI, modified nonresponder imputation; PASI 75, ≥75% reduction from baseline in Psoriasis Area and Severity Index; TFR, treatment failure rules.

Figure 4. PASI 90 response rates in the efficacy population



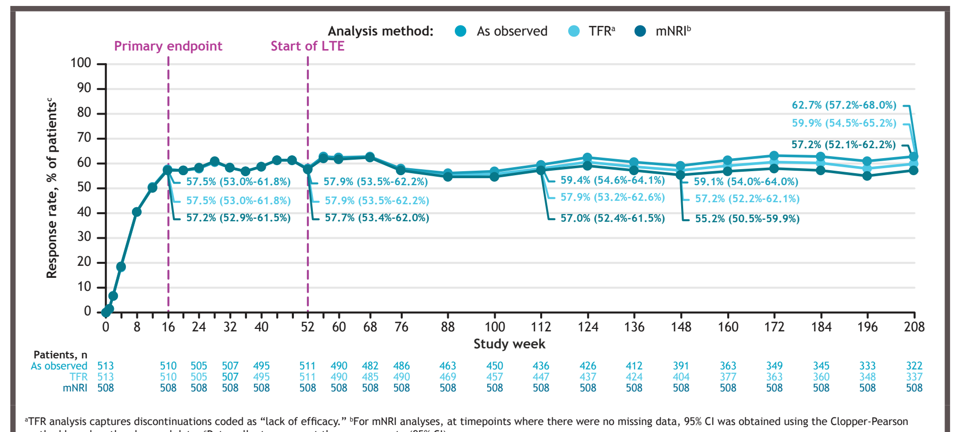
[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, at timepoints where there were no missing data, 95% CI was obtained using the Clopper-Pearson method based on the observed data. [c]Data callouts represent the response rate (95% CI).
CI, confidence interval; LTE, long-term extension; mNRI, modified nonresponder imputation; PASI 90, ≥90% reduction from baseline in Psoriasis Area and Severity Index; TFR, treatment failure rules.

Figure 5. PASI 100 response rates in the efficacy population



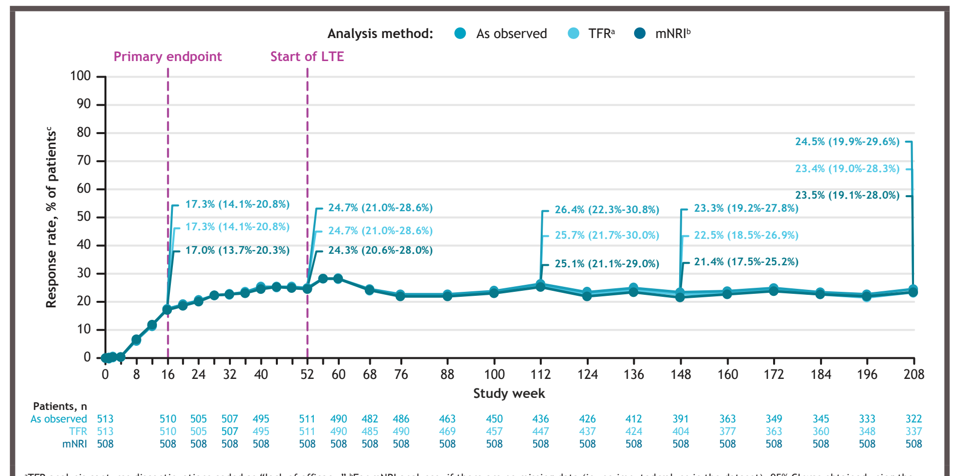
[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, if there are no missing data (ie, no imputed values in the dataset), 95% CI was obtained using the Clopper-Pearson method based on the observed data. [c]Data callouts represent the response rate (95% CI).
CI, confidence interval; LTE, long-term extension; mNRI, modified nonresponder imputation; PASI 100, 100% reduction from baseline in Psoriasis Area and Severity Index; TFR, treatment failure rules.

Figure 6. sPGA 0/1 response rates in the efficacy population



[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, at timepoints where there were no missing data, 95% CI was obtained using the Clopper-Pearson method based on the observed data. [c]Data callouts represent the response rate (95% CI).
CI, confidence interval; LTE, long-term extension; mNRI, modified nonresponder imputation; sPGA 0/1, static Physician Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline; TFR, treatment failure rules.

Figure 7. sPGA 0 response rates in the efficacy population



[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, if there are no missing data (ie, no imputed values in the dataset), 95% CI was obtained using the Clopper-Pearson method based on the observed data. [c]Data callouts represent the response rate (95% CI).
CI, confidence interval; LTE, long-term extension; mNRI, modified nonresponder imputation; sPGA 0, static Physician Global Assessment score of 0 (clear) and a ≥2-point improvement from baseline; TFR, treatment failure rules.

Conclusions

- Deucravacitinib demonstrated a consistent safety profile through 4 years with >4000 PY of exposure and with no increases in AE or SAE rates over time and no emergence of any new safety signals, except for increased rates of COVID-19 due to the concurrent global pandemic
  - Rates of serious infections (minus COVID-19), malignancies, and MACE through 4 years were comparable with what has been observed with approved psoriasis treatments in clinical trials and real-world databases
- PASI 75, PASI 90, PASI 100, sPGA 0/1, and sPGA 0 response rates were sustained through 4 years in over 500 patients treated continuously with deucravacitinib from Day 1 in the parent trials
- These data support the long-term safety and durable efficacy profile through 4 years of treatment with deucravacitinib, a first-in-class TYK2 inhibitor treatment for psoriasis

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Disclosures

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