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

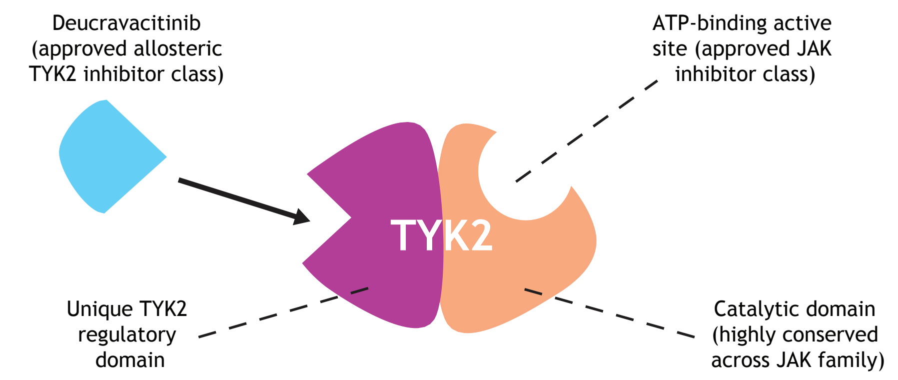
April W. Armstrong,[1] Mark Lebwohl,[2] Richard B. Warren,[3] Howard Sofen,[1,4] Shinichi Imafuku,[5] Mamitaro Ohtsuki,[6] Lynda Spelman,[7] Thierry Passeron,[8] Kim A. Papp,[9] Renata M. Kisa,[10] Victoria Berger,[10] Eleni Vritzali,[10] Kim Hoyt,[10] Matthew J. Colombo,[10] Subhashis Banerjee,[10] Bruce Strober,[11] Diamant Thaçi,[12] Andrew Blauvelt[13]

[1]University of California Los Angeles, Los Angeles, CA, USA; [2]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Salford, and NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Centre, Manchester, UK; [4]Dermatology Research Associates, Los Angeles, CA, USA; [5]Fukuoka University Faculty of Medicine, Fukuoka, Japan; [6]Jichi Medical University, Tochigi, Japan; [7]Veracity Clinical Research and Probity Medical Research, Brisbane, QLD, Australia; [8]Université Côte d'Azur, University Hospital of Nice, Nice, France; [9]Alliance Clinical Trials and Probity Medical Research, Waterloo, and the University of Toronto School of Medicine, Toronto, ON, Canada; [10]Bristol Myers Squibb, Princeton, NJ, USA; [11]Yale University School of Medicine, New Haven, and Central Connecticut Dermatology Research, Cromwell, CT, USA; [12]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [13]Oregon Medical Research Center, Portland, OR, USA

Background

- Tyrosine kinase 2 (TYK2) is an intracellular enzyme that mediates signaling of cytokines (eg, interleukin-23, Type I interferons) that 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 regulatory domain of TYK2 rather than to the catalytic domain where Janus kinase (JAK) 1,2,3 inhibitors bind[1,7] (**Figure 1**), representing the first in a new class of small molecules

Figure 1. Mechanism of action of deucravacitinib



Selectivity in cells[1,7]:
- ≥100-fold greater selectivity for TYK2 vs JAK1 and JAK3
- ≥2000-fold greater selectivity for TYK2 vs JAK2

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

- Two global phase 3 trials, POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751), demonstrated that in patients with moderate to severe plaque psoriasis, deucravacitinib 6 mg once daily (QD) was significantly more efficacious than placebo and apremilast based on the coprimary endpoints of ≥75% reduction from baseline in the Psoriasis Area and Severity Index (PASI 75) and static Physician 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[8,9]
  - Clinical responses were maintained through 52 weeks in patients who received continuous deucravacitinib treatment from Day 1[10]
- 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 shown to be maintained well through 2 years with no new safety signals compared with Year 1 in deucravacitinib-treated patients who entered the POETYK LTE trial[11,12]

Objective

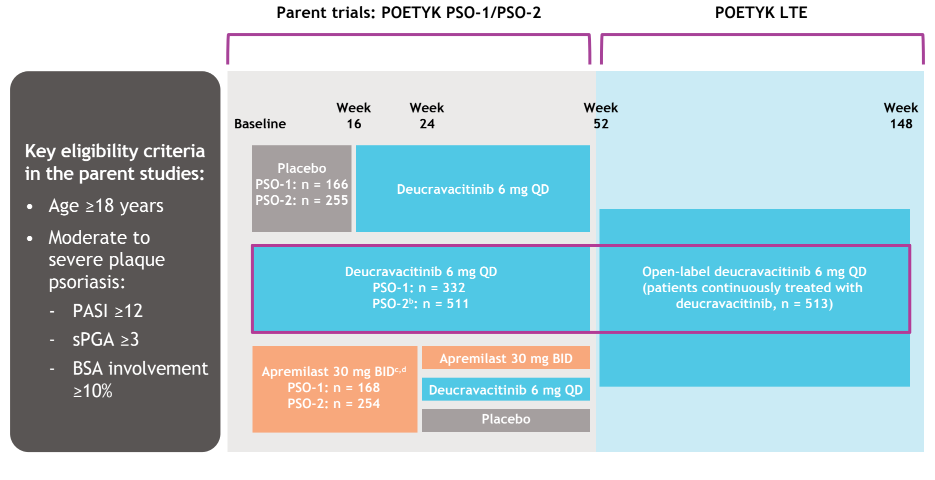
- To report the safety and efficacy of deucravacitinib for up to 3 years (Week 148) through the cutoff date (June 15, 2022) in patients with moderate to severe plaque psoriasis who participated in the POETYK PSO-1 and PSO-2 trials

Methods

Study design

- POETYK PSO-1 and PSO-2 were global, 52-week, phase 3, double-blind trials that randomized adults with moderate to severe plaque psoriasis 1:2:1 to oral placebo, deucravacitinib 6 mg QD, or apremilast 30 mg twice daily (BID) (**Figure 2**):
  - Patients randomized to placebo crossed over to deucravacitinib at Week 16
  - Patients randomized to deucravacitinib continued treatment through Week 52
  - Patients randomized to apremilast who did not achieve ≥50% reduction from baseline in PASI (PASI 50) (in POETYK PSO-1) or PASI 75 (in POETYK PSO-2) crossed over to deucravacitinib at Week 24
- 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 analysis populations[a]



[a]Includes patients with ≥1 dose of deucravacitinib 6 mg QD, n = 1519. [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: pooled parent trials (POETYK PSO-1 and PSO-2) and the POETYK LTE trial over 3 years in the as-treated population (patients receiving ≥1 dose of deucravacitinib)
  - Adverse events (AEs) were ascribed to the treatment group that patients were assigned to when the event first occurred
- Efficacy population: pooled parent trial (POETYK PSO-1 and PSO-2) patients who received continuous deucravacitinib treatment from Day 1 of the parent trials through Week 148

Outcomes

- Safety outcomes: AEs, serious AEs (SAEs), deaths, AEs leading to treatment discontinuation, and AEs of interest through the last data cutoff date of June 15, 2022
- Efficacy outcomes: achievement of PASI 75, ≥90% reduction from baseline in PASI (PASI 90), and sPGA 0/1

Statistical analysis

- Analyses of efficacy measures were conducted through the data cutoff date of June 15, 2022 (Week 148)
- Two methods for imputation of missing data were used as sensitivity analyses in addition to observed values:
  - **Treatment failure rules (TFR)**[13]: 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)**[14]: patients who either discontinued prior to Week 148 or reached Week 148 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
- Safety data were reported as exposure-adjusted incidence rate (EAIR) per 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])

Results

Patients

- A total of 1519 patients received ≥1 dose of deucravacitinib across the parent trials (POETYK PSO-1 and PSO-2) and the POETYK LTE trial
  - 843 patients were randomized to deucravacitinib on Day 1 and, of these, 513 patients were continuously treated with deucravacitinib, completed POETYK PSO-1 and PSO-2, and entered the POETYK LTE trial
- Baseline patient demographics and disease characteristics for the overall population are presented in **Table 1**

Exposure

- Exposure data through 36 months is shown in **Table 2**

Table 1. Baseline patient demographics and disease characteristics for the overall 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)
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)
Age at disease onset, mean (SD), y	29.0 (14.7)
Disease duration, mean (SD), y	18.8 (12.6)
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; LTE, long-term extension; PASI, Psoriasis Area and Severity Index; SD, standard deviation; sPGA, static Physician Global Assessment.

Table 2. Extent of exposure to deucravacitinib

Exposure	Deucravacitinib 6 mg QD (n = 1519)
≥1 dose, n (%)	1519 (100)
≥16 weeks of exposure, n (%)	1407 (92.6)
>12 months of exposure, n (%)	1178 (77.6)
>24 months of exposure, n (%)	1029 (67.7)
>36 months of exposure, n (%)	341 (22.4)
Total exposure, PY	**3294.3**
Median (min, max) exposure, days	935.0 (1, 1467)

This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of June 15, 2022.
LTE, long-term extension; min, max, minimum, maximum; PY, person-years; QD, daily.

Overall safety

- Overall cumulative safety outcomes through 2 and 3 years are presented in **Table 3**
- Aside from a slightly higher COVID-19 rate, AE rates through 3 years remained consistent with rates observed through 2 years

AEs of interest

- The incidence rates for major adverse cardiovascular events (MACE) and malignancies were low and were comparable through 2 and 3 years (**Table 4**)
- No venous thromboembolism (VTE) events or lymphoma were observed in Year 3

Table 3. Cumulative safety summary through 2 years and 3 years (as-treated population)

AE category	Cumulative through 2 years[a] (POETYK PSO-1 + PSO-2 + LTE)		Cumulative through 3 years[b] (POETYK PSO-1 + PSO-2 + LTE)	
	Deucravacitinib (n = 1519) Total PY = 2482.0		Deucravacitinib (n = 1519) Total PY = 3294.3	
	n (%)	EAIR/100 PY (95% CI)	n (%)	EAIR/100 PY (95% CI)
AEs	1214 (79.9)	**154.4 (146.0-163.4)**	1269 (83.5)	**144.8 (137.1-153.0)**
SAEs	145 (9.5)	**6.1 (5.2-7.2)**	167 (11.0)	**5.5 (4.7-6.4)**
Discontinued treatment due to AEs	69 (4.5)	**2.8 (2.2-3.5)**	78 (5.1)	**2.4 (2.0-3.0)**
Deaths	10 (0.7)[c]	**0.4 (0.2-0.7)**	10 (0.7)[d]	**0.3 (0.2-0.6)**
Most common AEs (EAIR/100 PY ≥5)				
Nasopharyngitis	271 (17.8)	**12.9 (11.5-14.5)**	302 (19.9)	**11.4 (10.2-12.7)**
COVID-19[e]	124 (8.2)	**5.1 (4.3-6.1)**	242 (15.9)	**8.0 (7.1-9.1)**
Upper respiratory tract infection	150 (9.9)	**6.5 (5.6-7.7)**	182 (12.0)	**6.2 (5.4-7.2)**

Not all patients were receiving deucravacitinib 6 mg QD continuously throughout this period. [a]This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of October 1, 2021. [b]This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of June 15, 2022. [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 due to heart failure and sepsis. 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. After Week 52, 6 deaths were due to COVID-19 (all in patients with risk factors for severe disease), and 1 was due to a ruptured aortic aneurysm in a patient with cardiovascular risk factors. One patient died due to an unknown cause >30 days after discontinuing treatment but was originally included in the 2-year data; this patient was not included in the 3-year data. [d]One additional death was due to COVID-19. [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.

Table 4. Cumulative AEs of interest through 2 years and 3 years (as-treated population)

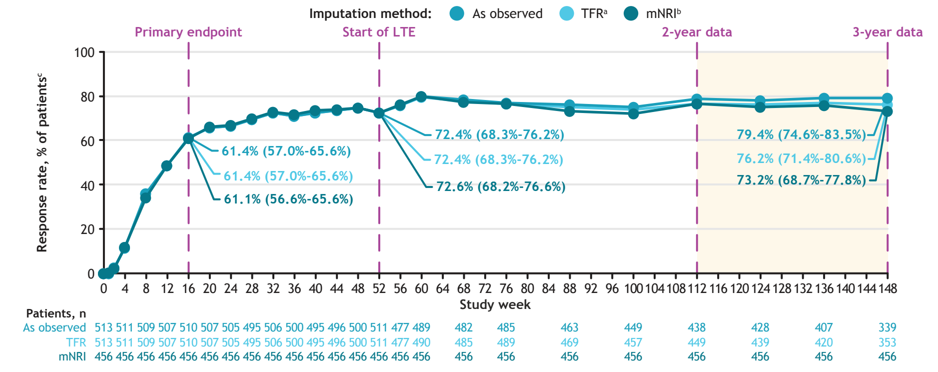
AE category	Cumulative through 2 years[a] (POETYK PSO-1 + PSO-2 + LTE)		Cumulative through 3 years[b] (POETYK PSO-1 + PSO-2 + LTE)	
	Deucravacitinib (n = 1519) Total PY = 2482.0		Deucravacitinib (n = 1519) Total PY = 3294.3	
	n (%)	EAIR/100 PY (95% CI)	n (%)	EAIR/100 PY (95% CI)
Serious infections	64 (4.2)	**2.6 (2.0-3.3)**	77 (5.1)	**2.5 (2.0-3.1)**
Herpes zoster				
Herpes zoster[c]	17 (1.1)	**0.7 (0.4-1.1)**	19 (1.3)	**0.6 (0.4-0.9)**
Ophthalmic herpes zoster[d]	1 (0.1)	**0 (0.0-0.3)**	1 (0.1)	**0.03 (0.0-0.22)**
COVID-19				
Serious COVID-19	30 (2.0)	**1.2 (0.8-1.7)**	37 (2.4)	**1.2 (0.8-1.6)**
Serious COVID-19 pneumonia	13 (0.9)	**0.5 (0.3-0.9)**	14 (0.9)	**0.4 (0.3-0.7)**
MACE[e]	9 (0.6)	**0.4 (0.2-0.7)**	11 (0.7)	**0.3 (0.2-0.6)**
VTE[f]	3 (0.2)	**0.1 (0.0-0.4)**	3 (0.2)	**0.1 (0.0-0.3)**
Malignancies	22 (1.4)	**0.9 (0.6-1.3)**	28 (1.8)	**0.9 (0.6-1.3)**
NMSC	11 (0.7)	**0.4 (0.2-0.8)**	14 (0.9)	**0.4 (0.3-0.7)**
Basal cell carcinoma	8 (0.5)	**0.3 (0.2-0.6)**	10 (0.7)	**0.3 (0.2-0.6)**
Squamous cell carcinoma[g]	4 (0.3)	**0.2 (0.1-0.4)**	4 (0.3)	**0.1 (0.0-0.3)**
Malignancies excluding NMSC	12 (0.8)	**0.5 (0.3-0.8)**	15 (1.0)[h]	**0.5 (0.3-0.8)**
Lymphoma	3 (0.2)	**0.1 (0.0-0.4)**	3 (0.2)	**0.1 (0.0-0.3)**
Hodgkin's disease	1 (0.1)	**0 (0.0-0.3)**	1 (0.1)	**0 (0.0-0.2)**
Leukemia	1 (0.1)	**0 (0.0-0.3)**	1 (0.1)	**0 (0.0-0.2)**

Not all patients were receiving deucravacitinib 6 mg QD continuously throughout this period. [a]This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of October 1, 2021. [b]This represents the pooled POETYK PSO-1, PSO-2, and LTE population through the cutoff date of June 15, 2022. [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 non-fatal stroke, non-fatal myocardial infarction, or cardiovascular death. [f]VTE was defined as deep vein thrombosis and pulmonary embolism. [g]Includes preferred terms of squamous cell carcinoma, squamous cell carcinoma of skin, and Bowen's disease. [h]Includes events of breast cancer and malignant melanoma (n = 2) and acute promyelocytic leukemia, B-cell lymphoma, colon cancer, colorectal cancer, pancreatic carcinoma, hepatocellular carcinoma, Hodgkin's disease, intraductal proliferative breast lesion, invasive ductal breast carcinoma, lung adenocarcinoma, nodal marginal zone B-cell lymphoma, and squamous cell carcinoma of the oral cavity (n = 1 each).
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

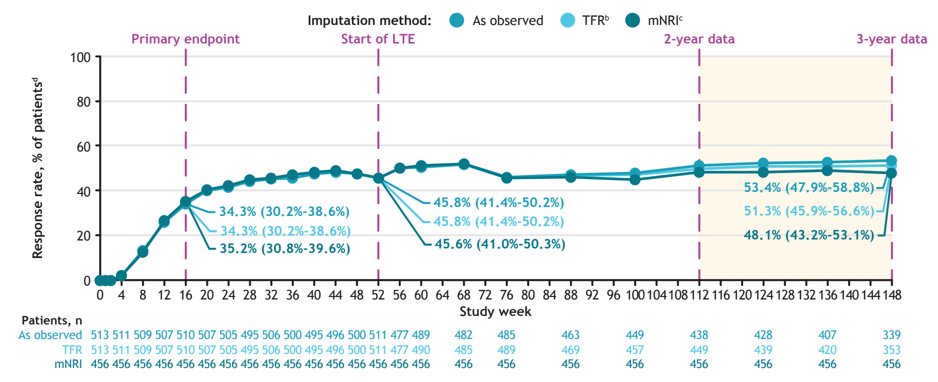
- The proportion of patients who achieved PASI 75, PASI 90, and sPGA 0/1 was sustained well from Week 52 (beginning of the POETYK LTE trial) through Week 148 (**Figure 3**, **Figure 4**, and **Figure 5**, respectively)
  - The response rates were comparable using as-observed, TFR, or mNRI imputation methods

Figure 3. PASI 75 response rates with continuous deucravacitinib treatment from Day 1 to 3 years



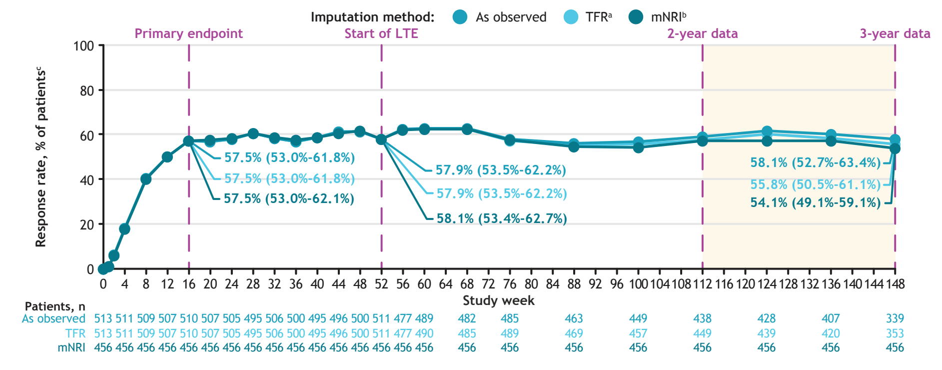
[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, at timepoints where there are no missing data, 95% CI was obtained using the Clopper-Pearson method based on the observed data. [c]Data callouts represent the response rate (95% CI).
CI, confidence interval; 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[a] response rates with continuous deucravacitinib treatment from Day 1 to 3 years



[a]PASI 90 results were not estimable at Weeks 1 and 2 using mNRI. [b]TFR analysis captures discontinuations coded as "lack of efficacy." [c]For mNRI analyses, at timepoints where there are no missing data, 95% CI was obtained using the Clopper-Pearson method based on the observed data. [d]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. sPGA 0/1 response rates with continuous deucravacitinib treatment from Day 1 to 3 years



[a]TFR analysis captures discontinuations coded as "lack of efficacy." [b]For mNRI analyses, at timepoints where there are 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.

Conclusions

- Deucravacitinib demonstrated a consistent safety profile through 3 years with no increases in AE or SAE rates over time and no emergence of any new safety signals
- Efficacy was sustained through 3 years in patients treated continuously with deucravacitinib from Day 1 in the parent trials
  - Clinical efficacy outcomes, including PASI 75, PASI 90, and sPGA 0/1, were sustained in patients who were continuously treated with deucravacitinib from baseline through Week 148
  - Efficacy results were consistent across several data imputation methods including observed values, TFR, and mNRI
- These findings provide additional support for the consistent safety profile and durable efficacy of deucravacitinib, the first of a new class of TYK2 inhibitor, over 3 years

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Speakers bureau: AbbVie, Amgen, Bausch Health/Valeant, Celgene, Galderma, Incyte, Janssen, Kyowa Kirin, Leo Pharma, Lilly, Merck, Novartis, Pfizer, and Sanofi Genzyme; Clinical research grants: AbbVie, Akros, Amgen, Anacor, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celgene, Coherus BioSciences, Dermavant, Dermira, DICE Therapeutics, Dow Pharma, Evelo Biosciences, Galderma, Gilead, GlaxoSmithKline, Incyte, Janssen, Kyowa Kirin, Leo Pharma, Lilly, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Takeda, and UCB; Honoraria: AbbVie, Acelyrin, Akros, Amgen, Aralez, Bausch Health/Valeant, Boehringer Ingelheim, Celgene, Celltrion, Coherus BioSciences, Dermavant, DICE Therapeutics, Forbion, Galderma, Janssen, Kyowa Kirin, Leo Pharma, Lilly, Meiji Seika Pharma, Merck, Mitsubishi Pharma, Novartis, Pfizer, Reistone, Sanofi Genzyme, Sandoz, Sun Pharma, Takeda, UCB, vTv Therapeutics, and Xencor; Scientific officer: Akros, Anacor, Arcutis, DICE Therapeutics, and Kyowa Kirin; Steering committees: AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Celgene, Janssen, Kyowa Kirin, Lilly, Merck, Novartis, Pfizer, Regeneron, Reistone, and Sanofi Genzyme; Advisory boards: AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Dow Pharma, Galderma, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. **RMK, VB, EV, MJC, and SB:** Employees and shareholders: Bristol Myers Squibb. **KH:** Consultant: Bristol Myers Squibb via Syneos Health. **BS:** Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Equillium, GlaxoSmithKline, Immunic Therapeutics, Janssen, Leo Pharma, Lilly, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, Ventyx Biosciences, and vTv Therapeutics; Speaker: AbbVie, Janssen, Lilly, and Sanofi Genzyme; Co-scientific director (consulting fee): CorEvitas Psoriasis Registry; Investigator: AbbVie, Cara Therapeutics, CorEvitas Psoriasis Registry, Dermavant, Dermira, and Novartis. **DT:** Research support and principal investigator (clinical trials funds to intitution): AbbVie, Almirall, Amgen, Biogen Idec, Bristol Myers Squibb, Boehringer Ingelheim, Galderma, GlaxoSmithKline, Janssen-Cilag, Leo Pharma, Lilly, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Roche, Sandoz-Hexal, Sanofi, and UCB; Consultant: AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Galapagos, Leo Pharma, Novartis, Pfizer, and UCB; Lecturer: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Janssen, Leo Pharma, Lilly, Merck Sharp & Dohme, Novartis, Pfizer, Roche-Posay, Sandoz-Hexal, Sanofi, Target RWE, and UCB; Scientific advisory board: AbbVie, Amgen, Bristol Myers Squibb, Boehringer Ingelheim, Janssen-Cilag, Leo Pharma, Lilly, Morphosis, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi, and UCB. **AB:** Speaker (with honoraria): AbbVie, Bristol Myers Squibb, Lilly, Pfizer, Regeneron, and Sanofi; Scientific adviser (with honoraria): AbbVie, Abcentra, Aclaris, Affibody, Aligos, Almirall, Alumis, Amgen, Anaptysbio, Apogee, Arcutis, Arena, ASLAN, Athenex, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, CTI BioPharma, Dermavant, EcoR1, Escient, Evelo Biosciences, Evommune, Forte Biosciences, Galderma, HighlightII Pharma, Incyte, InnoventBio, Janssen, Landos, Leo Pharma, Lilly, Lipidio, Merck, Nektar, Novartis, Pfizer, Rani, Rapt, Regeneron, Sanofi Genzyme, Spherix Global Insights, Sun Pharma, Takeda, TLL Pharmaceutical, TrialSpark, UCB, Union, Ventyx Biosciences, Vibliome, and Xencor; Clinical study investigator (institution has received clinical study funds): AbbVie, Acelyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, Evelo Biosciences, Evommune, Galderma, Incyte, Janssen, Leo Pharma, Lilly, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB, and Ventyx Biosciences.

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Email: aprilarmstrong@post.harvard.edu