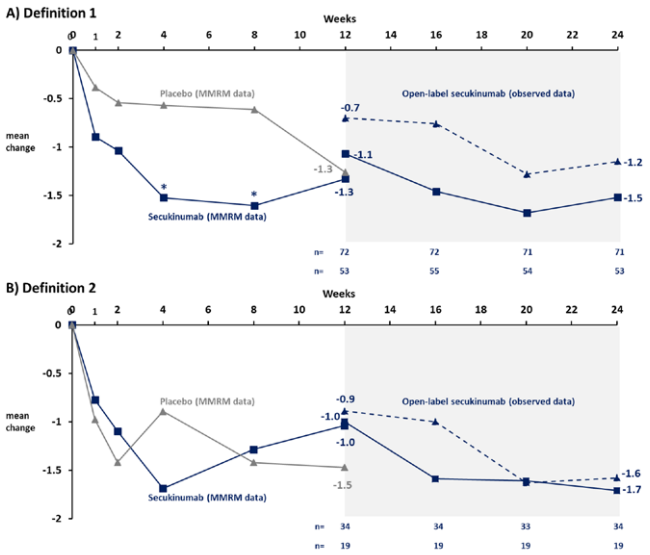
Disclosure of Interests: Maria-Antonietta D'Agostino Speakers bureau: Sanofi, Novartis, BMS, Janssen, Celgene, AbbVie, UCB pharma and Eli Lilly, Consultant of: Sanofi, Novartis, BMS, Janssen, Celgene, AbbVie, UCB pharma and Eli Lilly, Philip G Conaghan Speakers bureau: AbbVie, AstraZeneca, BMS, Eli Lilly, Galapagos, Gilead, Novartis and Pfizer, Consultant of: AbbVie, AstraZeneca, BMS, Eli Lilly, Galapagos, Gilead, Novartis and Pfizer, Corine Gaillez Shareholder of: Novartis and BMS, Employee of: Novartis, Maarten Boers Consultant of: BMS, Novartis, Pfizer, and GSK, Esperanza Naredo Speakers bureau: AbbVie, Roche, BMS, Pfizer, UCB, Eli Lilly, Novartis, Janssen and Celgene, Consultant of: AbbVie, Novartis and BMS, Grant/research support from: Eli Lilly, Philippe Carron Speakers bureau: Pfizer, MSD, Novartis, BMS, AbbVie, UCB, Eli Lilly, Gilead and Celgene, Consultant of: Pfizer, MSD, Novartis, BMS, AbbVie, UCB, Eli Lilly, Gilead and Celgene, Grant/research support from: UCB, MSD and Pfizer, Petra Hanova: None declared, Tomás Cazenave: None declared, Catherine Bakewell Speakers bureau: AbbVie, Novartis, Sanofi Genzyme, and consulting honoraria from Pfizer, UCB, and Janssen, Consultant of: AbbVie, Novartis, Sanofi Genzyme, and consulting honoraria from Pfizer, UCB, and Janssen, Anne-Marie Duggan Employee of: Novartis, Punit Goyanka Employee of: Novartis, Georg Schett Speakers bureau: AbbVie, BMS, Celgene, Gilead, Janssen, Eli Lilly, Novartis, Roche and UCB pharma

Figure: Global OMERACT-US enthesitis score change from baseline to Week 12 and from Week 12 to 24



*P < 0.05. **Definition 1:** MMRM difference (SE) at Week 12: -0.1 (0.5); 95% CI: (-1.0, 0.8); *P*=0.44. Within treatment group from Week 12 to 24: NS for both initial secukinumab and placebo-secukinumab groups. Between treatment groups from baseline to Week 24: -0.4; 95% CI: (-1.5, 0.7); *P*=0.50; NS. **Definition 2:** MMRM difference (SE) at Week 12: 0.4 (0.7); 95% CI: (-0.9, 1.8); *P*=0.26. Within treatment group from Week 12 to 24: -0.7; 95% CI: (-1.3, -0.2); *P*=0.02 for initial secukinumab group and NS for placebo-secukinumab group. Between treatment groups from baseline to Week 24: -0.1; 95% CI: (-1.5, 1.2); *P*=0.85; NS. n, number of evaluable patients; NS, non-significant

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OP0227

EFFICACY OF DEUCRAVACITINIB, AN ORAL, SELECTIVE TYROSINE KINASE 2 INHIBITOR, IN MUSCULOSKELETAL MANIFESTATIONS OF ACTIVE PSORIATIC ARTHRITIS IN A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

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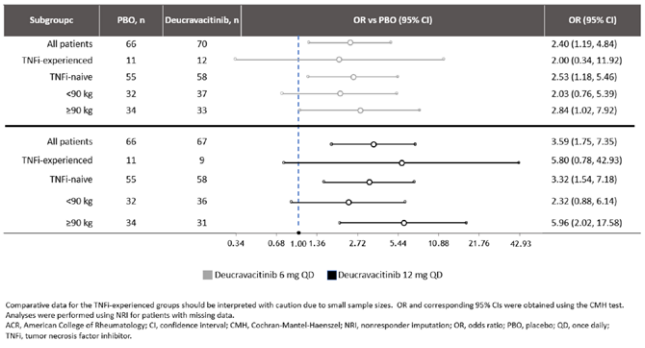
Background: Tyrosine kinase 2 (TYK2) is an intracellular kinase that mediates IL-23, IL-12, and IFNα/β signaling. Deucravacitinib is a novel, oral selective inhibitor of TYK2 acting via the TYK2 regulatory domain. Phase 2 results showed deucravacitinib was efficacious and well tolerated versus placebo (PBO) in patients with active psoriatic arthritis (PsA).

Objectives: This analysis further evaluated improvements in musculoskeletal disease manifestations in patients in the Phase 2 PsA trial.

Methods: The ongoing Phase 2 trial (NCT03881059) enrolled patients who had a PsA diagnosis for ≥6 months, met CASPAR criteria, had active disease (≥3 tender joints, ≥3 swollen joints, C-reactive protein [CRP] ≥3 mg/L), and had at least 1 active skin lesion. Patients either failed or were intolerant to at least 1 nonsteroidal anti-inflammatory drug, corticosteroid, conventional synthetic disease-modifying antirheumatic drug, and/or 1 TNF inhibitor (TNFi; ≤30%). Patients were randomized 1:1:1 to deucravacitinib 6 mg QD or 12 mg QD or PBO, and stratified by TNFi status (experienced vs naive) and body weight (<90 vs ≥90 kg). The primary endpoint, ACR20 response at Week 16, was met and significant improvements in enthesitis vs PBO were observed. The current prespecified subgroup analysis assessed the likelihood of achieving ACR20 response at Week 16 based on study stratification factors. A post hoc analysis evaluated mean change from baseline to Week 16 in ACR components (tender joint count, swollen joint count, Physician's Global Assessment of PsA, Patients' Global Assessment of disease activity, Patients' Global Assessment of pain, high-sensitivity CRP [hCRP], and HAQ-DI score). Analyses were descriptive using data as observed.

Results: Patients treated with deucravacitinib were numerically more likely to achieve ACR20 response at Week 16 compared with PBO-treated patients regardless of TNFi experience or body weight, although some of these groups were small (Figure). Improvements for deucravacitinib 6 mg and 12 mg QD versus PBO were observed in all ACR components, with apparent separation occurring as early as Week 4 on, for example, HAQ-DI (mean change from baseline, -0.2 vs -0.2 vs -0.1, respectively) and hCRP (mean change from baseline, -7.4 vs -5.2 vs 0.3, respectively) and maintained through Week 16 (Table).

Figure. ACR20 subgroup analysis at Week 16



Comparative data for the TNFi-experienced groups should be interpreted with caution due to small sample sizes. OR and corresponding 95% CIs were obtained using the CMH test. Analyses were performed using NRI for patients with missing data.
ACR, American College of Rheumatology; CI, confidence interval; CMH, Cochran-Mantel-Haenszel; NRI, nonresponder imputation; OR, odds ratio; PBO, placebo; QD, once daily; TNFi, tumor necrosis factor inhibitor.

Table 1. Mean (SD) change from baseline for ACR components

	TJC	SJC	PtGA	Pain	PGA	HAQ-DI	hCRP
Baseline[a]							
PBO	16.9 (9.8)	10.5 (7.7)	66.2 (15.8)	64.9 (18.2)	63.8 (14.8)	1.3 (0.6)	20.4 (39.1)
DEUC 6	18.1 (10.3)	11.9 (7.0)	68.2 (16.8)	63.6 (21.7)	68.2 (14.7)	1.3 (0.6)	17.6 (23.6)
DEUC12	19.4 (11.8)	11.3 (9.0)	63.6 (15.6)	63.8 (15.9)	63.3 (16.1)	1.3 (0.6)	16.5 (21.7)
Week 16[b]							
PBO	-4.6 (9.7)	-4.3 (8.0)	-13.4 (23.5)	-13.8 (21.5)	-19.9 (21.8)	-0.1 (0.4)	-3.3 (22.6)
DEUC 6	-9.3 (9.7)	-7.7 (5.8)	-28.7 (23.1)	-25.3 (26.1)	-33.6 (23.0)	-0.4 (0.5)	-14.2 (24.5)
DEUC 12	-12.2 (10.2)	-8.5 (9.1)	-27.6 (25.8)	-27.5 (25.0)	-32.2 (25.0)	-0.4 (0.6)	-10.9 (22.8)

PBO, n/N=58/66; DEUC 6, n/N=63/70; DEUC 12, n/N=59/67; n/N = number of patients who completed treatment/number of patients randomized; the number of patients with data available for individual components at each time point may vary.[a]Mean (SD). [b]Mean (SD) change from baseline.ACR, American College of Rheumatology; DEUC 6, deucravacitinib 6 mg QD; DEUC 12, deucravacitinib 12 mg QD; HAQ-DI, Health Assessment Questionnaire-Disability Index total score; hCRP, high-sensitivity C-reactive protein; PBO, placebo; PGA, Physician's Global Assessment of psoriatic arthritis; PtGA, Patients' Global Assessment of disease activity; QD, once daily; SJC, swollen joint count; TJC, tender joint count.

Conclusion: Analyses confirmed the efficacy of deucravacitinib versus PBO across TNFi and body weight subgroups. With deucravacitinib treatment, improvements were displayed in all ACR components.

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Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Galapagos, GlaxoSmithKline, Janssen, Novartis, Pfizer, UCB, Grant/research support from: AbbVie, Eli Lilly, GlaxoSmithKline, Novartis, Pfizer, UCB, Désirée van der Heijde Consultant of: AbbVie, Amgen, Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Cyxone, Daiichi, Eisai, Eli Lilly, Galapagos, Gilead, GlaxoSmithKline, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda, UCB Pharma. Director of Imaging Rheumatology BV, Frank Behrens Consultant of: Pfizer, AbbVie, Sanofi, Lilly, Novartis, Genzyme, Boehringer, Janssen, MSD, Celgene, Roche, Chugai, Bristol Myers Squibb, UCB Pharma, Grant/research support from: Pfizer, Janssen, Chugai, Celgene, Roche, Alan Kivitz Shareholder of: Pfizer, Sanofi, GlaxoSmithKline, Gilead Sciences, Inc., Novartis; Paid consultant: AbbVie, Boehringer Ingelheim, Flexion, Janssen, Pfizer, Sanofi, Regeneron, SUN Pharma Advanced Research, Gilead Sciences, Inc, Speakers bureau: Amgen, Horizon, Lilly, Novartis, Pfizer, Sanofi, Genzyme, Flexion, AbbVie, Thomas Lehman Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb, Lan Wei Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb, Marleen Nys Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb, Subhashis Banerjee Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb, Miroslawa Nowak Shareholder of: Bristol Myers Squibb, Employee of: Bristol Myers Squibb

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OP0228

EFFICACY AND SAFETY OF RISANKIZUMAB FOR ACTIVE PSORIATIC ARTHRITIS, INCLUDING PATIENTS WITH INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGIC THERAPIES: 24-WEEK RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, KEEPSAKE 2 TRIAL

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Background: Risankizumab (RZB) is a humanized immunoglobin G1 monoclonal antibody that specifically inhibits interleukin 23 by binding its p19 subunit. RZB is being investigated as a treatment for adults with psoriatic arthritis (PsA).
Objectives: To compare the efficacy and safety of RZB vs placebo (PBO) for the treatment of active PsA in patients who have had inadequate response or intolerance to 1 or 2 biologic therapies (Bio-IR) or to ≥ 1 conventional synthetic disease modifying antirheumatic drug (csDMARD-IR).
Methods: KEEPsAKE 2 (NCT03671148) enrolled adults with active PsA (≥ 5 swollen joints [SJC] and ≥ 5 tender joints [TJC]) who were Bio-IR or csDMARD-IR. Patients were randomized to receive blinded subcutaneous RZB 150 mg or PBO at weeks 0, 4, and 16. The primary endpoint was the proportion of patients achieving ≥ 20% improvement in American College of Rheumatology score (ACR20) at week 24. Ranked secondary endpoints and other secondary endpoints are shown in the Table. Safety was assessed throughout the study. Results reported here are from the 24-week double-blind period; the open-label period with all patients receiving RZB is ongoing.
Results: A total of 443 patients (RZB, N = 224; PBO, N = 219) were included in the analysis. Demographics and baseline disease characteristics were similar across treatment arms (mean SJC: 13.3; mean TJC: 22.6; mean duration of PsA: 8.2 years; mean body surface area involved with psoriasis [BSA] in patients with BSA ≥ 3%: 12.1%); 206 patients (46.5%) were Bio-IR. Significantly greater proportions of RZB-treated patients vs PBO-treated patients achieved the primary endpoint (51.3% vs 26.5%, respectively; $P < .001$) and all ranked secondary endpoints ($P < .001$ for all except for Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-Fatigue; $P < .009$]; Table). Other secondary outcomes also showed improvement for RZB- vs PBO-treated patients (Table). Serious adverse events were reported for 4.0% and 5.5% of RZB- and PBO-treated patients, respectively; serious infections were reported for 0.9% and 2.3%.
Conclusion: RZB resulted in significantly greater improvements in signs and symptoms of PsA compared with PBO and was well tolerated in patients who were Bio-IR or csDMARD-IR.

Table. Efficacy Results

	RZB 150 mg N = 224	PBO N = 219	Difference (95% CI)	*P* value[a]
Primary endpoint				
ACR20, %	51.3	26.5	24.5 (15.9, 33.0)	< .001***
Ranked secondary endpoints				
HAQ-DI score, change	−0.22	−0.05	−0.16 (−0.26, −0.07)	< .001***
PASI 90,[a] %	55.0	10.2	44.3 (33.9, 54.6)	< .001***
ACR20 at week 16, %	48.3	25.3	22.6 (13.9, 31.2)	< .001***
MDA, %	25.6	11.4	14.0 (7.0, 21.0)	< .001***
SF-36 PCS score, change	5.9	2.0	3.9 (2.4, 5.3)	< .001***
FACIT-Fatigue score, change	4.9	2.6	2.2 (0.6, 3.9)	.009**
Other secondary endpoints				
ACR50, %	26.3	9.3	16.6 (9.7, 23.6)	< .001†
ACR70, %	12.0	5.9	6.0 (0.8, 11.3)	.024†
Resolution of enthesitis,[a] %	42.9	30.4	13.8 (3.5, 24.2)	.009†
Resolution of dactylitis,[a] %	72.5	42.1	38.8 (22.9, 54.8)	< .001†

ACR20/ACR50/ACR70, ≥ 20/50/70% improvement in American College of Rheumatology score; FACIT-Fatigue, Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI, Health Assessment Questionnaire-Disability Index; MDA, minimal disease activity; PASI 90, ≥ 90% reduction in Psoriasis Area Severity Index; PBO, placebo; RZB, risankizumab; SF-36 PCS, 36-Item Short Form Health Survey Physical Component Summary.
All endpoints assessed at week 24 unless otherwise noted. All changes are mean changes from baseline.
***: statistically significant at 0.001 level, multiplicity controlled.
**: Statistically significant at 0.01 level; multiplicity controlled.
†: Nominal *P* value.
[a]For patients with involved body surface area ≥ 3% (PASI 90; RZB N = 123; PBO N = 119), enthesitis (RZB N = 147; PBO N = 158), or dactylitis (RZB N = 40; PBO N = 57) at baseline.

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