A Phase 4 Multicenter, Randomized, Open-Label, Efficacy Assessor-Blinded Study of Risankizumab Compared With Deucravacitinib for the Treatment of Adult Patients With Moderate Plaque Psoriasis Who Are Candidates for Systemic Therapy: 16-Week Results From IMMpactful

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OBJECTIVE

To assess the efficacy and safety of risankizumab (RZB) compared with deucravacitinib (DEU) in patients with moderate psoriasis (PsO) without prior biologic treatment

CONCLUSIONS

Treatment of biologic naïve patients with moderate PsO with RZB for 16 weeks resulted in a significantly higher proportion of patients achieving the co-primary endpoints, ≥ 90% improvement in Psoriasis Area and Severity Index (PASI 90) and static Physician Global Assessment of 0 or 1 (sPGA 0/1), than patients treated with DEU

Treatment of biologic naïve patients with moderate PsO with RZB for 16 weeks resulted in a significantly higher proportion of patients achieving all ranked secondary endpoints, PASI 100, and sPGA 0, than patients treated with DEU

Treatment satisfaction scores for Global Satisfaction, Effectiveness, and Convenience were higher for patients treated with RZB compared with patients treated with DEU at week 16

Safety results at week 16 were consistent with the known safety profile of RZB

These findings support the opportunity to elevate treatment outcomes in biologic naïve patients with moderate PsO

AbbVie and the authors thank the participants, study sites, and investigators who participated in this clinical trial. AbbVie funded this trial and participated in the trial design, research, analysis, data collection, interpretation of data, and the review and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship. Medical writing support was provided by Susan Olalekan, PhD of AbbVie.

Financial arrangements of the authors with companies whose products may be related to the present report are listed as declared by the authors: N. Magnolo has served as advisor and/or paid speaker for and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Celltrion, Dr. Wolff, Eli Lilly, Janssen, La Roche-Posay, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. J. Soung has served as a research investigator, scientific adviser, and/or speaker for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Castle Biosciences, Celgene, Dermavant, Eli Lilly, Janssen, KoBioLabs, Kyowa Kirin, LEO Pharma, National Psoriasis Foundation (nonprofit), Novartis, Ortho Dermatologics, Pfizer, Regeneron/Sanofi, and UCB. J. Frew has conducted advisory work for AbbVie, Boehringer Ingelheim, ChemoCentryx, Janssen, Kyowa Kirin, LEO Pharma, Pfizer, Regeneron, and UCB; participated in trials for Boehringer Ingelheim, CSL Pfizer, Eli Lilly, and UCB; and received research support from Ortho Dermatologics and Sun Pharma. A Costanzo reported receiving grants from AbbVie during the conduct of the study; grants from Galderma and Novartis; and personal fees from Eli Lilly, Janssen, Sanofi, and UCB outside the submitted work. M. Llamas-Velasco has been an advisory board member, consultant, research support, participated in clinical trials, and/or received honoraria for speaking with the following pharmaceutical companies: AbbVie, Almirall, Amgen, Boehringer, Celgene, Janssen, Leo, Lilly, Kyowa Kirin, Novartis, and UCB. M Bukhalo is an investigator on an AbbVie-funded study. R.K. Sivamani serves as an investigator for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Codex Labs, Dermavant, Eli Lilly, Incyte, Janssen, LEO Pharma, Merck, Moonlake, Novartis, and UCB. He serves as a consultant or speaker for AbbVie, Arbonne, Arcutis, Burt's Bees, Bristol Myers Squibb, Codex Labs, Eli Lilly, Galderma, Incyte, Leo, Novartis, Nutrafol, Pfizer, Phothera, Regeneron Pharmaceuticals, Sanofi, Sun, Trace Minerals, and UCB. A Moore has received honoraria or research funds from Abbvie, Aclaris, Acrotech, Arcutis, Bayer, Bristol Myers Squibb, Cara, Eli Lilly, Galderma, Genentech Roche, Incyte, Janssen, Novartis, Pfizer, Rapt, Regeneron, Roche, and Sanofi. T. Wu, J. Xie, M. Patel, D. Ashley, B. Kaplan, V. Stakias, and R. Espaillat are employees of AbbVie and may hold stock options. RB. Warren has received grants from AbbVie, Almirall, Amgen, Celgene, Janssen, Lilly, LEO Pharma, Novartis, Pfizer, and UCB. He has received personal fees from AbbVie, AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DiCE, Galderma, GSK, Immunocore, Janssen, Lilly, Leo, Meiji Pharma, Nektar Therapeutics, Novartis, Pfizer, RAPT Pharmaceuticals, Sanofi, Sun Pharma, Takeda, UCB & UNION.

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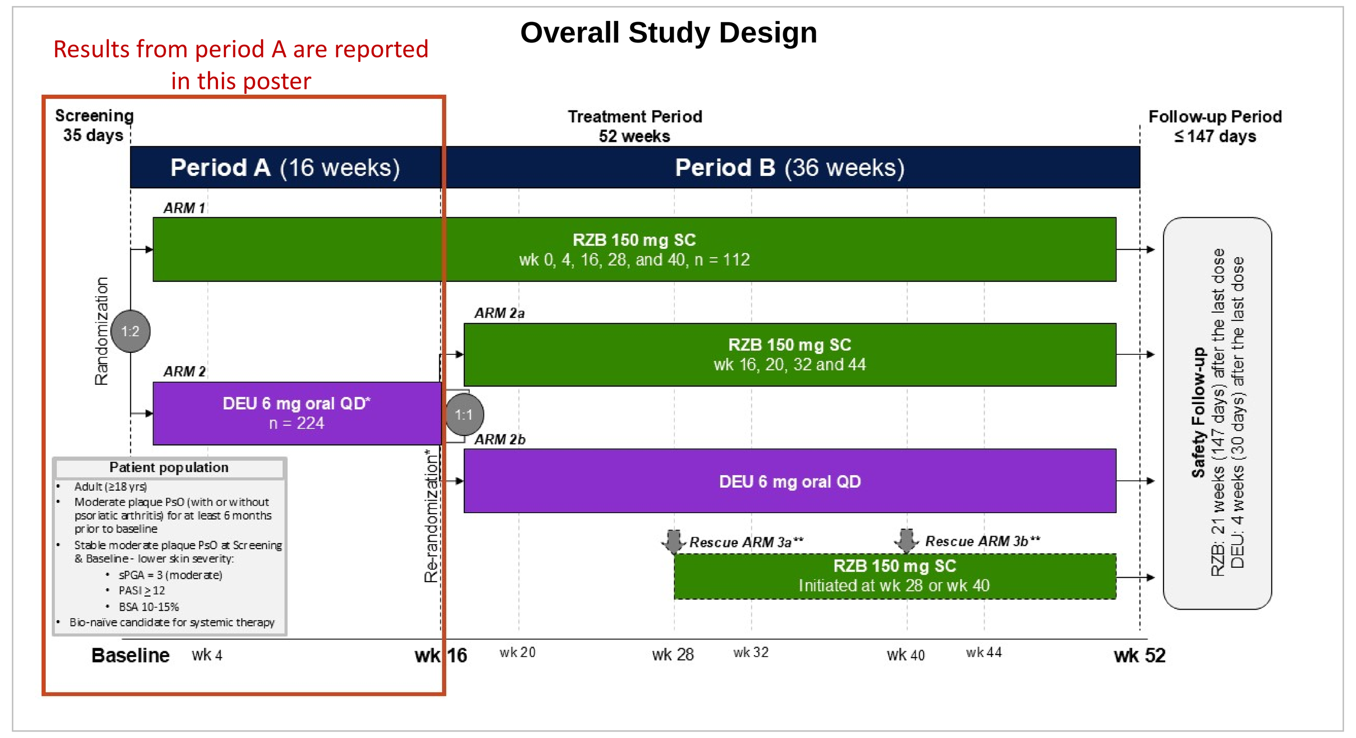
INTRODUCTION

- PsO is a chronic inflammatory disease that presents as thick and scaly skin plaques
- Treatment of PsO progresses from topical treatments to oral or injectable biologics depending on factors such as:
  - Disease severity[1]
  - Response to prior therapies[1]
- RZB is an approved anti-IL-23 humanized IgG1 monoclonal antibody for the treatment of moderate-to-severe PsO
- DEU is an approved tyrosine kinase 2 inhibitor for the treatment of moderate-to-severe PsO
- Treatment optimization is challenging for physicians in the absence of head-to-head comparisons
- IMMpactful is evaluating the safety and efficacy of RZB compared with DEU for the treatment of patients with moderate PsO without prior biologic treatment

DEU, deucravacitinib; PsO, psoriasis; RZB, risankizumab.

METHODS

- IMMpactful (NCT06333860) is a phase 4, global, multicenter, randomized, open-label, efficacy assessor-blinded, active comparator study investigating the effect of RZB compared with DEU in patients with moderate PsO
- Patients with moderate PsO (BSA 10%-15%, PASI ≥ 12, and sPGA = 3) eligible for systemic therapy who have not been previously treated with biologics were enrolled in IMMpactful
- The 52-week treatment period includes:
  - Period A (baseline to week 16): patients were randomized 1:2 to receive either RZB 150 mg as a single subcutaneous injection (SC) at baseline (day 1) and week 4 or DEU 6 mg orally once daily (QD)
  - Period B (week 16 to week 52): patients initially randomized to RZB in period A will continue to receive RZB 150 mg as a single injection every 12 weeks at week 16, 28, and 40. Patients initially randomized to DEU in period A will be re-randomized at the week 16 visit in a 1:1 ratio to RZB 150 mg at weeks 16, 20, 32, and 44 or DEU 6 mg orally QD up to week 52
    - ➢ Re-randomization will be stratified by PASI 90 response at week 16
    - ➢ Rescue RZB 150 mg SC will be offered to patients who are re-randomized to DEU and are sPGA > 2 at week 28 and 40
- Results from Period A (database lock: 22 May 2025) are presented here
- Co-primary endpoints for period A :
  - Achievement of PASI 90 at week 16
  - Achievement of sPGA 0/1 with at least a 2-grade improvement from baseline at week 16
- Ranked secondary endpoints for period A:
  - Achievement of PASI 100 at week 16



BSA, Body Surface Area; DEU, deucravacitinib; PASI, Psoriasis Area and Severity Index; PASI 90, ≥ 90% improvement in PASI; PsO, psoriasis; QD, once daily; RZB, risankizumab; SC, subcutaneous;; sPGA, static Physician Global Assessment; wk, weeks.
* Stratified by PASI 90 response status.
** Rescue with RZB for DEU arm offered to patients with sPGA > 2 at wk 28 or wk 40.

  - Achievement of sPGA 0 with at least a 2-grade improvement from baseline at week 16
- Additional endpoints, including change in PASI, and treatment satisfaction questionnaire for medication (TSQM) score, are also reported
- Non-responder imputation incorporating multiple imputation (NRI-MI) or mixed model repeated measures (MMRM) were used to handle missing data

RESULTS

Table 1. Patient Demographics and Baseline Characteristics in Period A

	RZB N = 131 n (%)	DEU N = 262 n (%)
Age (years), mean (SD)	47.3 (14.1)	44.8 (13.8)
Sex, n (%)		
Female	51 (38.9)	97 (37.0)
Male	80 (61.1)	165 (63.0)
Race, n (%)		
American Indian or Alaska native	0	5 (1.9)
Asian	8 (6.1)	19 (7.3)
Black or African American	6 (4.6)	13 (5.0)
White	117 (89.3)	224 (85.8)
Missing	0	1
BMI (kg/m^2), mean (SD)	29.9 (7.4)	29.5 (7.0)
PsA, n (%)	9 (6.9)	22 (8.4)
sPGA = 3 (moderate), n (%)	131 (100)	261 (99.6)
BSA, mean (SD)	13.2 (1.6)	13 (1.6)
PASI, mean (SD)	15.7 (4.2)	15.3 (3.3)
DLQI, mean (SD)	12.0 (7.6)	11.3 (6.8)
Duration of PsO (years), mean (SD)	16.1 (14.1)	14.1 (11.5)

BMI, body mass index; BSA, body surface area; DEU, deucravacitinib; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis; PsO, psoriasis; RZB, risankizumab; sPGA 3, static Physician Global Assessment of 3.

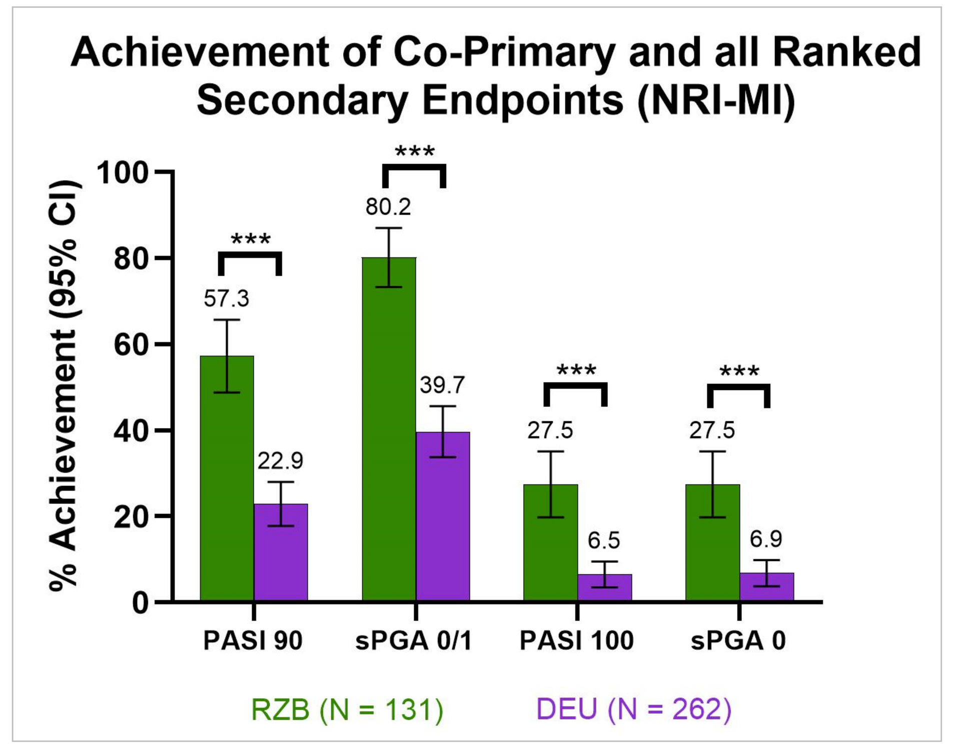
Table 2. Overview of Treatment-Emergent Adverse Events in Period A

	RZB N = 131 n (%)	DEU N = 261 n (%)
Adverse events (AEs)	44 (33.6)	112 (42.9)
AEs related to study drug	8 (6.1)	40 (15.3)
Severe AEs	1 (0.8)	3 (1.1)
Serious AEs	1 (0.8)	0
AEs leading to discontinuation of study drug	1 (0.8)	4 (1.5)
Areas of safety interest*		
Injection site reaction	2 (1.5)	N/A
Malignancies	0	1 (0.4)
Non melanoma skin cancer (NMSC)	0	1 (0.4)
Malignant tumors excluding NMSC	0	0
Hypersensitivity[a]	1 (0.8)	7 (2.7)
Serious hypersensitivity reactions	0	0
Hepatic events	1 (0.8)	1 (0.4)
Herpes zoster	0	2 (0.8)

DEU, deucravacitinib; MACE, major adverse cardiac event; N/A, not applicable; RZB, risankizumab.
*There were no events of MACE, extended MACE, serious infections, active tuberculosis, suicidal ideation and behavior, opportunistic infections excluding tuberculosis and herpes zoster, or adjudicated anaphylactic reaction reported in patients treated with RZB or DEU.
[a]Higher percentage of patients with hypersensitivity reactions were seen with DEU, including rash, dermatitis, and dermatitis acneiform.

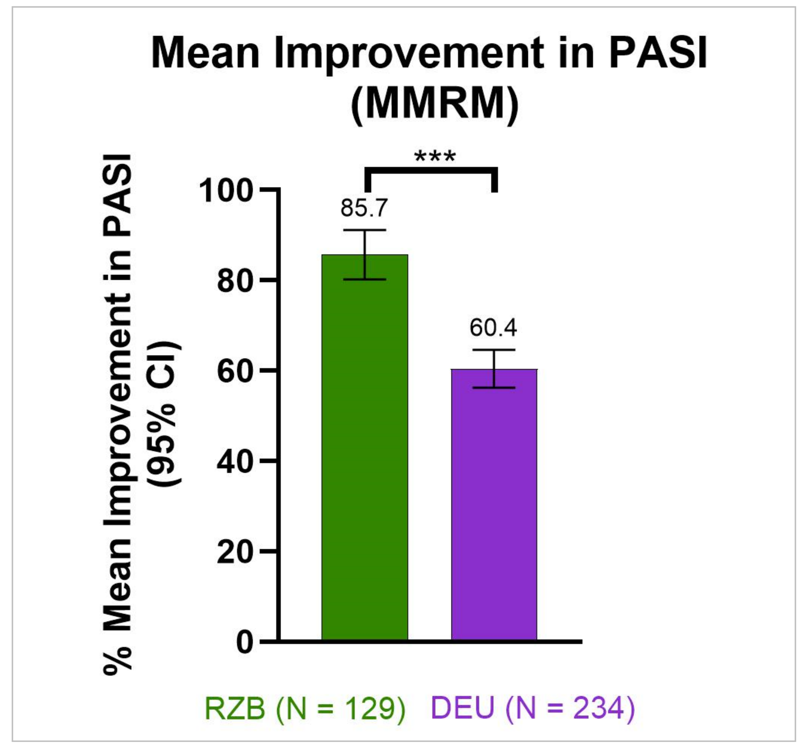
RESULTS

Figure 1. Significantly Higher Proportion of Patients Treated With RZB Achieved the Co-Primary and all Secondary Endpoints at Week 16



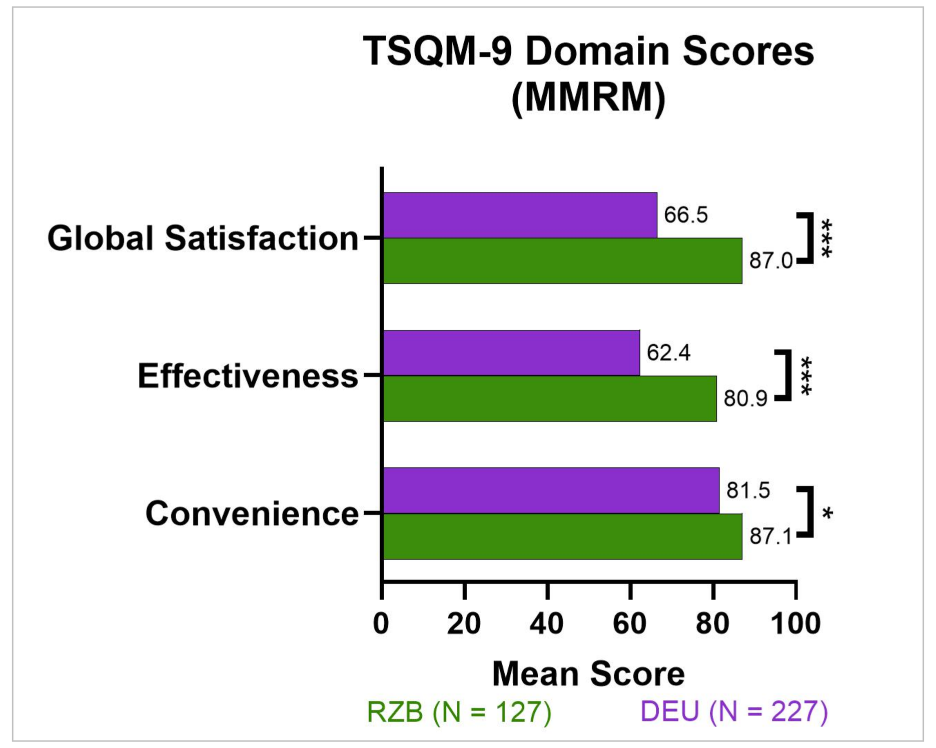
DEU, deucravacitinib; Non-Responder Imputation incorporating Multiple Imputation (NRI-MI); PASI 90, ≥ 90% improvement in Psoriasis Area and Severity Index; PASI 100, 100% improvement in PASI; RZB, risankizumab; sPGA 0/1, static Physician Global Assessment of 0 or 1; ****P* < .0001.

Figure 2. Higher Improvement in PASI in Patients Treated With RZB at Week 16



DEU, deucravacitinib; Mixed Model Repeated Measures (MMRM); PASI, Psoriasis Area and Severity Index; RZB, risankizumab; *** nominal *P* < .0001.

Figure 3. Higher TSQM-9 Scores Achieved by Patients Treated With RZB at Week 16



DEU, deucravacitinib; Mixed model repeated measures (MMRM); RZB, risankizumab; TSQM-9, treatment satisfaction questionnaire for medication version 9; *nominal *P* < .01; ***nominal *P* <.0001.

Patient Demographics and Baseline Characteristics

- Baseline characteristics were balanced across the RZB and DEU treatment groups **(Table 1)**
- Baseline PASI and BSA for patients in IMMpactful (moderate PsO) is generally lower than in patients in studies with moderate-to-severe PsO and can affect efficacy outcomes **(Table 1)**

Treatment-Emergent Adverse Events

- One serious AE (also considered severe), joint injury not related to the study drug, was reported in a patient without RZB discontinuation **(Table 2)**
- A single event of mild episcleritis, considered non-serious and not related to RZB, led to study drug discontinuation **(Table 2)**
- A single event of hypersensitivity, urticaria, was reported in a patient treated with RZB, and was considered mild, non-serious, and not related to the study drug **(Table 2)**
- A single event of increased hepatic enzyme was reported and had a reasonable possibility of being related to RZB **(Table 2)**
  - Patient was a 24-year-old male with obesity (BMI 34.9)
  - RZB was interrupted but restarted at week 28
  - Subsequently, the patient was diagnosed with non-serious hepatic steatosis, not related to RZB
- No MACE, active tuberculosis, serious infections, suicidal ideation, or deaths were reported

Achievement of Co-Primary Endpoints

- A significantly higher proportion of patients with moderate PsO treated with RZB (57.3%) achieved PASI 90 compared with DEU (22.9%) at week 16 (*P* < .0001) **(Figure 1)**
- A significantly higher proportion of patients with moderate PsO treated with RZB (80.2%) achieved sPGA 0/1 compared with DEU (39.7%) at week 16 (*P* < .0001) **(Figure 1)**
- Patients treated with RZB had higher change and mean improvement in PASI (nominal *P* < .0001) compared with patients treated with DEU **(Figure 2)**

Achievement of Ranked Secondary Endpoints

- A significantly higher proportion of patients with moderate PsO treated with RZB achieved PASI 100 (27.5%) compared with DEU (6.5%) at week 16 (*P* < .0001) **(Figure 1)**
- A significantly higher proportion of patients with moderate PsO treated with RZB (27.5%) achieved sPGA 0 compared with DEU (6.9%) at week 16 (*P* < .0001) **(Figure 1)**

Treatment Satisfaction Questionnaire for Medication

- Patients reported higher global satisfaction (nominal *P* < .0001), satisfaction for effectiveness (nominal *P* < .0001), and satisfaction with convenience (nominal *P* < .01), for subcutaneous RZB compared with oral DEU **(Figure 3)**