Efficacy of Risankizumab on Symptoms in Patients With Scalp Psoriasis in a Post-Hoc Analysis of the UnIIMMited Phase 4 Randomized Clinical Trial at Week 16

Eingun James Song,[1] Phoebe Rich,[2] Navid Ezra,[3] Harrison Nguyen,[4–6] Priya S. Mathur,[7] Brenton Bialik,[7] Chenyang Duan,[7] Richard Ta,[7] Toni Anschutz,[7] Lindsay Ackerman[8]

[1]Frontier Dermatology, Mill Creek, WA, USA; [2]Oregon Dermatology and Research Center, Portland, OR, USA; [3]California Dermatology Institute, Ventura, CA, USA; [4]Harrison Dermatology & Research Group, Missouri City, TX, USA; [5]University of Houston College of Medicine, Houston, TX, USA; [6]Baylor College of Medicine, Houston, TX, USA; [7]AbbVie Inc., North Chicago, IL, USA; [8]Medical Dermatology Specialists, Phoenix, AZ, USA

OBJECTIVE

Post-hoc analysis of Study-S in the UnIIMMited trial examining individual Psoriasis Symptom Scale components to better understand symptom presentation and resolution in scalp psoriasis

CONCLUSIONS

Risankizumab demonstrated significant improvements in the overall Psoriasis Symptom Scale and showed greater improvements in each individual symptom component compared with placebo in patients with scalp psoriasis at week 16

These findings support the efficacy of risankizumab in patients with scalp psoriasis

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INTRODUCTION

- Psoriasis (PsO) affects multiple body areas, with scalp involvement observed in 45–65% of patients[1,2]
- Involvement of high-impact sites such as the scalp increases disease burden and impacts on health-related quality of life[1–4]
- Risankizumab (RZB) is an interleukin-23 inhibitor approved for moderate-to-severe PsO
- Patient-reported PsO symptom severity is assessed using the Psoriasis Symptom Scale (PSS), which measures pain, itching, redness, and burning on a 5-point scale ranging from 0 (none) to 4 (very severe)
- Change from baseline at week 16 in PSS has been previously reported in the UnIIMMited phase 4 study of RZB in adults with moderate-to-severe genital (Study-G) or scalp (Study-S) PsO[5]
- Here, we further analyzed individual PSS components to better understand symptom presentation and resolution in scalp PsO

METHODS

Data Source and Patient Population

- This is a post-hoc analysis of Study-S in the UnIIMMited trial (NCT05969223)

METHODS CONTINUED

- Patients were randomized 1:1 to receive either 150 mg RZB or placebo (PBO) at weeks 0 and 4. At week 16 all patients received RZB **(Figure 1)**

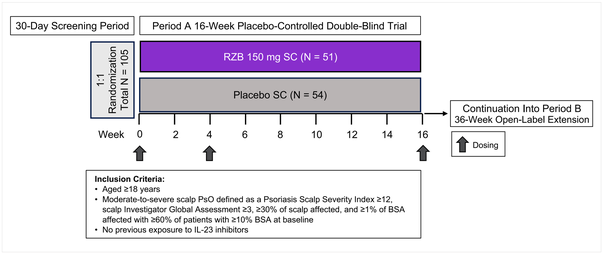
Outcomes

- The PSS was used to measure the severity of 4 types of PsO symptoms (pain, itching, redness, and burning) over a 24-hour recall period
  - Severity was measured on a 5-point scale ranging from 0 (none) to 4 (very severe)
- Change from baseline in total PSS alongside individual components (pain, itching, redness, burning) and proportion of patients achieving individual PSS 0 or 1 was reported through week 16

Data Analysis

- Baseline is defined as the last nonmissing value prior to the first dose of study drug or randomization if no study drug is given
- Patients with nonmissing baseline and at least 1 post-baseline value were included in the analyses
- *P* values were calculated using mixed-model repeated measures for continuous endpoints and Cochran-Mantel-Haenzel test for categorical endpoints
- Missing data was handled using nonresponder imputation for categorical endpoints and mixed-model repeated measures for continuous endpoints

Figure 1. UnIIMMited Study-S Design



BSA, body surface area; IL, interleukin; PsO, psoriasis; RZB, risankizumab; SC, subcutaneous.

RESULTS

Patient Demographics

- A total of 105 patients were enrolled (RZB, n = 51; PBO, n = 54)
- Demographics and baseline characteristics were generally similar between treatment groups **(Table 1)**

Table 1. Patient Demographics and Baseline Characteristics

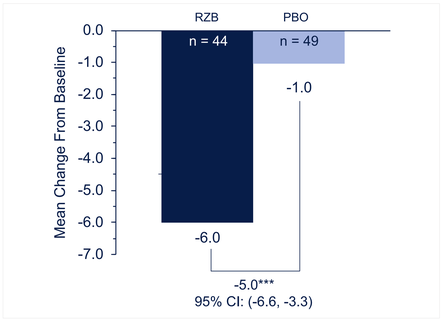
	RZB (N = 51)	PBO (N = 54)
Sex, female, n (%)	24 (47.1)	22 (40.7)
Age, years, mean (SD)	46.0 (14.8)	46.7 (14.2)
Body mass index (kg/m^2), n (%)		
<25	8 (15.7)	12 (22.2)
≥25 to <30	19 (37.3)	12 (22.2)
≥30	24 (47.1)	30 (55.6)
Body surface area, n (%)		
<10%	20 (39.2)	20 (37.0)
≥10%	31 (60.8)	34 (63.0)
Body surface area, mean (SD)	16.4 (16.1)	17.2 (17.6)
Prior biologic exposure, n (%)	20 (39.2)	19 (35.2)
Prior nonbiologic systemic exposure for psoriasis, n (%)	9 (17.6)	7 (13.0)
sPGA, n (%)		
3	38 (74.5)	42 (77.8)
4	13 (25.5)	12 (22.2)
DLQI, mean (SD)	13.4 (7.4)	13.1 (7.6)
Scalp IGA, n (%)		
3	36 (70.6)	42 (77.8)
4	15 (29.4)	12 (22.2)
PSSI, mean (SD)	35.1 (15.0)	32.5 (14.9)
PSS, mean (SD)	9.0 (3.9)	9.4 (4.3)

DLQI, Dermatology Life Quality Index; IGA, Investigator's Global Assessment; PBO, placebo; PSS, Psoriasis Symptom Scale; PSSI, Psoriasis Scalp Severity Index; RZB, risankizumab; SD, standard deviation; sPGA, static Physician's Global Assessment.

Outcomes

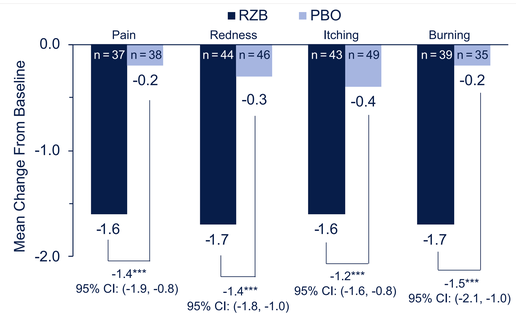
- At week 16, the change from baseline in total PSS was -6.0 vs -1.0 for patients receiving RZB vs PBO, respectively (*P* <.0001) **(Figure 2)**
- The week 16 change from baseline for RZB vs PBO in the individual PSS components were pain -1.6 vs -0.2, redness -1.7 vs -0.3, itching -1.6 vs -0.4, and burning -1.7 vs -0.2 **(Figure 3)**, respectively (all nominal *P* <.0001)
- The proportion of patients achieving PSS 0 or 1 at week 16 was numerically greater for RZB vs PBO (26.0% vs 11.3%, nominal *P* = .04) **(Figure 4)**
- The proportion of patients who achieved individual component PSS 0 or 1 at week 16 was numerically greater (all nominal *P* <.0001) in the RZB group vs those in the PBO group; 64.5% vs 20.0% for pain, 69.0% vs 17.0% for redness, 52.3% vs 18.0% for itching, and 65.7% vs 22.2% for burning **(Figure 5)**

Figure 2. Change From Baseline in Total PSS at Week 16 (MMRM)



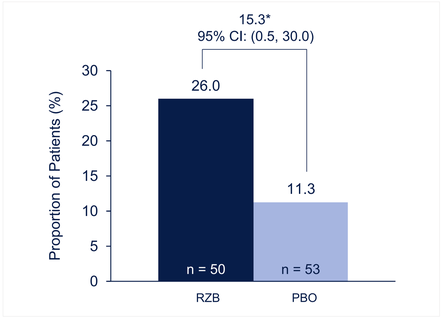
CI, confidence interval; MMRM, mixed-model repeated measures; PBO, placebo; PSS, Psoriasis Symptom Scale; RZB, risankizumab.
Among patients with baseline PSS total score ≥1.
***P <.001.

Figure 3. Change From Baseline in Individual PSS Components at Week 16 (MMRM)



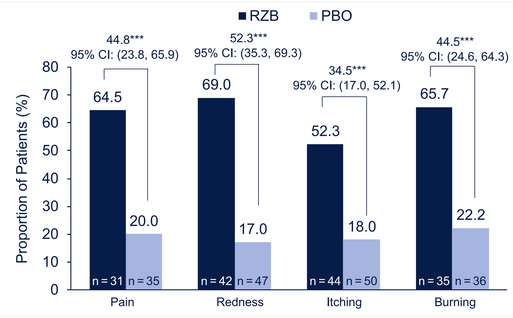
CI, confidence interval; MMRM, mixed-model repeated measures; PBO, placebo; PSS, Psoriasis Symptom Scale; RZB, risankizumab.
***Nominal *P* <.001. Among patients with baseline PSS individual score ≥1 for each PSS individual question, respectively.

Figure 4. Proportion of Patients Achieving Total PSS 0 or 1 at Week 16 (NRI)



CI, confidence interval; NRI, nonresponder imputation; PBO, placebo; PSS, Psoriasis Symptom Scale; RZB, risankizumab.
Among patients with baseline PSS total score >1.
Across the strata, 95% CI for adjusted difference and *P*-value were calculated according to the Cochran-Mantel-Haenzel test adjusted for strata (baseline body weight [≤100 kg, >100 kg] and number of prior biologic therapies for psoriasis [0, ≥1]) for the comparison of 2 treatment groups. In case of any stratum with 0 patients in both treatment groups, no stratification factor was controlled.
*Nominal *P* <.05.

Figure 5. Proportion of Patients Achieving Individual PSS Components 0 or 1 at Week 16 (NRI)



CI, confidence interval; NRI, nonresponder imputation; PBO, placebo; PSS, Psoriasis Symptom Scale; RZB, risankizumab.
Among patients with baseline PSS individual score >1 for each PSS individual question, respectively. Across the strata, 95% CI for adjusted difference and *P*-value were calculated according to the Cochran-Mantel-Haenzel test adjusted for strata (baseline body weight [≤100 kg, >100 kg] and number of prior biologic therapies for psoriasis [0, ≥1]) for the comparison of 2 treatment groups. In case of any stratum with 0 patients in both treatment groups, no stratification factor were controlled.
***Nominal *P* <.001.

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