A Phase 3b Study Evaluating the Safety and Efficacy of Risankizumab in Adult Patients with Moderate-to-Severe Plaque Psoriasis with Palmoplantar (non-pustular) Involvement

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OBJECTIVE

To assess the safety and efficacy of risankizumab (RZB) 150 mg versus placebo (PBO) for the treatment of moderate-to-severe psoriasis with non-pustular palmoplantar involvement (PPPsO)

CONCLUSIONS

Patients treated with RZB displayed a statistically significantly higher response rate in the primary and all ranked secondary endpoints compared to patients treated with PBO at week 16

For patients that continued RZB, efficacy response rate increased through week 52 and patients in the PBO group displayed similar efficacy trajectory once switched to RZB

No new safety signals were identified

RZB can provide effective management in a difficult-to-treat population of patients with moderate-to-severe psoriasis with predominantly palmoplantar involvement

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INTRODUCTION

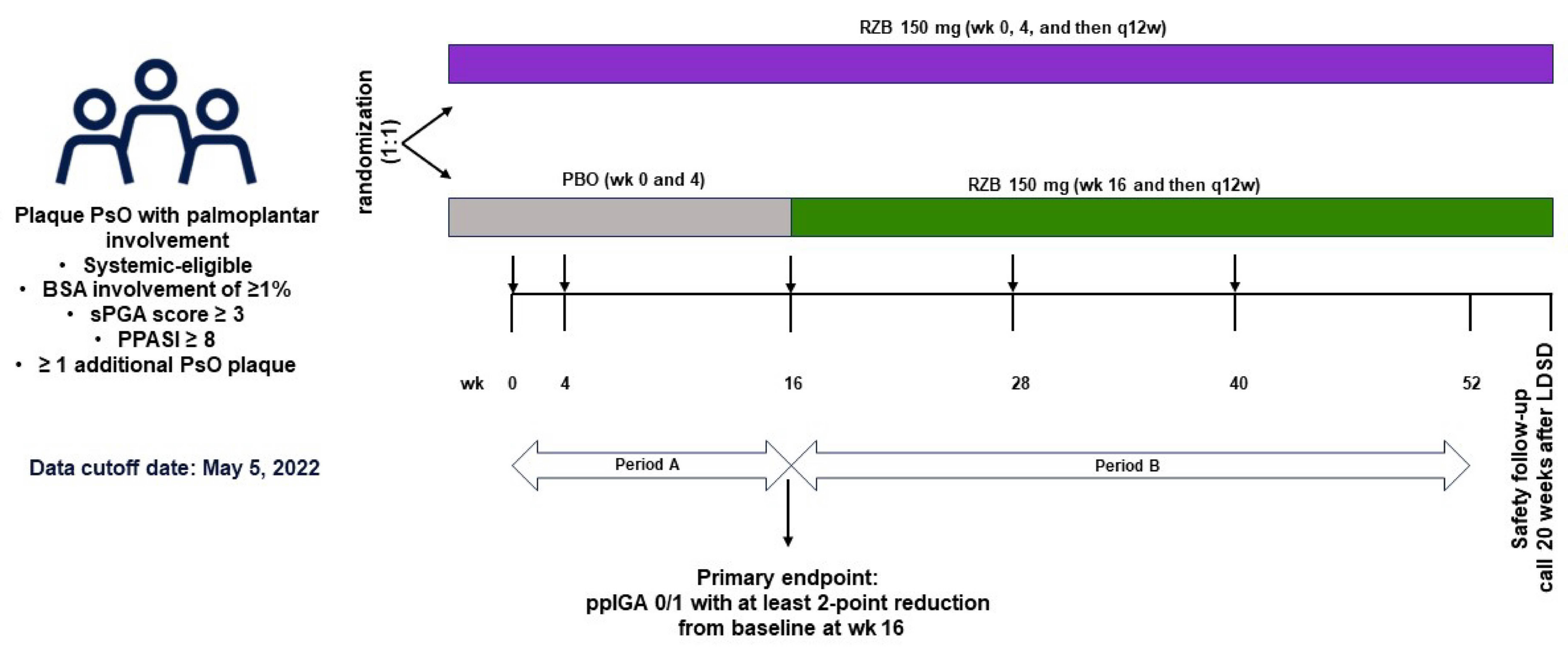
IMMprint is assessing the safety and efficacy of RZB in patients with PPPsO compared to PBO

- PPPsO is a chronic immune mediated disease that manifests as localized plaques on palms and soles of patients
- PPPsO is a difficult-to-treat disease
- Patients with PPPsO are rarely included in clinical trials due to lower PASI or BSA < 10% at baseline
  - Most available studies are subgroup analysis
    - Not powered to assess efficacy
- RZB is an IL-23 inhibitor approved for the treatment of moderate-to-severe plaque PsO and psoriatic arthritis
- RZB has shown efficacy in difficult-to-treat areas such as nail and scalp[1,2]
- In a double-blinded, randomized controlled trial, 33.3% and 22.1% of patients treated with secukinumab 300 or 150mg respectively achieved clear or almost clear palms and soles compared to placebo (1.5%, P < 0.001)[3]

RZB, risankizumab; PPPsO, palmoplantar non-pustular psoriasis; PsO, psoriasis; PASI, Psoriasis Area and Severity Index; BSA, Body Surface Area

METHODS

Overall Study Design


Plaque PsO with palmoplantar involvement
Systemic-eligible
BSA involvement of ≥1%
sPGA score ≥ 3
PPASI ≥ 8
≥ 1 additional PsO plaque
Data cutoff date: May 5, 2022
randomization (1:1)
RZB 150 mg (wk 0, 4, and then q12w)
PBO (wk 0 and 4)
RZB 150 mg (wk 16 and then q12w)
wk 0 4 16 28 40 52
Period A
Period B
Safety follow-up call 20 weeks after LDSD
Primary endpoint:
ppIGA 0/1 with at least 2-point reduction from baseline at wk 16

Primary endpoint

- ppIGA 0/1 with at least a 2-point reduction from baseline at week 16

Secondary endpoint (ranked)

- PPASI 75 at week 16
- PPASI 90 at week 16
- sPGA 0/1 with a 2-point reduction from baseline at week 16
- PPASI 100 at week 16

RZB, risankizumab; PsO, psoriasis; wk, week; mg, milligram; ppIGA 0/1, palmoplantar investigator's global assessment of clear or almost clear; PPASI 75, 90 or 100, ≥ 75%, 90% or 100% improvement in Palmoplantar Psoriasis Area and Severity Index; sPGA 0/1, static Physician's Global Assessment of clear or almost clear; BSA, Body Surface Area; q12w, every 12 weeks; LDSD, last dose of study drug

RESULTS

Demographics and Baseline Clinical Characteristics of Patients Enrolled in the IMMprint Trial

	RZB N = 87	PBO N = 87
Age years, mean (SD)	56.9 (12.9)	53.9 (14.3)
Sex, n (%)		
Female	40 (46.0)	45 (51.7)
Male	47 (54.0)	42 (48.3)
Ethnicity, n (%)		
Hispanic or Latino	28 (32.2)	25 (28.7)
Not Hispanic or Latino	59 (67.8)	62 (71.3)
Race, n (%)		
White	74 (85.1)	74 (85.1)
Black or African American	3 (3.4)	6 (6.9)
Asian	9 (10.3)	5 (5.7)
American Indian or Alaska Native	1 (1.1)	1 (1.1)
Native Hawaiian or other Pacific Islander	0	1 (1.1)
Other	0	0
Multiple	0	0
Weight (kg), mean (SD)	85.4 (21.7)	86.0 (18.9)
Body Mass Index (kg/m²), mean (SD)	30.3 (6.8)	30.3 (6.1)
Psoriatic arthritis, n (%)	10 (11.5)	4 (4.6)
Palmoplantar Investigator's Global Assessment, n (%)		
Moderate	67 (77.0)	68 (78.2)
Severe	20 (23.0)	19 (21.8)
Static Physician's Global Assessment		
Moderate	77 (88.5)	75 (86.2)
Severe	10 (11.5)	12 (13.8)
Psoriasis Area and Severity Index, mean (SD)	12.2 (9.4)	11.2 (8.1)
Palmoplantar Psoriasis Area and Severity Index, mean (SD)	22.5 (13.6)	22.5 (12.1)
Body Surface Area, mean (SD)	15.0 (14.6)	13.5 (14.8)
Previous biologic treatment, n (%)	9 (10.3)	10 (11.5)

RZB, risankizumab; PBO, placebo; n, number; kg, kilogram; SD, standard deviation;

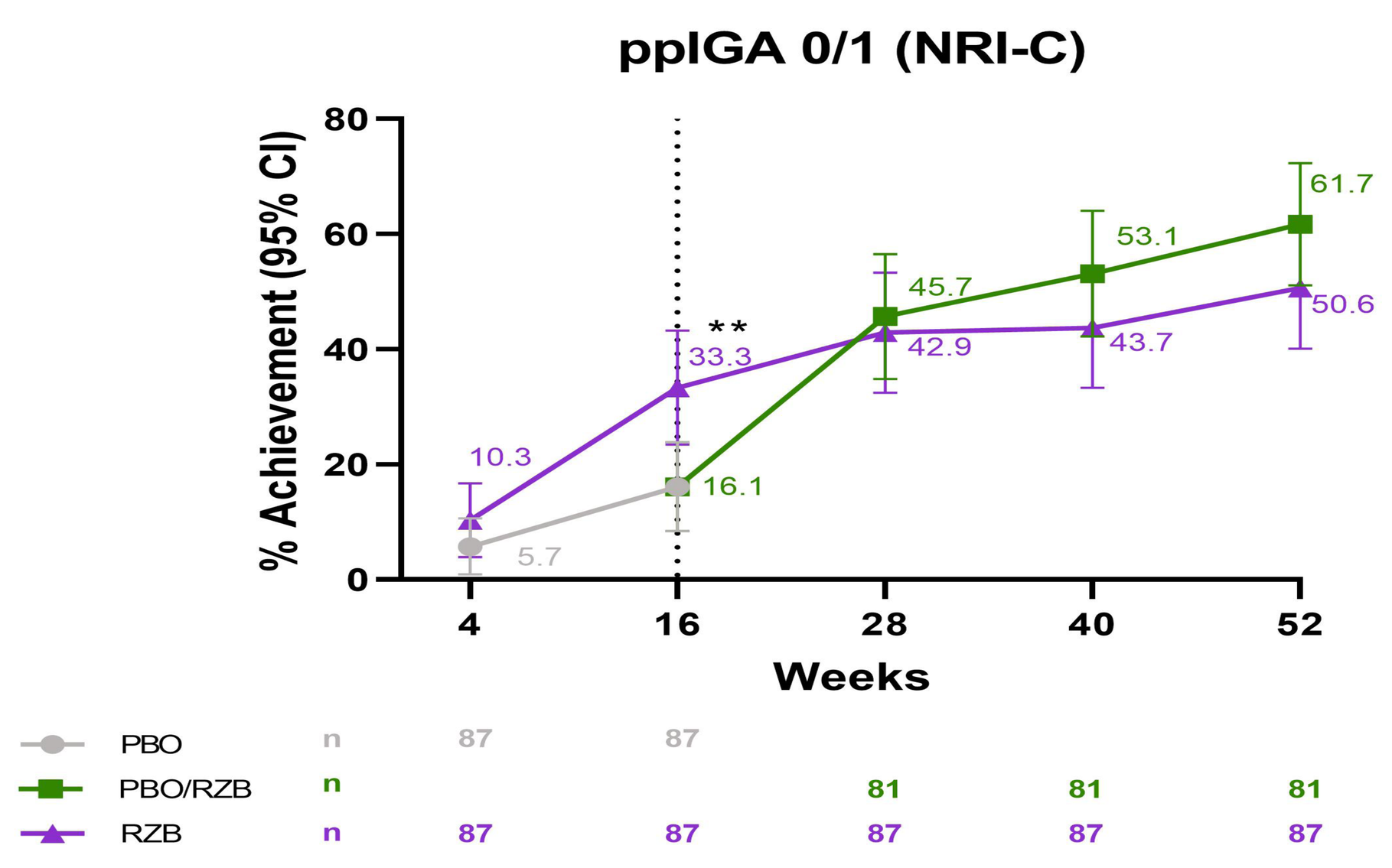
Overview of Treatment-Emergent Adverse Events in the IMMprint Trial

	Period A (week 16)				Period B (week 52)				All RZB	
	RZB N = 86 n (%)	RZB N = 86 PYs = 26.6 E (E/100PYs)	PBO N = 87 n (%)	PBO N = 87 PYs = 26.2 E (E/100PYs)	RZB N = 81 n (%)	RZB N = 81 PYs = 64.8 E (E/100PYs)	PBO/RZB N = 81 n (%)	PBO/RZB N = 81 PYs = 63.9 E (E/100PYs)	RZB N = 167 n (%)	RZB N = 167 PYs = 155.3 E (E/100PYs)
Adverse event (AE)	25 (29.1)	59 (221.8)	20 (23.0)	41 (156.5)	40 (49.4)	82 (126.5)	29 (35.8)	53 (82.9)	79 (47.3)	194 (124.9)
AE with reasonable possibility of being drug related	4 (4.7)	10 (37.6)	2 (2.3)	3 (11.5)	12 (14.8)	21 (32.4)	11 (13.6)	15 (23.5)	25 (15.0)	46 (29.6)
Severe AEs	6 (7.0)	8 (30.1)	3 (3.4)	6 (22.9)	3 (3.7)	4 (6.2)	2 (2.5)	2 (3.1)	10 (6.0)	14 (9.0)
Serious AEs	5 (5.8)	6 (22.6)	0	0	5 (6.2)	7 (10.8)	0	0	9 (5.4)	13 (8.4)
AE leading to discontinuation of study drug	3 (3.5)	3 (11.3)	1 (1.1)	2 (7.6)	0	0	2 (2.5)	2 (3.1)	5 (3.0)	5 (3.2)
Adjudicated Major Adverse Cardiac Event (MACE)	1 (1.2)	1 (3.8)	0	0	1 (1.2)	1 (1.5)	0	0	1 (0.6)	2 (1.3)
Extended MACE	3 (3.5)	3 (11.3)	0	0	1 (1.2)	1 (1.5)	0	0	3 (1.8)	4 (2.6)
Serious infections	0	0	0	0	1 (1.2)	1 (1.5)	0	0	1 (0.6)	1 (0.6)
Opportunistic infections excluing tuberculosis and herpes zoster	0	0	0	0	1 (1.2)	1 (1.5)	0	0	1 (0.6)	1 (0.6)
Injection site reaction	0	0	1(1.1)	1 (3.8)	3 (3.7)	3 (4.6)	0	0	3 (1.8)	3 (1.9)
Malignant tumor	1 (1.2)	1 (3.8)	0	0	0	0	1 (1.2)	1 (1.6)	2 (1.2)	2 (1.3)
Malignant tumor excluding non-melanoma skin cancer (NMSC)	0	0	0	0	0	0	1 (1.2)	1 (1.6)	1 (0.6)	1 (0.6)
NMSC	1 (1.2)	1 (3.8)	0	0	0	0	0	0	1 (0.6)	1 (0.6)
AE leading to death	0	0	0	0	1 (1.2)	1 (1.5)	0	0	1 (0.6)	1 (0.6)
AE related to COVID 19	4 (4.7)	4 (15.0)	2 (2.3)	2 (7.6)	12 (14.8)	14 (21.6)	8 (9.9)	11 (17.2)	24 (14.4)	29 (18.7)
Treatment emergent AEs ≥ 5% in either group										
COVID-19	3 (3.5)	3 (11.3)	2 (2.3)	2 (7.6)	11 (13.6)	12 (18.5)	7 (8.6)	9 (14.1)	21 (12.6)	24 (15.5)

RZB, risankizumab; PBO, placebo; E, events; PYs, patient years, N, number; there were no serious hypersensitivity, adjudicated anaphylactic, or active tuberculosis events reported

- Adverse event rates remain stable over time
- No new safety signal were observed
- One patient (prior cardiovascular risk factors) with adjudicated myocardial infarction in the RZB group subsequently died (> 140 days after last dose

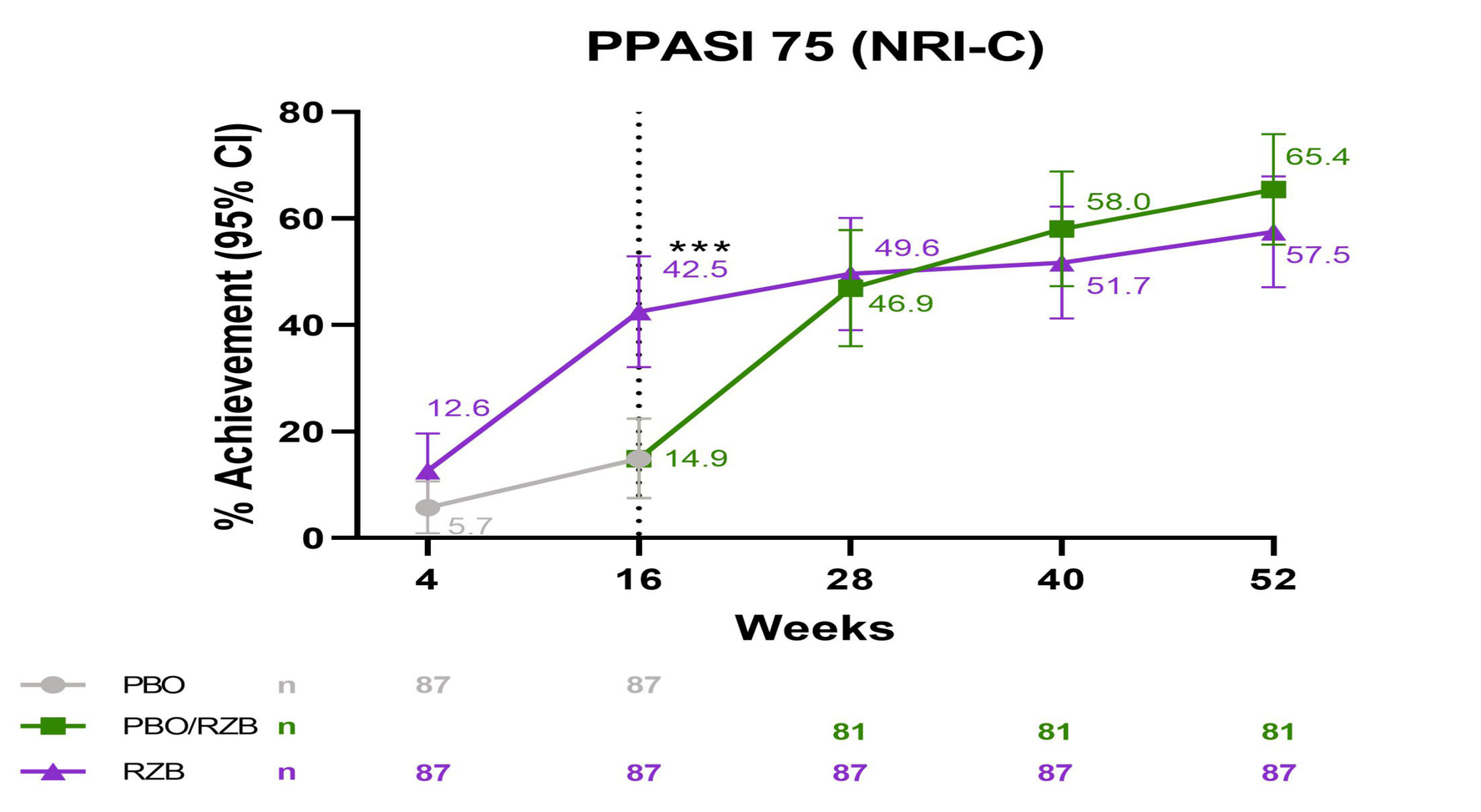
Achievement of ppIGA 0/1 by Patients Treated with RZB Compared to Patients Treated with PBO at Week 16

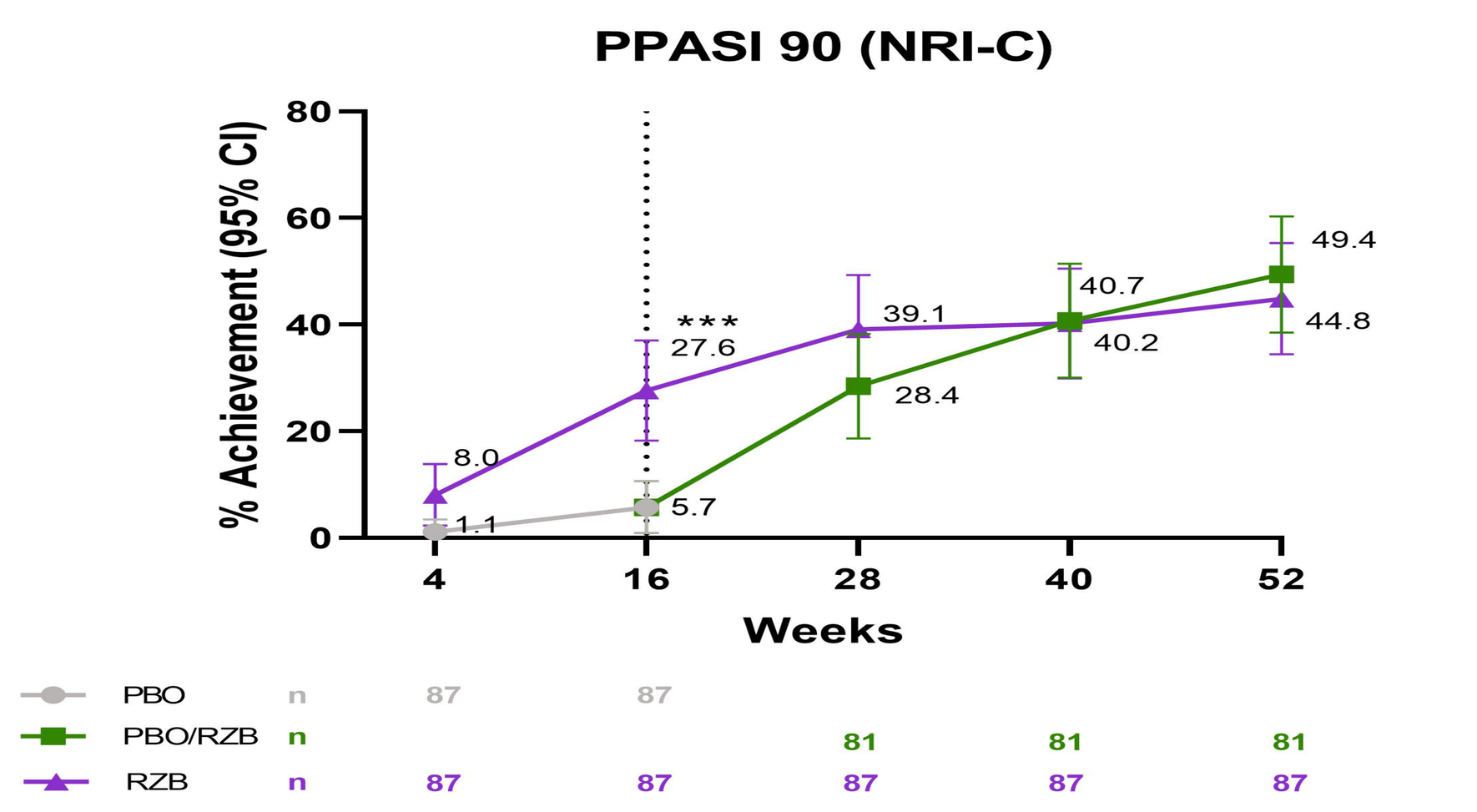


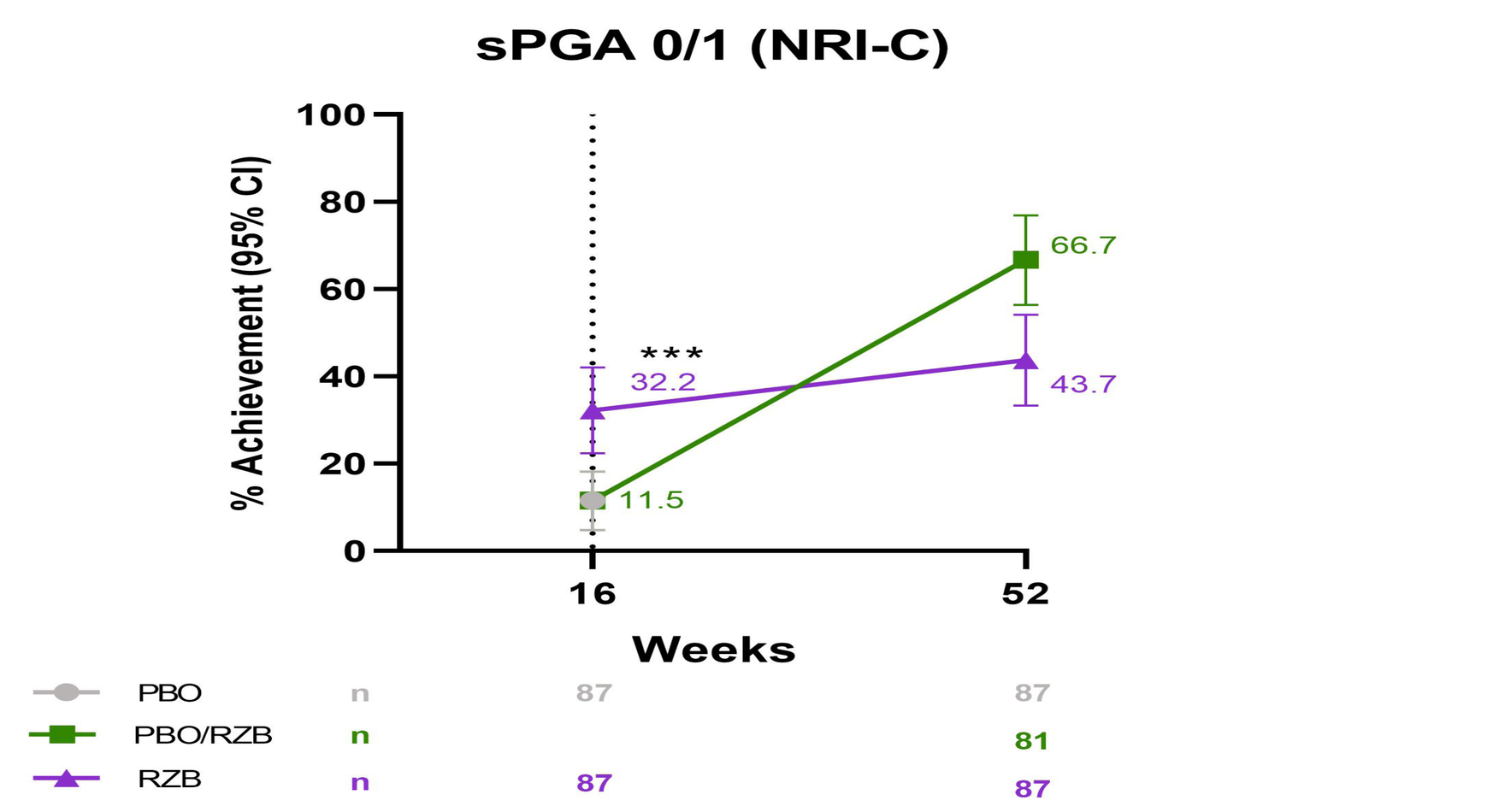
- At week 16, the rate of ppIGA 0/1 achievement was statistically significantly higher in the RZB group than the PBO group
- The rate of ppIGA 0/1 continued to increase until week 52 in the patients who continued RZB
- Patients who switched from PBO to RZB (PBO/RZB) at week 16 displayed a similar response trajectory to patients who started and continued in the RZB group

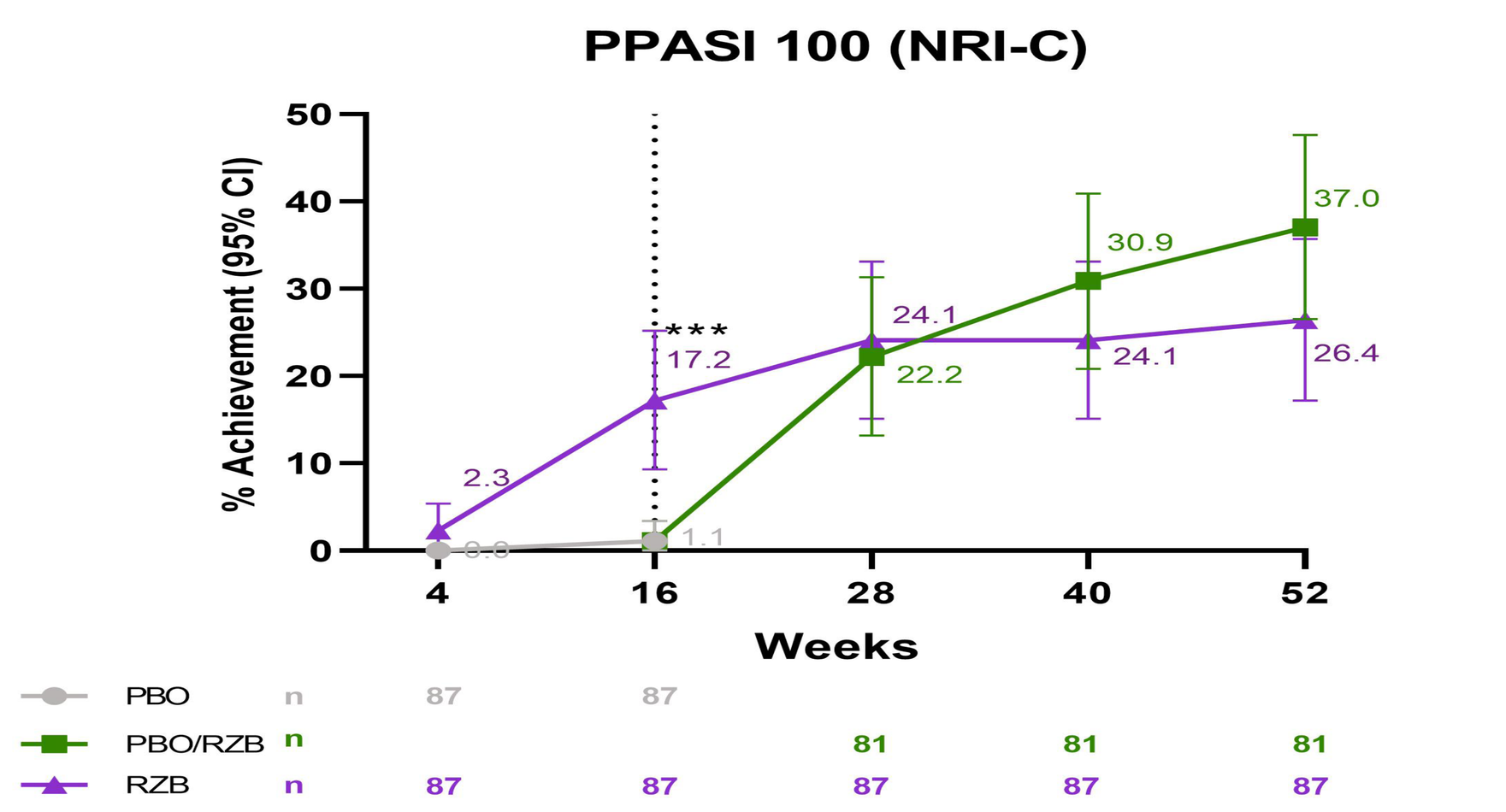
**P-value <0.01; RZB, risankizumab; PBO, placebo; PBO/RZB, placebo switch to risankizumab; ppIGA, palmoplantar investigator global assessment; CI, confidence interval; NRI-C, non-responder imputation incorporating multiple imputations to handle missing data due to COVID-19

Achievement of Ranked Secondary Endpoints by Patients Treated with RZB Compared to Patients Treated with PBO at Week 16









***P-value <0.001; RZB, risankizumab; PBO, placebo; PBO/RZB, placebo switch to risankizumab; PPASI 75, 90 or 100, ≥;75%, 90% or 100% improvement in palmoplantar psoriasis area and severity index; sPGA 0/1, static physician global assessment of clear or almost clear; CI, confidence interval; NRI-C, non-responder imputation incorporating multiple imputations to handle missing data due to COVID-19

- At week 16, the rate of PPASI 75 achievement was statistically significantly higher in the RZB group than the PBO group
- At week 16, the rate of PPASI 90 achievement was statistically significantly higher in the RZB group than the PBO group
- At week 16, the rate of sPGA 0/1 achievement was statistically significantly higher in the RZB group than the PBO group
- At week 16, the rate of PPASI 100 achievement was statistically significantly higher in the RZB group than the PBO group
- Response rates continued to increase until week 52 in the patients who continued RZB
- Patients who switched (PBO/RZB) at week 16 displayed a similar response trajectory to patients who started and continued in the RZB group