

Supplementary Information

American Journal of Clinical Dermatology, 2025

Long-Term Safety and Efficacy of Risankizumab to Treat Moderate-to-Severe Plaque Psoriasis:

Final LIMMitless Phase 3, Open-Label Extension Trial Results

Kim A. Papp, MD, PhD^{1,2} • Mark G. Lebwohl, MD³ • Lluís Puig, MD, PhD⁴ • Mamitaro Ohtsuki, MD, PhD⁵ • Stefan Beissert, MD⁶ • Melinda Gooderham, MD^{7,8} • Ahmad Z. Amin, MD⁹ • Tianshuang Wu, PhD¹⁰ • Simone Rubant, PhD¹⁰ • Brenton Bialik, PharmD¹⁰ • Doug Ashley, MD¹⁰ • Ahmed M. Soliman, PhD¹⁰ • Michael M. Chen, MD, PhD¹⁰ • Andrew Blauvelt, MD, MBA¹¹

¹Alliance Clinical Trials and Probit Medical Research, Waterloo, N2J 1C4 Ontario, Canada

²Division of Dermatology, University of Toronto School of Medicine, Toronto, Ontario, Canada

³Icahn School of Medicine at Mount Sinai, New York, NY, USA

⁴Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

⁵Jichi Medical University, Tochigi, Japan

⁶Department of Dermatology, University Hospital Carl Gustav Carus, TU Dresden, Dresden, Germany

⁷SKiN Centre for Dermatology, Probit Medical Research, Peterborough, Ontario, Canada

⁸Department of Medicine, Queen's University, Kingston, Ontario, Canada

⁹Department of Dermatology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA

¹⁰AbbVie Inc., North Chicago, IL, USA

¹¹Blauvelt Consulting, LLC, Lake Oswego, OR, USA

Supplementary Table 1 Baseline demographics and characteristics^a

Parameter	Continuous RZB 150 mg <i>N</i> = 897
Male, <i>n</i> (%)	633 (70.6)
Age, mean (SD), year	46.9 (13.5)
Weight, mean (SD), kg	88.5 (22.4)
Psoriatic arthritis, ^{b,c} <i>n</i> (%)	195 (23.3)
Prior treatment, <i>n</i> (%)	
Naïve to systemic therapy ^c	259 (30.9)
Prior biologic therapy ^c	317 (37.8)
Prior TNF antagonist therapy	163 (19.5)
BSA involvement, %, mean (SD)	26.7 (16.5)
PASI	
Mean (SD)	20.5 (8.0)
Median (Q1, Q3)	18.0 (14.7, 23.7)
NAPSI, mean (SD)	16.3 (21.5)
PSSI, mean (SD)	19.1 (15.3)
PPASI, mean (SD)	2.2 (6.0)
sPGA, <i>n</i> (%)	
Moderate (score of 3)	723 (80.6)
Severe (score of 4)	167 (18.6)
DLQI, mean (SD)	13.9 (7.2)

BSA, body surface area; DLQI, Dermatology Life Quality Index;
 NAPSI, Nail Psoriasis Severity Index; PASI, Psoriasis Area and Severity Index;
 Q1, Q3, quartile 1/3; PPASI, Palmoplantar Psoriasis Area and Severity Index;
 PSSI, Psoriasis Scalp Severity Index; RZB, risankizumab; sPGA, static Physician's
 Global Assessment; TNF, tumor necrosis factor

^aBaseline at the start of the base study

^bDiagnosed or suspected

^cBased on *N* = 838; data not collected in study NCT032553824

Supplementary Table 2 RZB-related treatment-emergent adverse events leading to RZB discontinuation

TEAEs leading to RZB discontinuation, events	Continuous RZB 150 mg N = 897
Malignancies	9 ^a
Infections	7 ^b
Worsening of psoriasis	2
Other	10 ^c

RZB, risankizumab; TEAE, treatment-emergent adverse event

^aMalignancies include breast cancer ($n = 2$), colon cancer ($n = 3$), gastric cancer ($n = 1$), prostate cancer ($n = 1$), and skin cancer ($n = 2$)

^bInfections include chronic hepatitis ($n = 1$), ear infection ($n = 1$), gastrointestinal infections ($n = 2$), respiratory infections ($n = 2$), and sexually transmitted infection ($n = 1$)

^cIncludes asthenia ($n = 1$), balance disorder ($n = 1$), abnormal laboratory findings ($n = 3$), osteonecrosis ($n = 1$), postherpetic neuralgia ($n = 1$), progressive supranuclear palsy ($n = 1$), and respiratory disorder ($n = 2$)

Supplementary Table 3 Most frequently reported TEAEs^a

Preferred term, events (E/100 PY)	Continuous RZB 150 mg
	<i>N</i> = 897 PY = 4921.2
Nasopharyngitis	616 (12.5)
Upper respiratory tract infection	346 (7.0)
Arthralgia	181 (3.7)
Headache	154 (3.1)
COVID-19	138 (2.8)
Hypertension	124 (2.5)
Back pain	96 (2.0)
Influenza	83 (1.7)
Sinusitis	75 (1.5)
Gastroenteritis	70 (1.4)
Urinary tract infection	69 (1.4)
Bronchitis	68 (1.4)
Diarrhea	61 (1.2)
Injection site erythema	54 (1.1)
Dermatitis contact	52 (1.1)
Cough	51 (1.0)
Fatigue	51 (1.0)

E/100 PY, events per 100 patient-years; RZB, risankizumab;
TEAE, treatment-emergent adverse event

^aMost frequent TEAEs defined as ≥ 1 E/100 PY; tabulated using Medical Dictionary for Regulatory Activities system organ class and preferred terms (version 24.0)

Supplementary Table 4 Treatment-emergent serious infections^a

Preferred term, events (E/100 PY)	Continuous RZB 150 mg
	N = 897 PY = 4921.2
Diverticulitis	4 (< 0.1)
Abscess limb	3 (< 0.1)
Appendicitis	3 (< 0.1)
Cellulitis	3 (< 0.1)
Pneumonia	3 (< 0.1)
Pyelonephritis acute	3 (< 0.1)
Sepsis	3 (<0.1)
COVID-19 pneumonia	2 (< 0.1)
Herpes zoster	2 (< 0.1)
Osteomyelitis	2 (<0.1)
Perirectal abscess	2 (< 0.1)
Pyelonephritis	2 (< 0.1)
Urinary tract infection	2 (< 0.1)
Abscess jaw	1 (< 0.1)
Arthritis bacterial	1 (< 0.1)
Bronchiolitis	1 (<0.1)
Chronic tonsillitis	1 (< 0.1)
<i>Clostridium difficile</i> colitis	1 (< 0.1)
COVID-19	1 (< 0.1)
Erysipelas	1 (< 0.1)
Fournier's gangrene	1 (< 0.1)
Gastroenteritis	1 (< 0.1)
Influenza	1 (< 0.1)
Meningitis	1 (< 0.1)
Neurosyphilis	1 (< 0.1)
Peritonitis	1 (< 0.1)
Peritonsillar abscess	1 (< 0.1)
Postprocedural infection	1 (< 0.1)
Postoperative abscess	1 (< 0.1)
Renal abscess	1 (< 0.1)
Urosepsis	1 (< 0.1)

E/100 PY, events per 100 patient-years; RZB, risankizumab

^aTabulated using Medical Dictionary for Regulatory Activities system organ class and preferred terms (version 24.0)

Supplementary Table 5 Proportions of patients achieving NAPSI = 0, PSSI = 0, or PPASI = 0

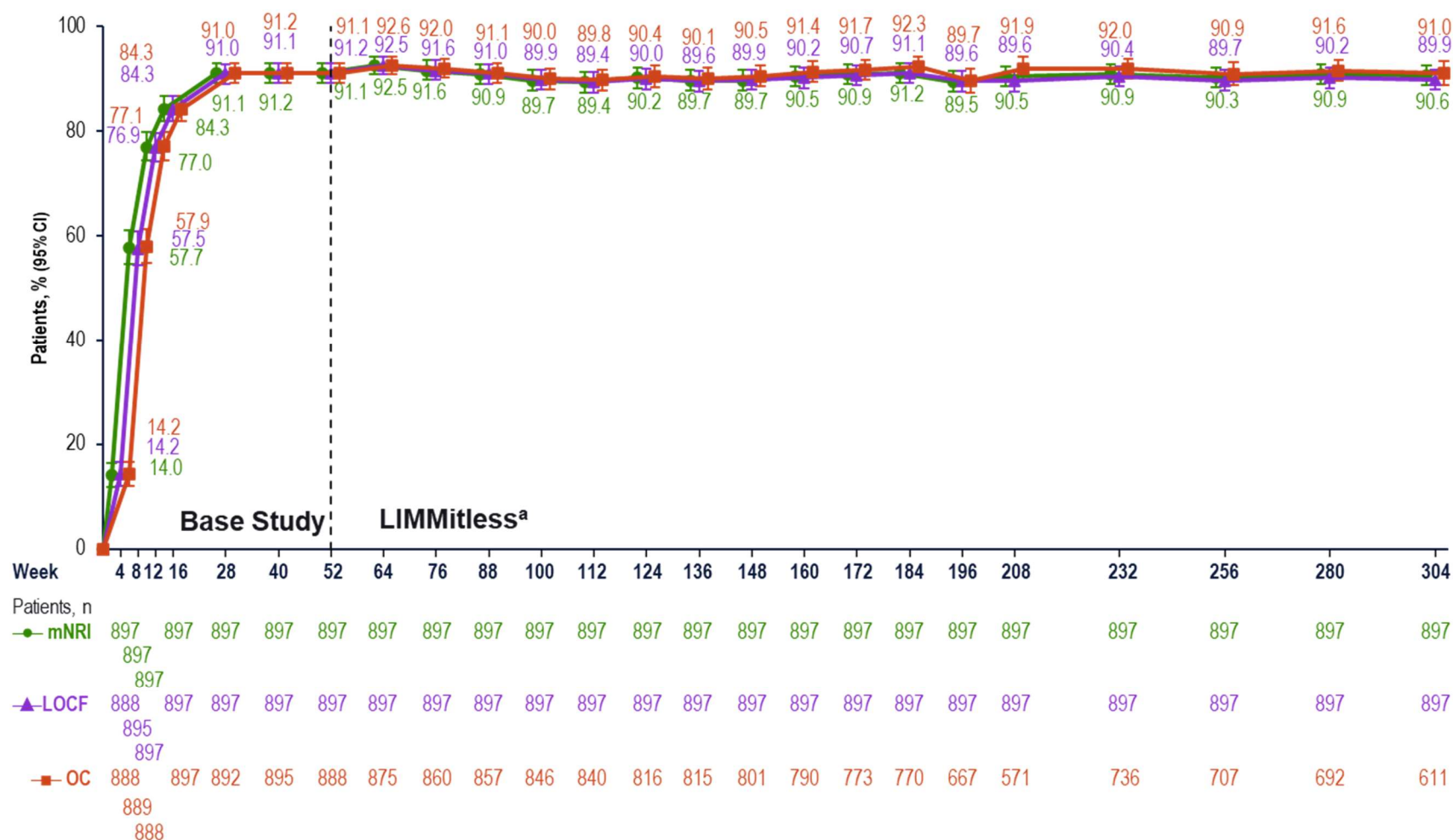
Patients, <i>n/n</i> (%)	Efficacy assessment								
	NAPSI = 0 ^a			PSSI = 0 ^b			PPASI = 0 ^c		
	OC	LOCF	mNRI	OC	LOCF	mNRI	OC	LOCF	mNRI
Week 16	118/534 (22.1)	118/534 (22.1)	118/547 (21.6)	593/757 (78.3)	593/757 (78.3)	593/770 (77.0)	207/263 (78.7)	207/263 (78.7)	207/266 (77.8)
Week 52	281/528 (53.2)	286/546 (52.4)	281/547 (51.4)	610/747 (81.7)	631/770 (81.9)	613/770 (79.6)	236/262 (90.1)	238/266 (89.5)	236/266 (88.7)
Week 304	275/366 (75.1)	393/547 (71.8)	351/547 (64.2)	419/496 (84.5)	645/770 (83.8)	435/770 (56.5)	173/184 (94.0)	249/266 (93.6)	224/266 (84.2)

LOCF, last observation carried forward; mNRI, modified nonresponder imputation; NAPSI, Nail Psoriasis Severity Index; OC, observed cases; PPASI, Palmoplantar Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index

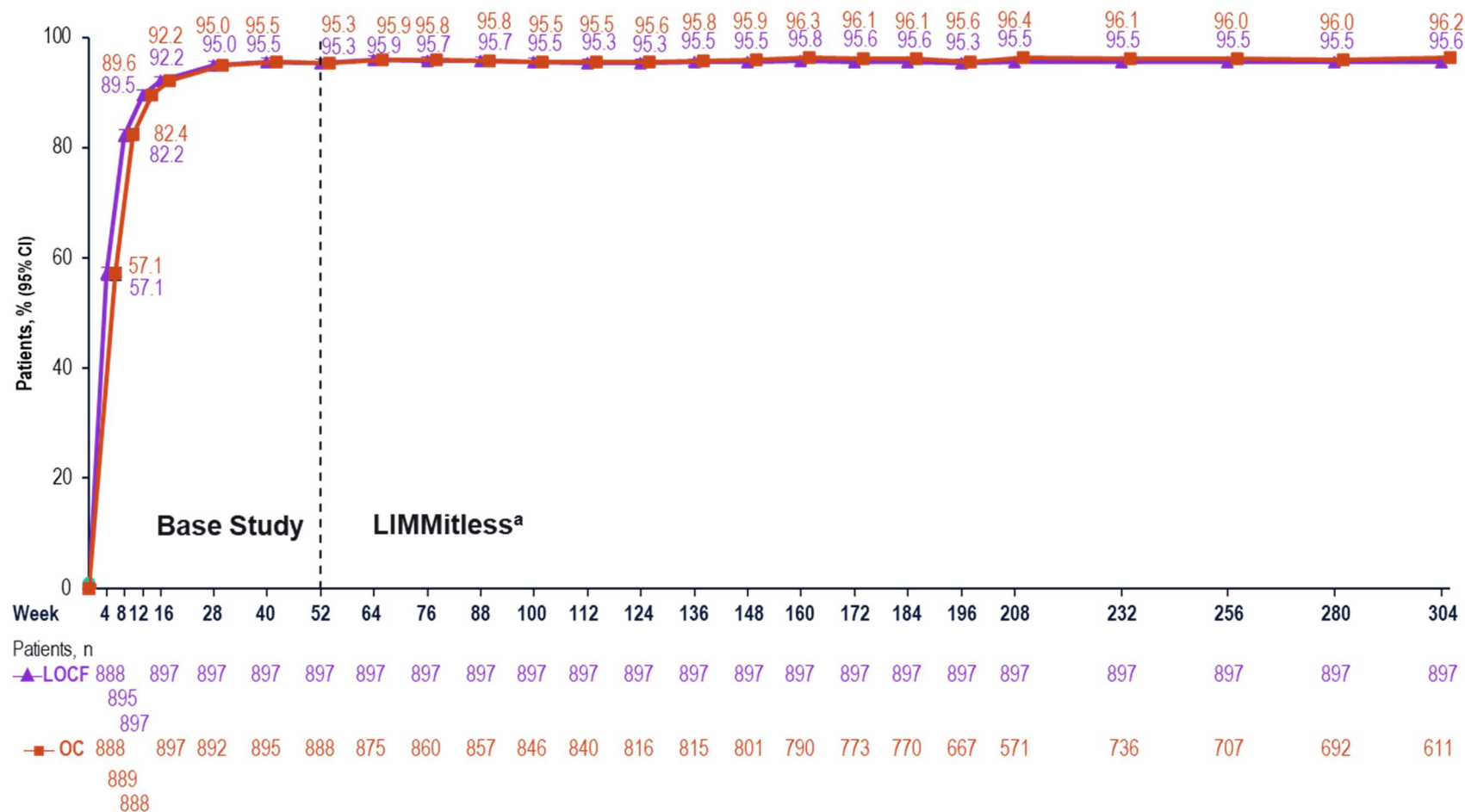
^aAmong patients with nail psoriasis at baseline

^bAmong patients with scalp psoriasis at baseline

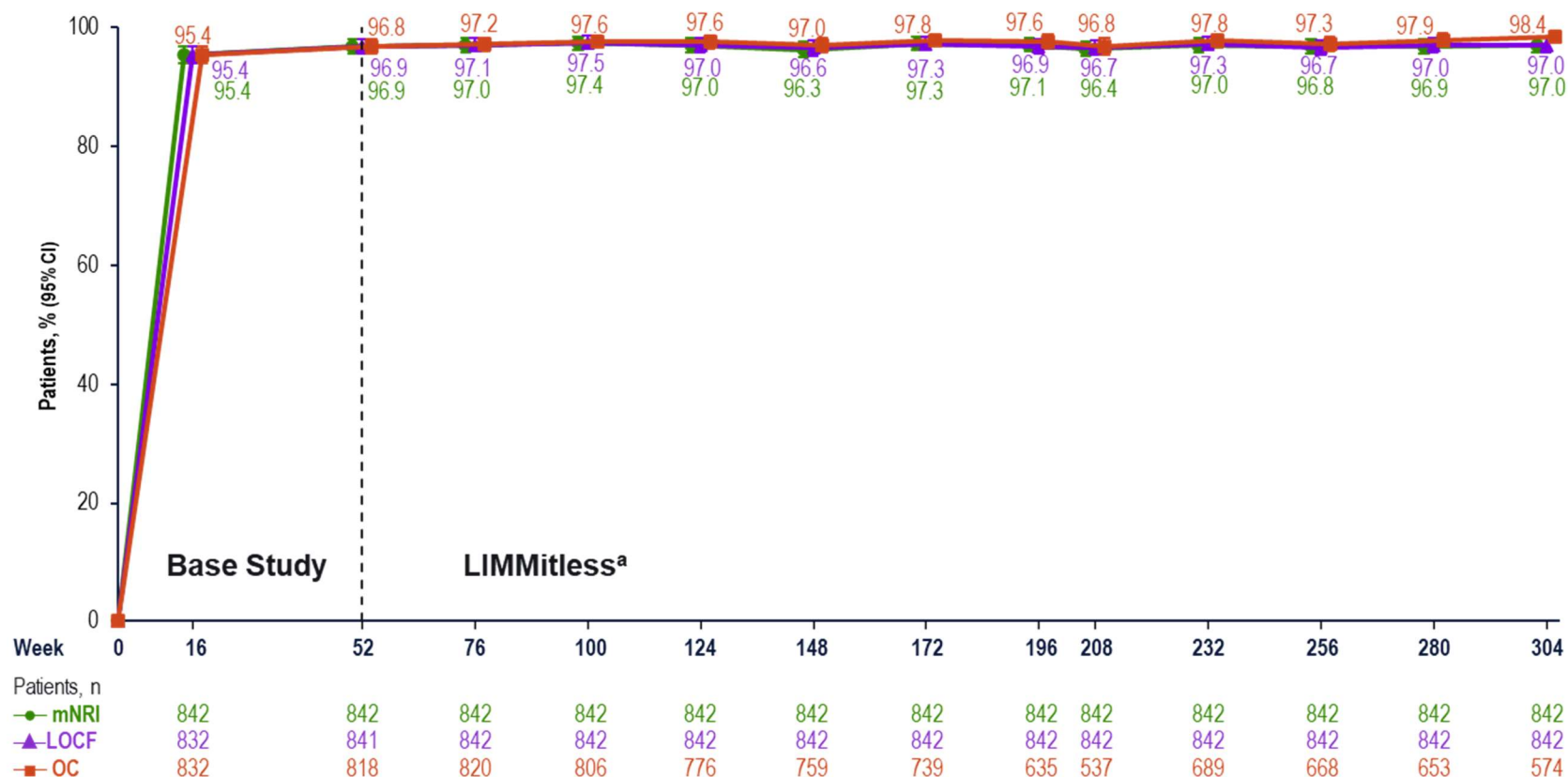
^cAmong patients with palm/sole psoriasis at baseline



Supplementary Fig. 1 Proportions of patients achieving PASI <3 over time. CI, confidence interval; LOCF, last observation carried forward; mNRI, modified nonresponder imputation; OC, observed cases; PASI, Psoriasis Area and Severity Index. ^aBecause of differences in base study lengths, some patients enrolled in the LIMMitless study earlier than 52 weeks



Supplementary Fig. 2 Mean percent improvement from baseline in PASI over time. CI, confidence interval; LOCF, last observation carried forward; OC, observed cases; PASI, Psoriasis Area and Severity Index. ^aBecause of differences in base study lengths, some patients enrolled in the LIMMitless study earlier than 52 weeks



Supplementary Fig. 3 Proportions of patients achieving ≥ 4 -point improvement in DLQI (MCID) over time among patients with baseline DLQI ≥ 4 . CI, confidence interval; DLQI 0/1, Dermatology Life Quality Index of no effect on quality of life; LOCF, last observation carried forward; MCID, minimal clinically important difference; mNRI, modified nonresponder imputation; OC, observed cases. ^aBecause of differences in base study lengths, some patients enrolled in the LIMMitless study earlier than 52 weeks