Baseline Characteristics and Interim Month 12 mNAPSI Results in Patients with Moderate-to-Severe Plaque Psoriasis and Concomitant Nail Psoriasis in PSoHO

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BACKGROUND

- Nail PsO affects ~50% of patients with PsO,[1] is difficult to treat, and is of high importance in patients with plaque PsO
- Real-world data on the long-term effectiveness of biologics for the treatment of nail PsO are needed
- The PSoHO is an ongoing, 3-year, international, prospective, non-interventional cohort study evaluating the effectiveness of anti–IL-17A biologics vs. other approved biologics in adults with moderate-to-severe plaque PsO with and without concomitant nail PsO[2]

OBJECTIVE

- This interim analysis describes nail PsO manifestations at baseline and improvements up to Month 12 in the subset of patients enrolled in the PSoHO with mNAPSI data at baseline and Month 12 who remained on initial treatment at Month 12

SUMMARY OF KEY FINDINGS

High proportions of patients with nail PsO showed improvement in mNAPSI50 or mNAPSI100 (complete resolution of nail PsO) with anti–IL-17A biologics in a real-world setting

Patients With Any Baseline Nail PsO

	mNAPSI50		mNAPSI100	
	Anti–IL-17A (N=123)	Other Biologics (N=140)	Anti–IL-17A (N=123)	Other Biologics (N=140)
Week 12	51.2	36.4	24.4	13.6
Month 6	69.9	61.4	40.7	34.3
Month 12	85.4	72.1	55.3	42.9

Patients With Moderate-to-Severe Baseline Nail PsO

	mNAPSI50		mNAPSI100	
	Anti–IL-17A (N=48)	Other Biologics (N=78)	Anti–IL-17A (N=48)	Other Biologics (N=78)
Week 12	56.3	35.9	18.8	7.7
Month 6	68.8	61.5	27.1	26.9
Month 12	89.6	74.4	41.7	34.6

Note: Data given as %

METHODS

Key Eligibility Criteria

Inclusion

- Patients (aged ≥18 years) with moderate-to-severe PsO for ≥6 months prior to baseline
- Initiating or switching biologic (or biosimilar) treatment during routine medical care

Exclusion

- Treatment initiation contraindicated due to country-specific approved indication
- Modifications to the dosing regimen of an existing biologic treatment
- Re-start of biologic treatment previously received at any point
- Completion of/withdrawal from the PSoHO
- Ongoing participation in another PsO study with any investigational product

Assessments and Statistical Analyses

- This analysis included patients with mNAPSI data at baseline and Month 12 who remained on initial treatment at Month 12
  - mNAPSI scores range from 0 to 130 for fingernails[3]; mNAPSI scores ≥20 were categorized as moderate-to-severe nail PsO[4]
- Patients were categorized at baseline as with nail PsO (mNAPSI ≥1) or without nail PsO (mNAPSI 0)
- The proportion of patients achieving mNAPSI improvement from baseline of 50% (mNAPSI50) or 100% (mNAPSI100) was assessed through Month 12
- Binary outcomes were imputed using NRI
- Cohorts for baseline data were compared using ANOVA or exact p-value from median test (Monte Carlo estimate) for continuous variables or the Fisher exact test for categorical variables
- Data through Month 12 were reported descriptively with 95% CIs calculated using the normal approximation

RESULTS

Baseline Demographics and Disease Characteristics

	Overall (N=449)	Patients Without Nail PsO (mNAPSI 0) (N=186)	Patients With Nail PsO (mNAPSI ≥1) (N=263)	p-Value
Age, years	45.4 (13.3)	44.1 (14.4)	46.4 (12.4)	.077[a]
Male, n (%)	302 (67.3)	109 (58.6)	193 (73.4)	**.001**[b]
Race, n (%)				
White	301 (67.0)	126 (67.7)	175 (66.5)	.839[b]
Asian	105 (23.4)	41 (22.0)	64 (24.3)	.651[b]
Not reported	43 (9.6)	19 (10.2)	24 (9.1)	.746[b]
BMI, kg/m²	29.2 (6.5)	29.1 (6.3)	29.3 (6.6)	.758[a]
Smoking, n (%)				
Never	174 (41.9)	93 (52.2)	81 (34.2)	**<.001**[b]
Current	112 (27.0)	36 (20.2)	76 (32.1)	
Former	129 (31.1)	49 (27.5)	80 (33.8)	
Time since onset of plaque PsO, years, median (lower quartile, upper quartile)	16.4 (8.5, 25.7)	14.6 (7.0, 25.6)	17.6 (9.3, 26.0)	.068[c]
PASI score	15.5 (9.1)	14.2 (9.3)	16.4 (8.9)	**.013**[a]
DLQI score	12.5 (7.7)	11.3 (7.6)	13.3 (7.7)	**.008**[a]
Diagnosis of PsA, n (%)	104 (23.2)	26 (14.0)	78 (29.7)	**<.001**[b]

[a] p-Value for mNAPSI 0 vs. mNAPSI ≥1 from ANOVA; [b] p-Value for mNAPSI 0 vs. mNAPSI ≥1 from the Fisher exact test; [c] Exact p-value for mNAPSI 0 vs. mNAPSI ≥1 from median test (Monte Carlo estimate)
Notes: Data are mean (SD) unless stated otherwise. p-Values <.05 shown in bold

- Proportions of males and smokers were significantly higher in the group with nail PsO compared with the group without nail PsO
- Patients with nail PsO had more severe skin disease (higher mean PASI scores) and a significantly greater proportion of people with PsA compared with patients without nail PsO

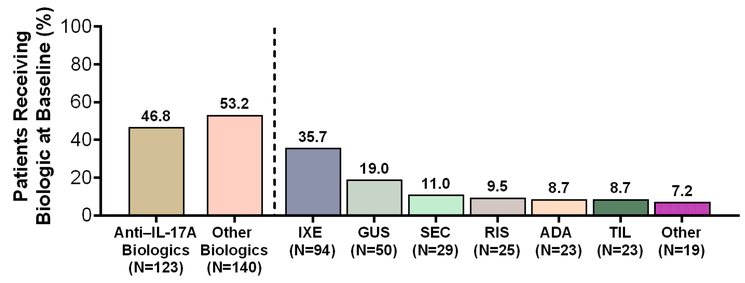
Baseline Nail PsO Characteristics[a]

	Patients With Nail PsO (mNAPSI ≥1)			
	Overall (N=263)	Anti–IL-17A (N=123)	Other Biologics (N=140)	p-Value
mNAPSI				
Mean (SD)	24.8 (21.9)	23.9 (24.3)	25.7 (19.6)	.516[b]
Median (lower quartile, upper quartile)	19 (8, 36)	15 (6, 36)	22 (11, 36)	**.003**[c]
mNAPSI ≥20 (moderate-to-severe)	126 (47.9)	48 (39.0)	78 (55.7)	**.009**[d]
mNAPSI ≥40 (severe)	60 (22.8)	29 (23.6)	31 (22.1)	.883[d]
Nail PsO features				
Onycholysis/oil-drop dyschromia	206 (78.3)	95 (77.2)	111 (79.3)	.843[e]
Nail pitting	205 (77.9)	85 (69.1)	120 (85.7)	**.002**[e]
Nail crumbling	113 (43.0)	53 (43.1)	60 (42.9)	.076[e]
Splinter hemorrhages	104 (39.5)	47 (38.2)	57 (40.7)	.737[e]
Hyperkeratosis	104 (39.5)	46 (37.4)	58 (41.4)	.454[e]
Leukonychia	95 (36.1)	35 (28.5)	60 (42.9)	.198[e]
Red spots	35 (13.3)	17 (13.8)	18 (12.9)	.788[e]

[a] Not shown for the subgroup without baseline nail PsO because baseline mNAPSI=0; [b] p-Value from ANOVA; [c] Exact p-Value from median test (Monte Carlo estimate); [d] p-Value from the Fisher exact test; [e] p-Value from the Fisher exact test (Monte Carlo estimate)
Notes: Data are n (%) unless stated otherwise. p-Values <.05 shown in bold

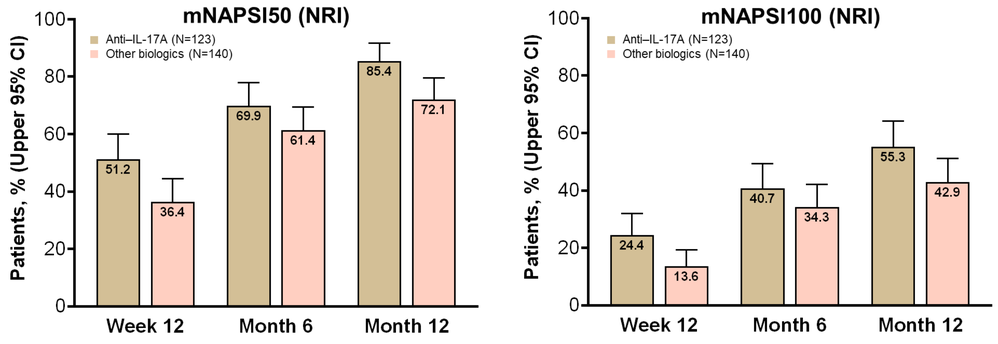
- The proportion of people with moderate-to-severe nail PsO at baseline was significantly higher in the other biologics group compared with the anti–IL-17A group
- The proportion of people with nail pitting at baseline was significantly higher in the other biologics group compared with the anti–IL-17A group

Distribution of Biologics in Patients With Baseline Nail PsO



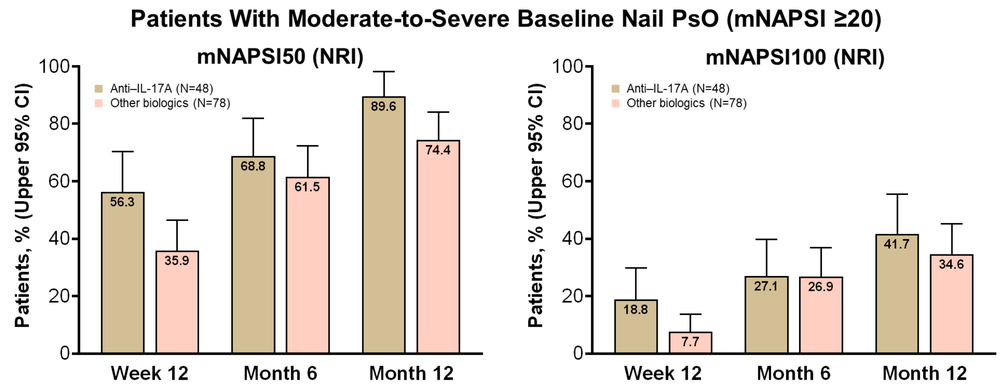
Note: Other includes ustekinumab (N=10), brodalumab (N=5), etanercept (N=2), infliximab (N=1), and certolizumab (N=1)

Improvement or Clearance of Baseline Nail PsO Through Month 12 With Anti–IL-17A and Other Biologics



Note: 95% CIs calculated using the normal approximation

Improvement or Clearance of Moderate-to-Severe Baseline Nail PsO Through Month 12 With Anti–IL-17A and Other Biologics



Note: 95% CIs calculated using the normal approximation

CONCLUSIONS

- In this interim analysis of the PSoHO, high proportions of patients with nail PsO at baseline achieved improvements at Month 12 with anti–IL-17A biologics
- 55% of patients achieved complete clearance of nail PsO at Month 12 with anti–IL-17A biologics vs. 43% with other biologics
- Similar results were observed for patients with severe baseline nail PsO
- Data from this analysis of patients with PsO in a real-world setting are consistent with results from clinical studies[5]

Limitations

- Non-randomized observational study open to potential selection and information bias
- This interim analysis used a subset of patients with non-missing data for Month 12 who remained on initial treatment and therefore may not be representative of the total population
- No comparative analysis was conducted and no adjustments were made for measured confounders
- Grouping of non-anti–IL-17A biologics into a single category may not reflect variabilities within the class

Abbreviations:

ADA=adalimumab; ANOVA=analysis of variance; BMI=body mass index; CI=confidence interval; DLQI=Dermatology Life Quality Index; GUS=guselkumab; IL=interleukin; IXE=ixekizumab; mNAPSI=modified Nail Psoriasis Severity Index; mNAPSI50/100=50%/100% improvement from baseline in mNAPSI; NRI=non-responder imputation; PASI=Psoriasis Area and Severity Index; PsA=psoriatic arthritis; PsO=psoriasis; PSoHO=Psoriasis Study of Health Outcomes; RIS=risankizumab; SD=standard deviation; SEC=secukinumab; TIL=tildrakizumab

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