Ixekizumab Improves Nail, Scalp, and Skin Response and Quality of Life Independent of Baseline Psoriasis Severity: Results From the Psoriasis in Special Areas (PSoSA) Study

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OBJECTIVE

- To evaluate the effectiveness of ixekizumab in patients with mild or moderate/severe nail PsO in real-world settings

CONCLUSION

- In real-world settings, patients with moderate-to-severe PsO initiating ixekizumab saw improvements in nail, skin, and scalp response as well as QoL as early as 4 weeks and sustained through 24 weeks, independent of nail PsO severity at baseline

Limitations

- As an ongoing study, the data for many patients at Week 24 are forthcoming

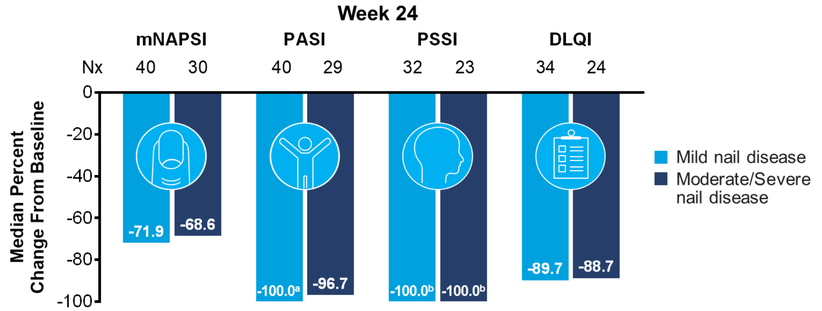
Fall Clinical 2024; Las Vegas, USA; 24-27 October 2024

BACKGROUND

- Ixekizumab is a highly selective interleukin-17A monoclonal antibody that has shown efficacy in treating patients with PsO, including challenging body areas such as nails[1-3]
- However, real-world data on the efficacy of ixekizumab in treating challenging body areas are currently lacking

SUMMARY OF KEY FINDINGS

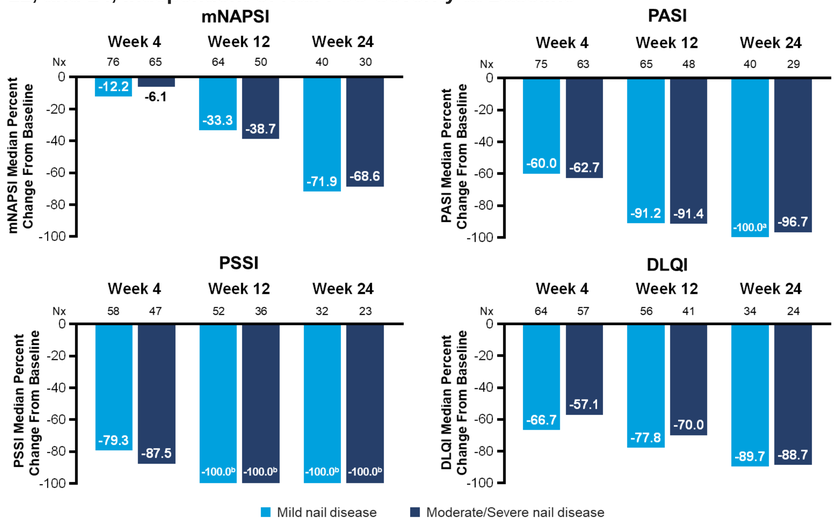
In this real-world study, patients with PsO initiating ixekizumab experienced improved nail, scalp, and skin PsO, as well as improved QoL, through to Week 24, independent of nail PsO severity at baseline



[a]Median PASI score of 0; a PASI score of 0 indicates the absence of PsO of the skin; [b]Median PSSI score of 0; a PSSI score of 0 indicates the absence of PsO on the scalp.
Note: Percent change calculated based on number of patients who had completed each timepoint and with non-missing data; patients with a baseline score of 0 were excluded from PASI, PSSI and DLQI calculations.

RESULTS

Improvements in Nail, Skin, and Scalp PsO, and QoL Were Observed at Weeks 4, 12, and 24, Independent of Nail PsO Severity at Baseline



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Methods

Study Design

- PSoSA is a US-based, 52-week, ongoing, prospective, multicenter, single-arm, observational study

Inclusion Criteria

- Adult patients (≥18 years) who present within the usual course of care
- Eligible for ixekizumab treatment in accordance with FDA labeling with a diagnosis of moderate-to-severe plaque PsO, as determined by the investigator
- Nail involvement (mNAPSI >0)
- First-time treatment with ixekizumab

Exclusion Criteria

- Overt onychomycosis or any significant disease in the fingernails other than PsO, as determined by the investigator
- Treatment initiation contraindicated due to US-approved indication
- Current participation in another PsO or psoriatic arthritis study that includes treatment with ixekizumab or an investigational product and/or intervention

Statistical Analyses and Assessments

- A descriptive analysis of the interim data from the PSoSA study is presented
  - The analysis includes only patients who had data available at Week 4, Week 12, or Week 24
- The median percent change from baseline for the following outcomes were assessed at Weeks 4, 12, and 24:
  - mNAPSI, a measure of fingernail PsO, with higher scores (range, 0-130) indicating greater severity
  - PASI, a measure of PsO, with higher scores (range, 0-72) indicating greater severity
  - PSSI, a measure of scalp PsO, with higher scores (range, 0-72) indicating greater severity
  - DLQI, a measure of quality of life, with higher scores (range, 0-30) indicating greater impairment
- Outcomes were assessed in 2 subgroups: patients with mild nail PsO at baseline (mNAPSI scores <20) and those with moderate/severe nail PsO at baseline (mNAPSI scores ≥20)

Results

Baseline Demographics and Disease Characteristics

	Patients in Second Interim Analysis of PSoSA	
	Mild Nail Disease (N=101)	Moderate/Severe Nail Disease (N=81)
Age, years	50.2 (14.5)	50.7 (16.5)
Male, n (%)	52 (51.5)	52 (64.2)
BMI, kg/m²	31.9 (7.8)	27.8 (5.7)
Race, n (%)		
American Indian or Alaska Native	1 (1.0)	1 (1.2)
Asian	11 (10.9)	14 (17.3)
Black or African American	6 (5.9)	2 (2.5)
White	80 (79.2)	58 (71.6)
Other	3 (3.0)	6 (7.4)
Time since PsO diagnosis, years	12.9 (13.7)	12.1 (13.6)
BSA % involvement	16.9 (16.8)	20.2 (21.6)
PASI, median (Q1, Q3)	6.2 (3.4, 11.7)	7.2 (4.4, 15.3)
mNAPSI, median (Q1, Q3)	10.0 (5.0, 13.0)	33.0 (24.0, 52.0)
PSSI, median (Q1, Q3)	6.0 (0.5, 13.0)	8.0 (2.0, 18.0)
DLQI, median (Q1, Q3)	11.0 (6.0, 20.0)	11.0 (6.0, 18.0)
Previous use of biologic therapy, n (%)	34 (33.7)	19 (23.5)

Note: Data are mean (SD) unless stated otherwise.

References

1. Blauvelt A, et al. *Br J Dermatol*. 2021;184:1047-1058. 2. Reich K, et al. *J Dermatolog Treat*. 2017;28:282-287. 3. Dennehy EB, et al. *J Drugs Dermatol*. 2016;15:958-961.

Abbreviations: *BMI=body mass index; BSA=body surface area; DLQI=Dermatology Life Quality Index; FDA=US Food and Drug Administration; mNAPSI=modified Nail Psoriasis Severity Index; NRS=Numeric Rating Scale; Nx=number of patients with non-missing data; PASI=Psoriasis Area Severity Index; PsO=psoriasis; PSoSA=PSOriasis Special Areas; PSSI=Psoriasis Scalp Severity Index; Q=quartile; QoL=quality of life; SD=standard deviation*

Disclosures: S. Lipner has consulted for: Eli Lilly and Company; and has received grants from: BelleTorus Corporation and Moberg Pharma; **C. Owen** is an investigator for: AbbVie, Acrotech, Alumis, Amgen, AnaptysBio, Arcutis, Bausch Health, Bristol Myers Squibb, CAGE Bio, Celgene, Connect Biopharma, Dermavant, DS Biopharma, Eli Lilly and Company, Ethica, Evidera, Forte, Galapagos NV, Galderma, Horizon Therapeutics, Incyte Corporation, Janssen, Novan, Novartis, Pfizer, Regeneron, Sanofi, Teres Bio, Ventyx Biosciences, and Vyne Therapeutics; **N. Korman** has received grants, research support, and/or honoraria from and/or has served as a speaker and/or consultant for: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, ChemoCentryx, Eli Lilly and Company, Galderma, Genentech, Immune Pharma, Janssen, Kyowa Kirin, LEO Pharma, Menlo Therapeutics, Novartis, Pfizer, Principia Biopharma, Regeneron, Sun Pharma, Trevi Therapeutics, UCB Pharma, and XBiotech; **W. Malatestinic**, **M. J. Murage**, and **A.S. Mehrabadi** are current employees and shareholders of: Eli Lilly and Company; **M. Feely McDonald** is associate staff at: Mount Sinai Hospital, Mount Sinai West, and Mount Sinai Morningside; is an employee and shareholder of: Eli Lilly and Company; and has received consulting, travel, or speaker fees from: Aerolase, American Academy of Dermatology, Castle Biosciences, CeraVe-L'Oréal, DREAM USA, Galderma Aesthetics, Glow Recipe, La Roche-Posay-L'Oréal, Revian, Sonoma Pharmaceuticals, Sun Pharma, and Suneva Medical; **J. F. Merola** is a consultant and/or investigator for: AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi Regeneron, Sun Pharma, and UCB Pharma

Medical writing assistance was provided by Philip Reardon, PhD, of ProScribe – Envision Pharma Group, and was funded by Eli Lilly and Company