Simultaneous Genital Skin Clearance and Patient-Reported Outcome Responses at Weeks 24 and 52 in Patients With Moderate-to-Severe Genital Psoriasis Treated With Ixekizumab: An Analysis of the Phase 3 Clinical Trial IXORA-Q

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Sponsored by Eli Lilly and Company

Dermatologische Wissenschafts- und Fortbildungsakademie (DWFA) - 27th Tagung; Cologne, Germany; November 29 - December 01, 2024

OBJECTIVE

- To assess the efficacy of ixekizumab through evaluation of simultaneous clinical genital skin clearance and PRO responses in patients with moderate-to-severe genital PsO

CONCLUSION

- Patients with genital PsO treated with ixekizumab demonstrated simultaneous clinical genital skin clearance outcomes and meaningful PRO responses at Week 24 and Week 52

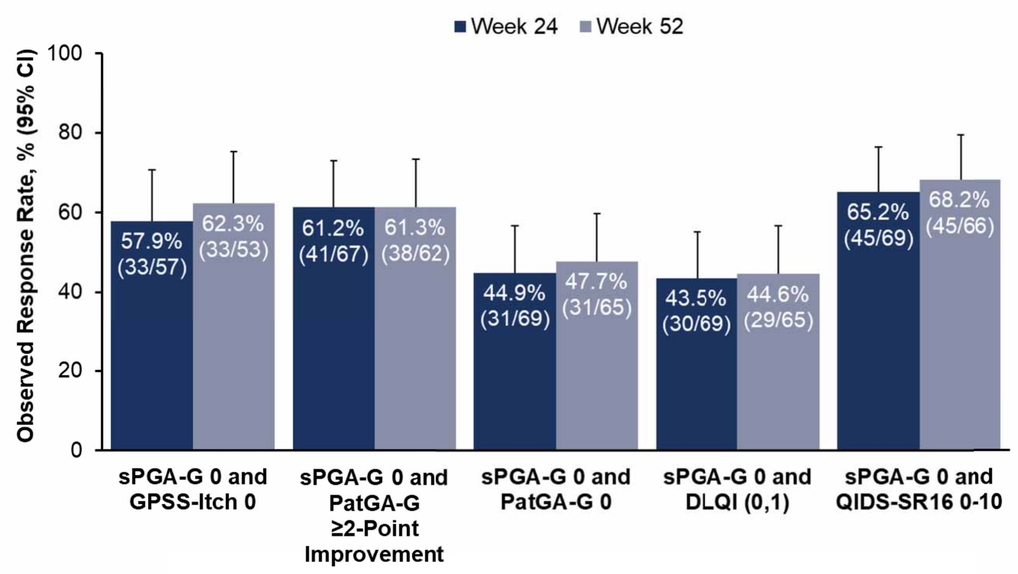
RESULTS

Baseline Demographics and Disease Characteristics for Overall Population and Week 52 Responders

	IXE Q2W/ IXE Q4W Overall (N=74)	IXE Q2W/IXE Q4W Week 52 Simultaneous Responders: sPGA-G 0 +				
		GPSS-Itch 0 (n=33)	PatGA-G ≥2-Point Improvement (n=38)	PatGA-G 0 (n=31)	DLQI (0,1) (n=29)	QIDS-SR16 0-10 (n=45)
Age, years	43.1 (13.0)	40.6 (13.2)	41.8 (14.5)	42.1 (13.3)	39.9 (12.5)	41.3 (13.7)
Male, n (%)	56 (75.7)	20 (60.6)	23 (60.5)	18 (58.1)	17 (58.6)	29 (64.4)
BMI, kg/m²	30.7 (7.6)	30.0 (8.3)	30.3 (8.0)	28.6 (5.8)	29.1 (6.5)	30.7 (8.0)
Time since genital PsO onset, years	9.4 (10.0)	8.6 (7.6)	9.6 (10.6)	8.0 (7.9)	8.3 (7.6)	9.3 (9.9)
sPGA-G	3.4 (0.6)	3.4 (0.7)	3.3 (0.7)	3.4 (0.6)	3.3 (0.7)	3.4 (0.7)
GPSS-Itch	5.9 (2.4)	6.7 (2.0)	6.3 (2.3)	5.9 (2.5)	6.0 (2.3)	5.9 (2.5)
PatGA-G	3.4 (1.1)	3.5 (1.1)	3.5 (1.1)	3.3 (1.2)	3.3 (1.2)	3.2 (1.2)
DLQI	12.3 (7.2)	13.3 (7.3)	12.7 (7.4)	11.9 (7.2)	11.9 (7.4)	12.5 (7.5)
QIDS-SR16	4.1 (3.4)	4.0 (3.2)	4.2 (3.6)	3.7 (3.2)	3.6 (3.3)	4.0 (3.6)

Note: Data are mean (SD) unless stated otherwise

Simultaneous Clinical Genital Skin Clearance and PRO Responses Were Maintained From Week 24 to Week 52



Note: Data are for the IXE Q2W/IXE Q4W treatment group

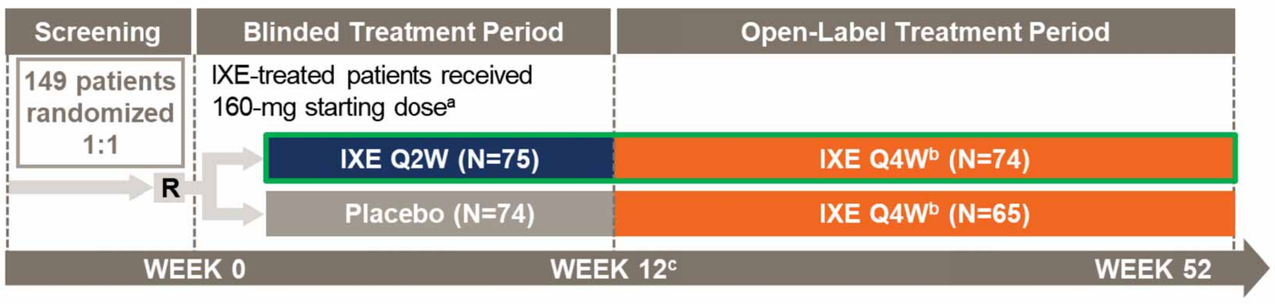
BACKGROUND

- Individuals with genital PsO experience genital itching, pain, and burning that negatively affect their HRQoL, including daily activities, moods, and emotions[1]
- Ixekizumab, a high-affinity monoclonal antibody that selectively targets IL-17A, demonstrated rapid and persistent improvement in genital PsO up to 52 weeks in a Phase 3 trial of patients with moderate-to-severe genital PsO (IXORA-Q, NCT02718898)[2,3]

METHODS

Study Design and Key Inclusion Criteria[2]

- The IXORA-Q study was conducted from April 2016 to February 201



- Key inclusion criteria:
  - Male or female age ≥18 years with chronic plaque PsO for ≥6 months
  - Plaque PsO in a non-genital area (BSA involvement ≥1%[d])
  - Overall sPGA and sPGA-G ≥3 (6-point scale)
  - Failed to respond to/intolerant of ≥1 topical therapy[e] for genital PsO

[a] Given as two 80-mg subcutaneous injections at Week 0; patients assigned to placebo received 2 subcutaneous injections of placebo at Week 0 and 1 subcutaneous injection Q2W through Week 12; [b] Option to step up to IXE Q2W at Weeks 24, 28, and 40; [c] At Week 12, patients in the IXE Q2W group received 1 dose of 80 mg IXE and 1 dose of placebo; patients in the placebo group received 2 doses of 80 mg IXE; [d] Approximately 40% of patients enrolled could have BSA involvement of 1% to <10%, and the majority were to have ≥10% BSA involvement; [e] Topical corticosteroids, calcineurin inhibitors, and/or vitamin D analogs

Post Hoc Analysis: Simultaneous Clinical Genital Skin Clearance and PRO Responses

	Clinical Genital Skin Clearance	PRO Responses			
	sPGA-G[4]	GPSS-Itch[5]	PatGA-G[4]	DLQI[6,7]	QIDS-SR16[8,9]
Outcome measured	Clinical severity of genital PsO	Severity of itching in the genital area	Severity of genital PsO	Effect on patient's HRQoL	Severity of depressive symptoms
Scoring	6-point NRS, from 0 (clear) to 5 (severe)	11-point NRS, from 0 (none) to 10 (worst imaginable)	6-point NRS, from 0 (clear) to 5 (severe)	10-item questionnaire, total score banding from 0-1 (no effect) to 21-30 (extremely large effect)	16-item questionnaire, total score banding from 0-10 (none or mild) to 21-27 (very severe)
Response rate (observed)	% with score 0 (clear)	% with score 0 (no itch)	• % with ≥2-point improvement • % with score 0 (clear)	% with score 0-1	% with score 0-10 (none or mild)

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Abbreviations:

BMI=body mass index; BSA=body surface area; CI=confidence interval; DLQI=Dermatology Life Quality Index; DLQI (0,1)=DLQI response of clear or almost clear; GPSS-Itch=Genital Psoriasis Symptoms Scale itch item; HRQoL=health-related quality of life; IL=interleukin; IXE=ixekizumab; IXE Q2W=80 mg IXE every 2 weeks; IXE Q4W=80 mg IXE every 4 weeks; NRS=Numeric Rating Scale; PatGA-G=Patient's Global Assessment of Genital Psoriasis; PRO=patient-reported outcome; PsO=psoriasis; QIDS-SR16=Quick Inventory of Depressive Symptomatology-Self Report-16 items; R=randomization; SD=standard deviation; sPGA=static Physician's Global Assessment; sPGA-G=sPGA of Genitalia

Disclosures:

- **J. C. Cather** is on the speakers bureau for: AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, LEO Pharma, and Pfizer; has served on advisory boards or as a consultant for: AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, and Sanofi Genzyme; and is an investigator for: AbbVie, Bristol Myers Squibb, ChemoCentryx, Eli Lilly and Company, Galderma, Janssen, Pfizer, Sun Pharma, and UCB Pharma; **J. Soung** has received honoraria and/or grants as a speaker, advisory board member, and/or investigator for: AbbVie, Amgen, Boehringer Ingelheim, Cassiopeia Pharmaceuticals, Celgene, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, Novan, Novartis, Pfizer, Roche, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, and Valeant Pharmaceuticals; **G. Yosipovitch** has conducted clinical trials for or received research funds and/or honoraria for serving on the scientific advisory boards of: AbbVie, Arcutis, Eli Lilly and Company, Escient Pharmaceuticals, Galderma, Kiniksa Pharmaceuticals, LEO Pharma, Novartis, Pfizer, Regeneron, and Sanofi; **C. Ryan** is on the speakers bureau of: AbbVie, Eli Lilly and Company, and Novartis; has received honoraria from: AbbVie, Aqua Pharma, Boehringer Ingelheim, Bristol Myers Squibb, Dr Reddy's Laboratories, Eli Lilly and Company, Medimetriks, Novartis, Sanofi, and UCB Pharma; and is on the advisory board of: AbbVie, Aqua Pharma, Boehringer Ingelheim, Bristol Myers Squibb, Dr Reddy's Laboratories, Eli Lilly and Company, Janssen, Medimetriks, Sanofi, and UCB Pharma; **M. El Rayes**, **B. Konicek**, **E. Edson-Heredia**, **K. See** and **A. Schloebe** are employees and shareholders of: Eli Lilly and Company; **M. McKean-Matthews** is an employee of: Syneos Health; **M. Gooderham** has been an investigator, speaker, and/or advisor for: AbbVie, Akros Pharma, Amgen, Arcutis, Aristea Therapeutics, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Incyte Corporation, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Merck, MoonLake Immunotherapeutics, Nimbus Therapeutics, Novartis, Pfizer, Regeneron, Reistone Biopharma, Roche, Sanofi Genzyme, Sun Pharma, and UCB Pharma
- Medical writing assistance was provided by Anja Becher, PhD, and Clare Weston, MSc, of ProScribe – Envision Pharma Group, and was funded by Eli Lilly and Company
- Previously presented at the American Academy of Dermatology San Diego, USA; 8-12 March 2024