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Initial report on the Month 12 results from the Psoriasis Study of Health Outcomes (PSoHO) for patients with moderate-to-severe psoriasis treated with biologics in the real-world setting

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BACKGROUND

- Psoriasis (PsO) severely impacts the health and quality of life of patients, and disease management is an ongoing challenge[1]
- Real-world data on the long-term effectiveness of different biologics for PsO treatments are needed
- The Psoriasis Study of Health Outcomes (PSoHO) is a 3-year, international, prospective, non-interventional cohort study of patients comparing the effectiveness of anti–interleukin (IL)-17A biologics (ixekizumab, secukinumab) with other approved biologics in patients with moderate-to-severe PsO initiating or switching to a new biologic[2]
  - Countries participating are Argentina, Australia, Austria, Brazil, Canada, Colombia, France, Germany, Hungary, Israel, Italy, Korea, Mexico, the Netherlands, Poland, Portugal, Romania, Saudi Arabia, Spain, Switzerland, Taiwan, United Arab Emirates, and the United Kingdom

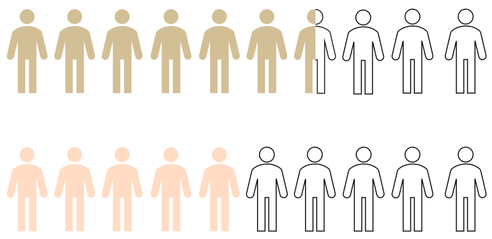
OBJECTIVES

- The primary endpoint was to compare the proportion of patients achieving at least 90% improvement from baseline in Psoriasis Area and Severity Index (PASI 90) and/or static Physician's Global Assessment (sPGA) (0,1) at 12±4 weeks following initiation of, or switching to, a new biologic
- Other endpoints evaluated the following:
  - The proportion of patients achieving PASI 90 and/or sPGA (0,1) at 6 months and 12 months following initiation of, or switching to, a new biologic
  - 100% improvement from baseline in PASI (PASI 100) at Week 12, Month 6, and Month 12
  - Durability of treatment effectiveness: The proportion of patients meeting the primary endpoint who maintained at least 75% improvement from baseline in PASI and/or sPGA (0,1) or improvement in sPGA ≥2 points from baseline at both Month 6 and Month 12
  - The proportion of patients who maintained at least PASI 90 and/or sPGA (0,1) and/or ≥2-point improvement in sPGA at Months 6 and 12
  - The proportion of patients who reported PASI 100 at Week 12 and maintained PASI 100 at Months 6 and 12

SUMMARY OF KEY FINDINGS

- The PSoHO study demonstrated the real-world effectiveness and durability of treatments targeting IL-17A for achieving skin clearance in patients with PsO

Achievement of Durability of Treatment[a] Effectiveness at Month 12



64% of the **anti–IL-17A inhibitor** cohort

vs.

49% of the **other biologics** cohort

[a] Patients meeting the primary endpoint who maintained at least PASI 75 and/or sPGA (0,1) or ≥2-point improvement in sPGA from baseline at both Month 6 and Month 12

CONCLUSIONS

- In this interim analysis in a real-world setting conducted in patients with moderate-to-severe PsO, response rates were higher for patients treated with anti–IL-17A biologics compared with other biologics
  - The percentage of patients achieving PASI 90 and/or sPGA (0,1) at Week 12 and Month 6 was significantly higher for patients treated with anti–IL-17A biologics
  - Response rates increased steadily over time, with a few exceptions for individual biologic treatments
- The durability of treatment effectiveness at Month 12 was high in patients with moderate-to-severe PsO receiving biologic therapies; the highest rate was observed for patients treated with anti–IL-17A biologics
- Results were consistent using all 3 methods of analysis: observed data, NRI, and multiple imputation

LIMITATIONS

- This was an interim analysis using a subset of patients with non-missing data for Month 12
- A reduced sample size and potential selection bias mean data may not be representative of the total population
- Real-world data may be biased due to unmeasured confounding
- Grouping of non–anti–IL-17A biologics into a single category may not reflect variabilities within the class, particularly the individual drug cohorts with small sample sizes

METHODS

Key Eligibility Criteria

Inclusion

- Patients (age 18-80 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
- Restart of biologic treatment previously received at any point
- Completion of/withdrawal from PSoHO
- Ongoing participation in another PsO study with any investigational product

Statistical Analyses

- This interim analysis included a subset of patients (N=910) with non-missing PASI and/or sPGA data and describes the primary and key secondary outcomes through Month 12
- Data were reported descriptively and with non-responder imputation (NRI)
- Data were summarized by biologic treatment class (anti–IL-17A vs. other biologics) and by individual treatments[a]
- Demographic and clinical characteristics were compared using the Fisher exact test, analysis of variance, or Mood's median test
- Differences between groups were evaluated using observed data, NRI, and multiple imputation (NRI values presented)
- Longitudinal analysis was conducted using a repeated measures analysis with generalized linear mixed models (GLMM) or logistic regression analyses
  - The models included treatment, visit, region, and sex as categorical fixed effects and age and baseline score as continuous fixed effects
  - For GLMM, the interaction of treatment and visit was also included, and within-patient errors were modeled using an unstructured covariance structure

[a] Individual treatments: ixekizumab, secukinumab, risankizumab, brodalumab, tildrakizumab, guselkumab, adalimumab, ustekinumab

SUPPLEMENT: RESULTS
- Patient Disposition

ABBREVIATIONS

ADA=adalimumab; BMI=body mass index; BROD=brodalumab; BSA=body surface area; CI=confidence interval; DLQI=Dermatology Life Quality Index; GLMM=generalized linear mixed model; GUS=guselkumab; HADS-A=Hospital Anxiety and Depression Scale–Anxiety; HADS-D=Hospital Anxiety and Depression Scale–Depression; IL=interleukin; IXE=ixekizumab; n=number of patients in each subset; N=total number of patients; NRI=non-responder imputation; PASI=Psoriasis Area and Severity Index; PASI 75/90/100=75%/90%/100% improvement from baseline in PASI; PsO=psoriasis; PSoHO=Psoriasis Study of Health Outcomes; Q=quartile; RIS=risankizumab; SD=standard deviation; SEC=secukinumab; sPGA=static Physician's Global Assessment; TILD=tildrakizumab; UST=ustekinumab

DISCLOSURES

- **A. Costanzo** has served as an advisory board member or consultant for, received fees speaker's honoraria from, or participated in clinical trials for: AbbVie, Almirall, Biogen, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi Genzyme, and UCB Pharma; **C. F. Paul** has been a consultant, speaker, and/or investigator for: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, Mylan, Novartis, Pfizer, Pierre Fabre, Sanofi, and UCB Pharma; **J.-M. Carrascosa** has been an advisory board member, speaker, and/or consultant for and/or has participated in clinical studies for: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Sandoz, Sanofi Regeneron, and UCB Pharma; **Y. Tada** has been a consultant, scientific advisor, investigator, and/or speaker for: AbbVie, Boehringer Ingelheim, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Meiji Seika Pharma, and Sanofi Genzyme; **A. Brnabic**, **C. Schuster**, **C. Reed**, and **M. Abrahamy** are employees and/or shareholders of: Eli Lilly and Company; **E. Riedl** was an employee and shareholder of: Eli Lilly and Company, at the time of the study; **A. Pinter** has served as an investigator and/or speaker and/or advisor for: AbbVie, Almirall Hermal, Amgen, Biogen, BioNTec, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GlaxoSmithKline, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Merck Sharp & Dohme, Mitsubishi Tanabe Pharma, Novartis, Pascoe Natural Healthcare, Pfizer, Regeneron, Roche, Sandoz, Sanofi Genzyme, Schering-Plough, Tigercat Pharma, and UCB Pharma
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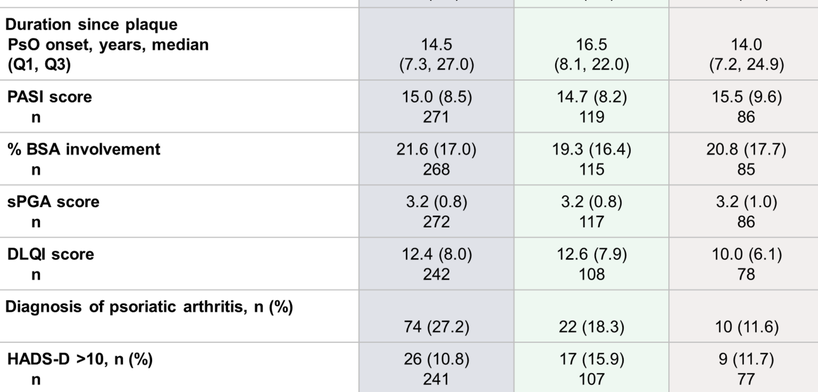
RESULTS

Demographics and Baseline Characteristics

	IXE (N=272)	SEC (N=120)	RIS (N=86)	BROD (N=29)	TILD (N=54)	GUS (N=155)	ADA (N=111)	UST (N=52)
Age, years	48.0 (14.1)	44.6 (12.4)	43.9 (12.2)	41.1 (12.9)	45.4 (14.7)	44.7 (13.2)	45.0 (13.9)	47.6 (14.5)
Male, n (%)	170 (62.5)	63 (52.5)	53 (61.6)	17 (58.6)	34 (63.0)	99 (63.9)	69 (62.2)	33 (63.5)
BMI, kg/m² **25 to <30, n (%)** **≥30, n (%)** **n**	29.0 (6.4) 100 (36.9) 94 (34.6) 271	28.8 (6.5) 45 (37.5) 39 (32.5) 120	29.0 (7.2) 23 (27.1) 35 (41.2) 85	27.6 (5.8) 5 (17.2) 13 (44.8) 29	28.5 (6.6) 19 (35.8) 19 (35.8) 53	28.8 (6.3) 55 (35.7) 56 (36.4) 154	27.9 (5.7) 46 (42.6) 28 (25.9) 108	28.7 (5.9) 20 (39.2) 15 (29.4) 51
Race, n (%) **White** **Asian** **Not reported** **Other**	 198 (72.8) 41 (15.1) 30 (11.0) 3 (1.1)	 95 (79.2) 17 (14.2) 7 (5.8) 2 (1.7)	 60 (69.8) 12 (14.0) 13 (15.1) 1 (1.2)	 21 (72.4) 6 (20.7) 2 (6.9) 0	 50 (92.6) 3 (5.6) 0 1 (1.9)	 76 (49.0) 60 (38.7) 20 (12.9) 1 (0.6)	 96 (86.5) 3 (2.7) 12 (10.8) 0	 44 (84.6) 3 (5.8) 5 (9.6) 0
Duration since plaque PsO onset, years, median (Q1, Q3)	14.5 (7.3, 27.0)	16.5 (8.1, 22.0)	14.0 (7.2, 24.9)	14.6 (8.1, 20.2)	17.0 (7.1, 25.7)	15.8 (8.9, 24.8)	13.5 (5.7, 22.8)	15.4 (9.9, 25.9)
PASI score **n**	15.0 (8.5) 271	14.7 (8.2) 119	15.5 (9.6) 86	15.7 (8.3) 29	14.9 (8.1) 54	14.1 (9.6) 155	14.2 (7.8) 111	15.3 (7.3) 52
% BSA involvement **n**	21.6 (17.0) 268	19.3 (16.4) 115	20.8 (17.7) 85	24.6 (17.9) 29	20.8 (13.6) 54	20.7 (18.7) 154	21.9 (18.9) 107	22.9 (16.2) 49
sPGA score **n**	3.2 (0.8) 272	3.2 (0.8) 117	3.2 (1.0) 86	3.1 (0.8) 28	3.1 (0.9) 54	3.2 (0.8) 155	3.2 (0.6) 111	3.0 (0.7) 52
DLQI score **n**	12.4 (8.0) 242	12.6 (7.9) 108	10.0 (6.1) 78	13.8 (7.9) 28	11.7 (7.2) 35	10.7 (7.8) 139	12.6 (7.4) 92	11.5 (7.7) 44
Diagnosis of psoriatic arthritis, n (%)	74 (27.2)	22 (18.3)	10 (11.6)	6 (20.7)	11 (20.4)	34 (21.9)	18 (16.2)	8 (15.4)
HADS-D >10, n (%) **n**	26 (10.8) 241	17 (15.9) 107	9 (11.7) 77	1 (3.6) 28	5 (14.7) 34	15 (10.9) 138	8 (8.7) 92	2 (4.5) 44
HADS-A >10, n (%) **n**	57 (23.7) 241	26 (24.3) 107	15 (19.5) 77	4 (14.3) 28	12 (35.3) 34	28 (20.3) 138	19 (20.7) 92	10 (22.7) 44
Any previous conventional therapy, n (%) **n**	205 (75.6) 271	87 (72.5) 120	72 (83.7) 86	25 (86.2) 29	47 (87.0) 54	114 (73.5) 155	102 (91.9) 111	42 (80.8) 52
Previous biologic therapy, n (%) **n**	104 (38.4) 271	39 (32.5) 120	35 (40.7) 86	13 (44.8) 29	16 (29.6) 54	102 (65.8) 155	9 (8.1) 111	16 (30.8) 52

Data are presented as mean (SD) unless otherwise indicated. Missing data are not included

Percentage of Patients (NRI) Achieving the Primary Endpoint at Week 12 and PASI 90 and/or sPGA (0,1) at Months 6 and 12

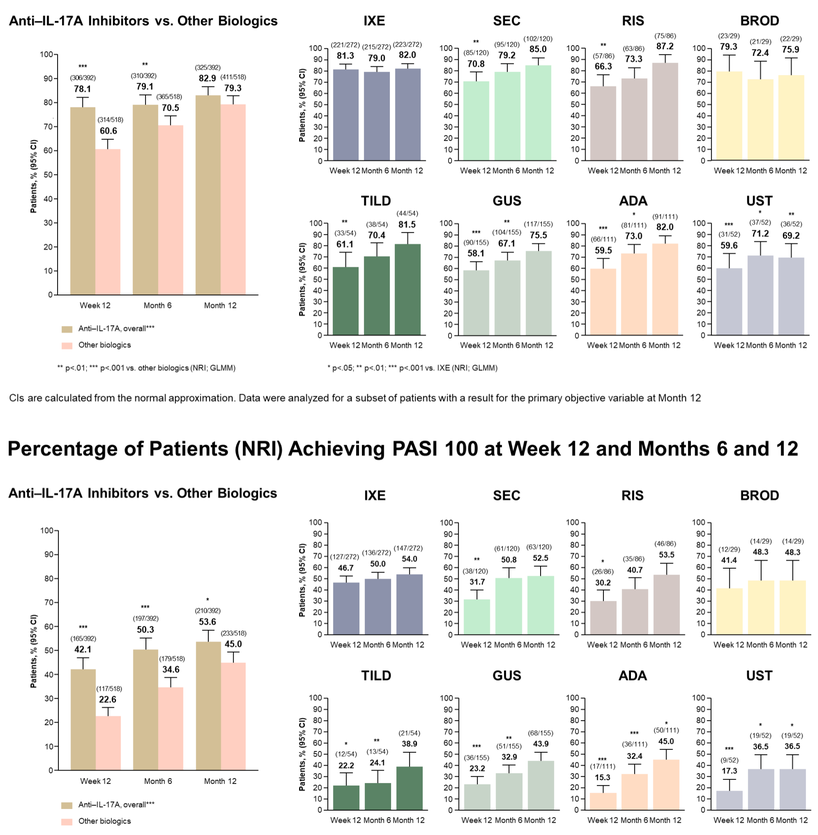


** p<.01; *** p<.001 vs. other biologics (NRI; GLMM)

* p<.05; ** p<.01; *** p<.001 vs. IXE (NRI; GLMM)

CIs are calculated from the normal approximation. Data were analyzed for a subset of patients with a result for the primary objective variable at Month 12

Percentage of Patients (NRI) Achieving PASI 100 at Week 12 and Months 6 and 12



* p<.05; *** p<.001 vs. other biologics (NRI; GLMM)

* p<.05; ** p<.01; *** p<.001 vs. IXE (NRI; GLMM)

CIs are calculated from the normal approximation. Data were analyzed for a subset of patients with a result for the primary objective variable at Month 12

Percentage of Patients (NRI) Achieving Durability of Treatment Effectiveness at Month 12[a]

*** p<.001 vs. other biologics (NRI; logistic regression)

* p<.05; *** p<.001 vs. IXE (NRI; logistic regression)

CIs are calculated from the normal approximation. Data were analyzed for a subset of patients with a result for the primary objective variable at Month 12

[a] Durability of treatment effectiveness was defined as the percentage of patients achieving PASI 90 and/or sPGA (0,1) at Week 12 and PASI 75 and/or ≥2-point improvement in sPGA at Months 6 and 12

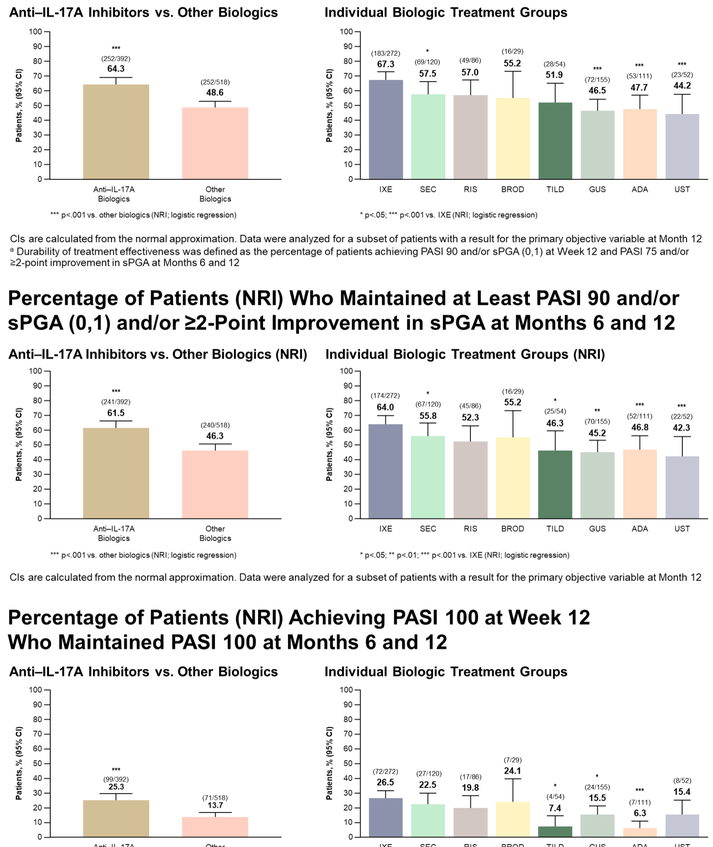
Percentage of Patients (NRI) Who Maintained at Least PASI 90 and/or sPGA (0,1) and/or ≥2-Point Improvement in sPGA at Months 6 and 12

*** p<.001 vs. other biologics (NRI; logistic regression)

* p<.05; ** p<.01; *** p<.001 vs. IXE (NRI; logistic regression)

CIs are calculated from the normal approximation. Data were analyzed for a subset of patients with a result for the primary objective variable at Month 12

Percentage of Patients (NRI) Achieving PASI 100 at Week 12 Who Maintained PASI 100 at Months 6 and 12



*** p<.001 vs. other biologics (NRI; logistic regression)

* p<.05; *** p<.001 vs. IXE (NRI; logistic regression)

CIs are calculated from the normal approximation. Data were analyzed for a subset of patients with a result for the primary objective variable at Month 12

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