Treatment Patterns over 12 Months in Patients with Moderate-to-Severe Psoriasis from the Psoriasis Study of Health Outcomes (PSoHO)

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BACKGROUND

- Biologics have become the mainstay for treatment of moderate-to-severe plaque PsO; recent real-world studies have shown that switching from one biologic to another may be needed to maintain clinical improvement over time[1,2]
- The Psoriasis Study of Health Outcomes (PSoHO), a 3-year, international, prospective, non-interventional cohort study, was conducted to compare the effectiveness of anti–IL-17A biologics (ixekizumab, secukinumab) with other approved biologics[a] in patients with moderate-to-severe PsO initiating or switching to a new biologic[3]

OBJECTIVE

- This analysis reported treatment patterns, switches, and discontinuations from baseline to Month 12 in patients receiving biologics in a real-world setting

[a] Adalimumab, brodalumab, certolizumab, etanercept, guselkumab, infliximab, risankizumab, tildrakizumab, and ustekinumab

LIMITATIONS

- Limitations of this analysis include the following:
  - Small patient numbers in select treatment groups (ie, brodalumab, certolizumab, etanercept, infliximab)

CONCLUSIONS

- In this analysis of the real-world PSoHO study, both the combination of biologics with conventional systemic drugs and concomitant use of topical treatment for patients with moderate-to-severe PsO was infrequent
- Additionally, most patients remained on their treatment prescribed at baseline, with no apparent pattern for switching therapies across treatment types
- These real-world data illustrate treatment patterns in patients with PsO receiving biologics, and can inform treatment decisions

METHODS

Key Eligibility Criteria

Inclusion

- Patients (aged ≥18 years) with moderate-to-severe PsO for ≥6 months prior to baseline
  - Participating countries include 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 UK
- 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 study
- Ongoing participation in another PsO study with any investigational product

Statistical Analyses

- This analysis included 1981 eligible patients[3]
- Pairwise comparisons of baseline demographics between ixekizumab vs. other individual biologics, respectively, were performed using Fisher's exact test or chi-squared test for categorical variables and ANOVA, Mood's median test or exact p-value from median test (Monte Carlo estimate) for continuous variables
  - $p<.05$ was considered statistically significant
- Baseline characteristics, concomitant use, and changes in treatment up through Month 12 were reported descriptively and were summarized by individual treatment groups

RESULTS

Demographics and Baseline Characteristics[a]

	All (N=1981)	IXE (N=532)	SEC (N=241)	RIS (N=259)	BROD (N=64)	TILD (N=95)	GUS (N=303)	ADA (N=284)	UST (N=127)
Age, years	45.3 (13.6)	47.4 (14.1)	45.4 (12.8)	44.1 (13.7)**	44.1 (14.0)	45.1 (13.6)	44.2 (13.2)*	45.1 (13.0)**	46.4 (14.5)
Male, n (%)	1143 (57.7)	313 (58.8)	129 (53.5)	161 (62.2)	37 (57.8)	57 (60.0)	179 (59.1)	163 (57.4)	77 (60.6)
BMI, kg/m²	29.0 (6.7)	29.4 (6.6)	28.9 (6.5)	28.6 (6.9)	29.5 (7.5)	29.3 (7.3)	29.0 (6.7)	29.3 (6.6)	28.0 (5.6)**
Race, n (%)									
White	1441 (72.7)	394 (74.1)	182 (75.5)	169 (65.3)	40 (62.5)	90 (94.7)	162 (53.5)	248 (87.3)	99 (78.0)
Asian	296 (14.9)	67 (12.6)	36 (14.9)	53 (20.5)	20 (31.3)	3 (3.2)	100 (33.0)	7 (2.5)	8 (6.3)
Other/not reported	238 (12.0)	68 (12.8)	22 (9.1)	37 (14.3)	5 (7.8)	1 (1.1)	40 (13.2)	29 (10.2)	19 (15.0)
Time since onset of plaque PsO, years, median (Q1, Q3)	14.0 (6.8, 23.8)	13.9 (6.7, 25.3)	14.9 (6.0, 21.8)	13.7 (8.2, 23.5)	12.9 (6.5, 20.9)	15.4 (6.5, 25.7)	14.9 (7.8, 24.4)	14.2 (6.3, 25.0)	12.1 (6.3, 23.7)
PASI	14.5 (8.6)	14.4 (8.5)	15.0 (8.7)	15.4 (9.8)	16.3 (8.5)	14.1 (8.5)	14.6 (9.3)	13.3 (7.1)	14.4 (7.9)
BSA % involvement	21.3 (17.7)	20.6 (17.2)	22.3 (18.1)	20.6 (18.9)	24.2 (18.3)	20.3 (16.7)	21.7 (18.5)	20.6 (16.6)	22.6 (17.7)
sPGA score, n (%)									
Moderate	988 (50.7)	267 (50.6)	120 (50.8)	102 (40.8)	37 (59.7)	42 (44.7)	143 (47.7)	170 (60.5)	68 (54.8)
Severe	610 (31.3)	176 (33.3)	66 (28.0)	93 (37.2)	18 (29.0)	27 (28.7)	101 (33.7)	69 (24.6)	37 (29.8)
Very severe	76 (3.9)	16 (3.0)	18 (7.6)	15 (6.0)	3 (4.8)	2 (2.1)	14 (4.7)	5 (1.8)	2 (1.6)
DLQI[b]	12.6 (7.8)	12.6 (7.9)	13.5 (7.7)	11.8 (7.3)	13.6 (7.8)	10.8 (7.6)	12.3 (8.1)	12.9 (7.6)	12.3 (8.0)
Diagnosis of PsA,[c] n (%)	461 (23.3)	161 (30.3)	66 (27.4)	32 (12.4)*	16 (25.0)	18 (18.9)**	71 (23.4)**	64 (22.5)**	19 (15.0)*
Nail PsO,[d] n (%)	750 (37.9)	221 (41.5)	84 (34.9)	88 (34.1)	19 (29.7)	50 (52.6)	115 (38.1)	105 (37.0)	45 (35.7)
Prior conventional therapy, n (%)	1565 (79.0)	393 (74.0)	180 (74.7)	199 (76.8)	54 (84.4)	83 (87.4)	225 (74.3)	265 (93.3)*	106 (83.5)*
Prior biologics,[e] n (%)	706 (35.7)	204 (38.4)	87 (36.1)	111 (42.9)	23 (35.9)	30 (31.6)	178 (58.7)*	25 (8.8)*	35 (27.6)**

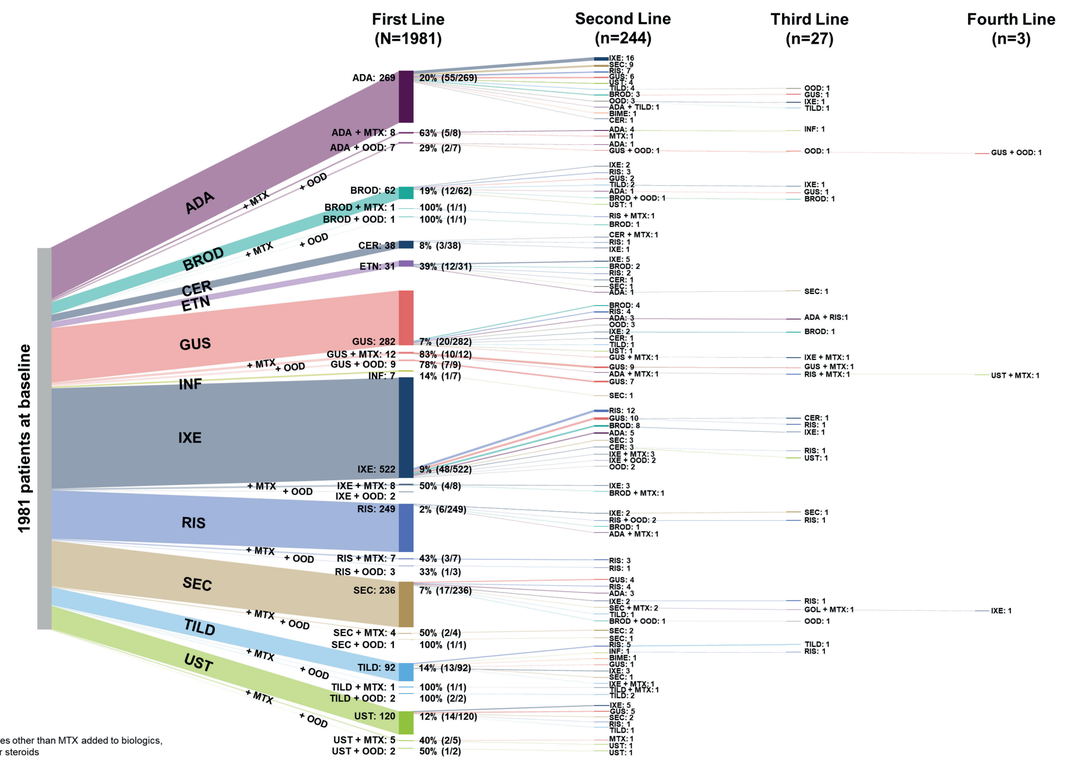
Statistically significant differences in the proportion of patients between IXE vs. other biologics class were denoted as: * p≤.001; ** p≤.05

[a] Only treatment groups with ≥50 patients are reported; [b] DLQI was measured on a 0-30 scale; [c] PsA diagnosis was recorded by the dermatologist based on the medical history and/or information provided by the patient; [d] Recorded as a simple yes/no question (Investigator assessed);
[e] Information about prior biologic use missing in 1 patient

Note: Data are presented as mean (SD) unless otherwise indicated

Concomitant Therapy From Baseline to Month 12

	All (N=1981)	IXE (N=532)	SEC (N=241)	RIS (N=259)	BROD (N=64)	TILD (N=95)	GUS (N=303)	ADA (N=284)	UST (N=127)
Concomitant systemic therapy, n (%)	55 (2.8)	7 (1.3)	5 (2.1)	8 (3.1)	1 (1.6)	2 (2.1)	11 (3.6)	13 (4.6)	7 (5.5)
Methotrexate	31 (1.6)	4 (0.8)	3 (1.2)	5 (1.9)	0	1 (1.1)	5 (1.7)	8 (2.8)	4 (3.1)
Cyclosporin	9 (0.5)	0	0	3 (1.2)	1 (1.6)	0	1 (0.3)	2 (0.7)	2 (1.6)
Apremilast	6 (0.3)	1 (0.2)	1 (0.4)	1 (0.4)	0	1 (1.1)	1 (0.3)	0	1 (0.8)
Acitretin	3 (0.2)	1 (0.2)	0	0	0	0	0	2 (0.7)	0
Steroids	3 (0.2)	1 (0.2)	0	0	0	0	1 (0.3)	1 (0.4)	0
Others	5 (0.3)	0	1 (0.4)	1 (0.4)	0	0	3 (1.0)	0	0
Concomitant topical therapy, n (%)	179 (9.0)	45 (8.0)	17 (7.1)	35 (13.5)	1 (1.6)	9 (9.5)	33 (10.9)	30 (10.6)	4 (3.1)
Calcineurin inhibitors	10 (0.5)	0	2 (0.8)	1 (0.4)	0	1 (1.1)	4 (1.3)	2 (0.7)	0
Corticosteroids	131 (6.6)	33 (6.2)	8 (3.3)	25 (9.7)	1 (1.6)	7 (7.4)	23 (7.6)	26 (9.2)	4 (3.1)
Retinoids	2 (0.1)	0	0	2 (0.8)	0	0	0	0	0
Vitamin D analogues	48 (2.4)	14 (2.6)	5 (2.1)	10 (3.9)	0	2 (2.1)	8 (2.6)	7 (2.5)	0
Others	28 (1.4)	7 (1.3)	6 (2.5)	5 (1.9)	0	2 (2.1)	6 (2.0)	2 (0.7)	0



Note: OOD (other oral drug) refers to oral therapies other than MTX added to biologics, which include acitretin, apremilast, cyclosporin, or steroids

Concomitant Therapy From Baseline to Month 12

- Among all patients (n=1981):
  - 9.0% (n=179) received ≥1 topical treatment, particularly corticosteroids (6.6%; n=131) and vitamin D analogues (2.4%; n=48)
  - 2.8% (n=55) received concomitant systemic therapies, predominantly methotrexate (1.6%; n=31)
- Across individual biologics:
  - Prescription of concomitant systemic treatment (mainly methotrexate) at baseline was comparable
  - Concomitant topical therapy use ranged from 1.6% (brodalumab) to 13.5% (risankizumab), with corticosteroids prescribed most frequently, irrespective of biologic used

Treatment Switching Patterns From Baseline to Month 12

- Among all patients (n=1981):
  - 8.2% (n=163) had switched from their assigned biologic therapy to another at least once
  - 4.3% (n=86) discontinued biologic treatment
  - 0.7% (n=14) received additional conventional systemic treatment
- Across individual biologics:
  - The proportions of patients switching to another biologic at least once from baseline up to Month 12 were highest among those receiving adalimumab (14.8%; n=42/284), tildrakizumab (14.7%; n=14/95), and brodalumab (14.1%; n=9/64), and <8% for the other biologics
  - Up to Month 12, the addition of non-biologic systemic therapies was generally low (≤3.1%), as was the discontinuation of biologic treatment across the different biologics (1.1-7.4%)

ABBREVIATIONS

ADA=adalimumab; ANOVA=analysis of variance; BIME=bimekizumab; BMI=body mass index; BROD=brodalumab; BSA=body surface area; CER=certolizumab; DLQI=Dermatology Life Quality Index; ETN=etanercept; GOL=golimumab; GUS=guselkumab; IL=interleukin; INF=infliximab; IXE=ixekizumab; MTX=methotrexate; OOD=other oral drug; PASI=Psoriasis Area and Severity Index; PsA=psoriatic arthritis; PsO=psoriasis; PSoHO=Psoriasis Study of Health Outcomes; Q1=first quartile; Q3=third quartile; RIS=risankizumab; SD=standard deviation; SEC=secukinumab; sPGA=static Physician's Global Assessment; TILD=tildrakizumab; UST=ustekinumab

DISCLOSURES

- **G. Fabbrocini** has no conflicts of interest to declare; **A. Reich** has worked as a consultant or speaker for: AbbVie, Bioderma, Celgene, Chema-Elektromet, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Medac, Menlo Therapeutics, Novartis, Pierre Fabre, Sandoz, and Trevi Therapeutics; and has participated as Principal Investigator or Sub-Investigator in clinical trials sponsored by: AbbVie, Drug Delivery Solutions, Galderma, Genentech, Janssen, Kymab, LEO Pharma, Menlo Therapeutics, Merck Sharp & Dohme, MetrioPharm, Novartis, Pfizer, and Trevi Therapeutics; **J.-M. Carrascosa** has been an advisory board member, speaker, and/or consultant 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; **S. D. Smith** has been an advisor for and/or received speaking fees and/or served as an investigator in clinical trials for: AbbVie, Amgen, Biogen, Bristol Myers Squibb, Eli Lilly and Company, Janssen Cilag, LEO Pharma, Novartis, Pfizer, Sanofi Genzyme, and UCB Pharma; **S. Khattri** has worked as a consultant and/or been an investigator and/or served on the speaker's bureau for: AbbVie, Bristol Myers Squibb, Eli Lilly and Company, LEO Pharma, Pfizer, Regeneron, Sanofi, and UCB Pharma; **A. Brnabic**, **C. Schuster**, **C. Reed**, and **J. Hill** are employees and minor shareholders of: Eli Lilly and Company; **E. Riedl** has received consulting fees from Eli Lilly and Company; has received honoraria from: Eli Lilly and Company and Pelpharma; and is a minor shareholder of, has a patent issued, and was previously employed by: Eli Lilly and Company; **M. Augustin** has served as a consultant or lecturer for and/or has received research grants from companies manufacturing drugs for PsO, including: AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Centocor, Eli Lilly and Company, Galderma, Hexal, Incyte Corporation, Janssen, LEO Pharma, Medac, Merck Sharp & Dohme, Mylan, Novartis, Pfizer, Sandoz, UCB Pharma, and Viatris
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