Benefits of Concomitant Treatment With Ixekizumab and Tirzepatide for Patients With Psoriatic Disease and Overweight/Obesity: An Overview of Results From the TOGETHER Trials

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Joseph F. Merola[1], Andreas Pinter[2], Paolo Gisondi[3], Lluís Puig[4], Shikha Singla[5], Rubén Queiro Silva[6], Catherine Bakewell[7], Roberto Caporali[8], Allyson Perry[9], Bomina Park[9], Louis Sanden[9], Mark G. Lebwohl[10]

[1]UT Southwestern Medical Center and O'Donnell School of Public Health, Dallas, USA, [2]University Hospital Frankfurt am Main, Germany, [3]University of Verona, Verona, Italy, [4]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [5]Medical College of Wisconsin, Milwaukee, USA, [6]Central University Hospital of Asturias, Avenida de Roma, Spain, [7]Intermountain Healthcare Medical Group, Salt Lake City, USA, [8]University of Milan and ASST Pini-CTO, Milan, Italy, [9]Eli Lilly and Company, Indianapolis, USA, [10]Icahn School of Medicine at Mount Sinai, New York, USA

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OBJECTIVE

- To present an overview of clinical outcomes and PROs at Week (W)36 across the 2 trials to examine the therapeutic impact of concomitant ixekizumab and tirzepatide

CONCLUSIONS

- Across both TOGETHER-PsO and TOGETHER-PsA, concomitant treatment of PsO or PsA and obesity or overweight with ixekizumab and tirzepatide was associated with improved disease activity, weight, and PRO outcomes while also demonstrating favorable cardiometabolic effects and a safety profile generally consistent with the known profile of each medicine[3,5]
- These findings support the potential for an integrated immunometabolic approach with ixekizumab plus tirzepatide that may address both obesity/overweight and psoriatic disease, highlighting obesity as a modifiable risk factor that may influence psoriatic disease outcomes.

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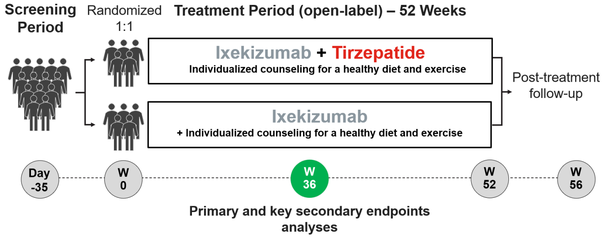
BACKGROUND

- PsO and PsA share immunometabolic pathways and a high global prevalence of obesity (25-33%) or overweight (35-36%), with obesity treatment recommended as part of patient care[1-4]
- TOGETHER-PsO (NCT06588283)[5] and TOGETHER-PsA (NCT06588296)[3] are open-label, assessor-blinded Phase 3b clinical trials that evaluated the efficacy and safety of concomitant ixekizumab and tirzepatide vs. ixekizumab alone in adults with moderate-to-severe PsO or active PsA and obesity/overweight

METHODS: TOGETHER Program Study Design[5]

- Key Inclusion Criteria
  - Patients ≥18 years with:
    - Moderate-to-severe plaque PsO or active PsA[a]
    - BMI ≥30 kg/m^2, or BMI ≥27 to <30 kg/m^2 with ≥1 weight-related comorbidity[b]



[a]Active PsA defined as the presence of ≥3 of 68 tender joints and ≥3 of 66 swollen joints at screening (Visit 1) and randomization (Visit 2); [b]Hypertension, dyslipidemia, obstructive sleep apnea, cardiovascular disease, or T2D.
Notes: In TOGETHER-PsA, 279 randomized with 8 enrolled without weight-related comorbidity; in TOGETHER-PsO, 281 randomized and 7 excluded.

KEY RESULTS

Concomitant Ixekizumab + Tirzepatide Was Associated With Consistent Multi-Domain Benefits Across TOGETHER-PsO and TOGETHER-PsA

Domain	TOGETHER-PsO (N=274)	TOGETHER-PsA (N=271)
Primary endpoint	✓ PASI 100 and ≥10% weight reduction	✓ ACR50 and ≥10% weight reduction
Disease activity	✓ PASI 100	✓ ACR50
Concomitant response (broader)	✓ PASI 75 and ≥5% weight reduction	✓ ACR20 and ≥5% weight reduction
Clinically meaningful weight reduction	✓ ≥10% weight reduction	✓ ≥10% weight reduction
Quality of life/function	✓ DLQI (0,1), SF-36 PCS	✓ HAQ-DI, PsAID-12, FACIT-F, SF-36 PCS and MCS
Cardiometabolic health	✓ SBP, DBP, lipids, and HbA1c[5]	✓ SBP, lipids, and HbA1c[3]
Safety profile	✓ No new safety signals[5a]	✓ No new safety signals[3a]

[a]SAEs (PsO: 6.0% [IXE] and 3.6% [IXE+TZP]) vs. PsA: 7.6% [IXE] and 3.6% [IXE+TZP]); AEs leading to treatment discontinuation (PsO: 1.5% [IXE] and 3.6% [IXE+TZP]) vs. PsA: 5.3% [IXE] and 5.1% [IXE+TZP])

Baseline Demographics and Disease Characteristics

	TOGETHER-PsO		TOGETHER-PsA	
	IXE (N=136)	IXE + TZP (N=138)	IXE (N=133)	IXE + TZP (N=138)
Age, years	45.7 (12.5)	45.6 (13.0)	54.8 (11.9)	55.3 (11.8)
Female, n (%)	61 (44.9)	62 (44.9)	92 (69.2)	97 (70.3)
Weight, kg	115.5 (28.0)	112.1 (29.0)	107.6 (24.4)	104.6 (25.2)
Screening BMI, mean (SD) kg/m^2	39.2 (7.9)	39.3 (10.2)	38.3 (7.4)	37.0 (7.8)
Screening BMI category, n (%)				
≥27 to <30 kg/m^2	12 (8.8)	14 (10.1)	14 (10.5)	20 (14.5)
≥30 to <35 kg/m^2	36 (26.5)	43 (31.2)	40 (30.1)	52 (37.7)
≥35 to <40 kg/m^2	31 (22.8)	31 (22.5)	34 (25.6)	30 (21.7)
≥40 kg/m^2	57 (41.9)	50 (36.2)	45 (33.8)	36 (26.1)
Time since PsO or PsA diagnosis, years	16.0 (13.6)	13.2 (12.3)	8.0 (8.3)	9.9 (11.0)
PASI total score	19.1 (7.1)	20.4 (8.9)	3.3 (5.9)	3.2 (4.7)
DAPSA	NA	NA	55.4 (24.3)	47.2 (22.7)
Advanced therapy–experienced, n (%)	49 (36.0)	45 (32.6)	82 (61.7)	89 (64.5)
Itch NRS	7.4 (2.0)	7.1 (2.1)	NA	NA
DLQI	11.0 (6.7)	11.2 (6.7)	NA	NA
FACIT-F	38.5 (10.3)	37.9 (9.8)	27.3 (11.6)	27.0 (11.9)
PsAID-12	NA	NA	5.9 (1.8)	5.8 (2.0)
HAQ-DI	NA	NA	1.3 (0.6)	1.3 (0.6)
SF-36 PCS	45.9 (10.1)	44.2 (10.2)	33.1 (9.0)	32.8 (9.0)
SF-36 MCS	49.9 (10.0)	51.8 (9.2)	48.8 (12.2)	48.4 (10.8)

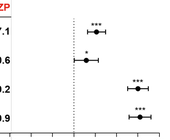
Notes: Data are mean (SD) unless stated otherwise. mITT population.

RESULTS

Concomitant Ixekizumab + Tirzepatide Was Associated With Higher Response Rates vs. Ixekizumab Alone for Primary and Key Secondary Outcomes at W36 in TOGETHER-PsO and TOGETHER-PsA

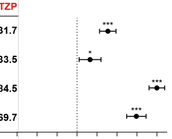
TOGETHER-PsO		Response, % (N=274)	
Endpoint Type	Endpoint or Measure	IXE	IXE + TZP
Primary endpoint	Simultaneous PASI 100 and ≥10% weight reduction	5.8	27.1
Disease activity	PASI 100	29.0	40.6
Weight reduction	≥10% weight reduction	9.1	69.2
Concomitant response (broader)	Simultaneous PASI 75 and ≥5% weight reduction	17.9	79.9

*p<.05, **p<.001 vs. ixekizumab.
Notes: G-computation with treatment, screening BMI group, sex, and treatment history (advanced therapy–naïve vs. experienced) as factors in the logistic regression model. Missing data were handled by multiple imputation (25 imputations per arm).

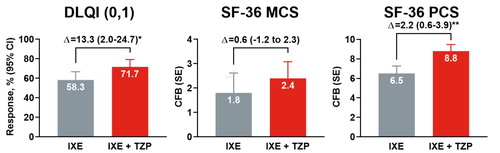


TOGETHER-PsA		Response, % (N=271)	
Endpoint Type	Endpoint or Measure	IXE	IXE + TZP
Primary endpoint	Simultaneous ACR50 and ≥10% weight reduction	0.8	31.7
Disease activity	ACR50	20.4	33.5
Weight reduction	≥10% weight reduction	4.5	84.5
Concomitant response (broader)	Simultaneous ACR50 and ≥5% weight reduction	10.3	69.7

*p<.05, ***p<.001 vs. ixekizumab.
Notes: G-computation with treatment, screening BMI group, sex, and treatment history (advanced therapy–naïve vs. experienced) as factors in the logistic regression model. Missing data were handled by multiple imputation (25 imputations per arm).

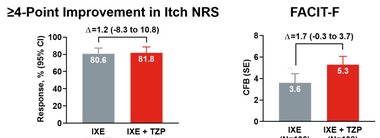


Concomitant Ixekizumab + Tirzepatide Was Associated With Greater Improvement in DLQI (0,1) and SF-36 PCS but not SF-36 MCS vs. Ixekizumab Alone at W36 in TOGETHER-PsO



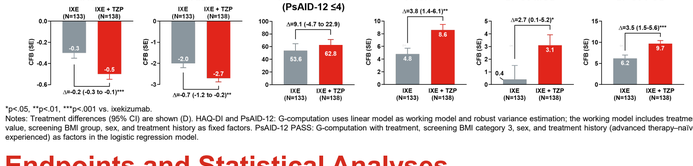
*p<.05, **p<.01 vs. ixekizumab.
Notes: Treatment differences (95% CI) are shown (D). DLQI (0,1): participants with baseline DLQI >1 (N=129/135); values missing after an intercurrent event imputed with MMRM-predicted DLQI scores; logistic-regression G-computation (treatment, screening BMI group, sex, treatment history). SF-36 PCS/MCS: change from baseline with LOCF; G-computation with a linear working model (treatment, baseline value, screening BMI group, sex, treatment history) and robust variance; n analyzed 109/121.

No Significant Differences in Itch NRS Improvement or FACIT-F Scores Were Observed Between Concomitant Ixekizumab + Tirzepatide and Ixekizumab Alone at W36 in TOGETHER-PsO



Notes: Treatment differences (95% CI) are shown (D). Itch NRS ≥4-point improvement: participants with baseline Itch NRS ≥4 (N=127/123); values missing after an intercurrent event imputed with MMRM-predicted scores; logistic-regression G-computation. FACIT-F: change from baseline with LOCF; linear-model G-computation with robust variance (n analyzed: 112/122).

Concomitant Ixekizumab + Tirzepatide Was Associated With Greater Improvement in Functional, Mental, and QoL Measures vs. Ixekizumab Alone at W36 in TOGETHER-PsA



*p<.05, **p<.01, ***p<.001 vs. ixekizumab.
Notes: Treatment differences (95% CI) are shown (D). HAQ-DI and PsAID-12: G-computation uses linear model as working model and robust variance estimation; the working model includes treatment, baseline value, screening BMI group, sex, and treatment history as fixed factors. PsAID-12 PASS: G-computation with treatment, screening BMI category 3, sex, and treatment history (advanced therapy–naïve vs. experienced) as factors in the logistic regression model.

Endpoints and Statistical Analyses

Endpoints (at W36)

	TOGETHER-PsO	TOGETHER-PsA
Primary endpoints	▪ Simultaneous PASI 100 and ≥10% weight reduction	▪ Simultaneous ACR50 and ≥10% weight reduction
Key secondary endpoints	▪ PASI 100, and ≥10% weight reduction, Simultaneous PASI 75 and ≥5% weight reduction,	▪ ACR50, ≥10% weight reduction, and simultaneous ACR20 and ≥5% weight reduction
PRO measures	▪ DLQI (0,1),[a] ≥4-point improvement in Itch NRS,[b] FACIT-F,[c] and SF-36[d] MCS and PCS	▪ HAQ-DI,[e] PsAID-12 total score,[f] PsAID-12 PASS,[g] FACIT-F,[c] and SF-36[d] MCS and PCS
Cardiometabolic measures	▪ Blood pressure, lipids, and Hb1Ac	▪ Blood pressure, lipids, and Hb1Ac

[a]In participants with baseline DLQI >1. DLQI (0,1) indicates no or minimal impact of disease on QoL; [b]In participants with Itch NRS score ≥4 points at baseline. The Itch NRS is a patient-administered, single-item, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable"; "The FACIT-F uses 0 ("not at all") to 4 ("very much") NRS to assess fatigue and its impact in the past 7 days. (The SF-36 assesses health-related quality of life. The SF-36 acute form is a 36-item, generic, patient-completed measure designed to assess the 8 health domains (Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health); [e]The HAQ-DI is a PRO questionnaire that consists of 20 questions referring to 8 domains of functioning; [f]PsAID-12 is a patient-reported questionnaire composed of 12 health domains; [g]Defined as PsAID-12 ≤4.

Statistical Analyses

- Key primary and secondary endpoints were controlled for multiplicity, whereas cardiometabolic and PRO endpoints were p-values reported nominally

Notes: Primary and key secondary (binary/composite) endpoints were analyzed by logistic regression G-computation (unconditional risk difference) adjusted for the randomization stratification factors (screening BMI group, sex, prior advanced therapy experience); data after intercurrent events were excluded and missing data were handled by multiple imputation (25 imputations per treatment arm, imputed on the continuous scale and then dichotomized). DLQI (0,1) and Itch NRS responses were derived from MMRM-predicted values of the underlying continuous scores. For FACIT-F and SF-36 MCS and PCS, last observation carried forward approach was applied to impute when other numeric-baseline was available.

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