Late-breaker Presentation – 79178

Concomitant therapy with ixekizumab plus tirzepatide in adults with psoriatic arthritis and overweight or obesity demonstrated superior disease control compared to ixekizumab alone: results from the Ph3b TOGETHER-PsA trial

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BACKGROUND AND OBJECTIVE

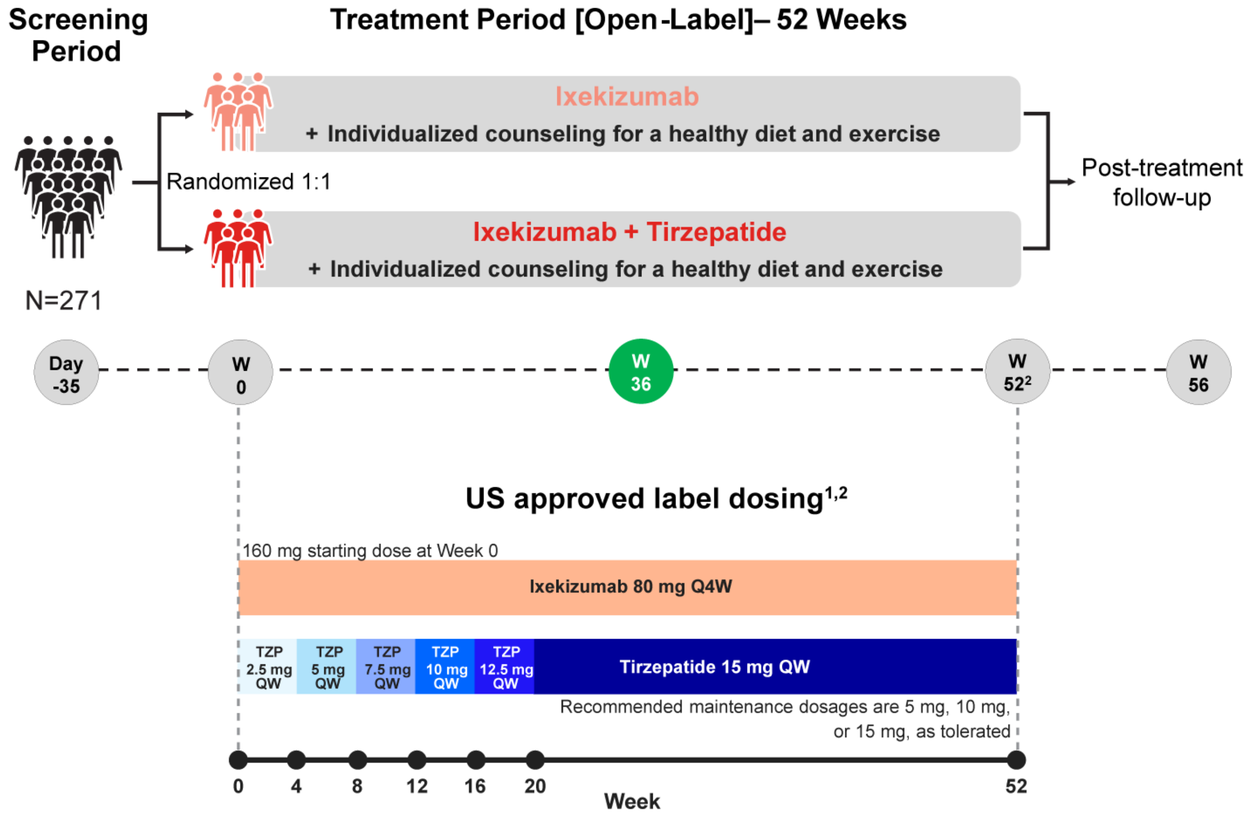
- Overweight and obesity occur in 72-82%[1, 2] of patients with PsA. Guidelines advocate for assessment of obesity and weight loss as part of comprehensive PsA care[3].
- Up to 30-40% of individuals with psoriasis (PsO) develop psoriatic arthritis (PsA)[4, 5], where there is a ceiling of therapeutic effect with current therapies[6].
- Obesity is associated with worse clinical outcomes among patients with PsA and PsA is associated with increased cardiovascular comorbidities compared to the general population[7].
- Concomitant administration of a first-line biologic, ixekizumab (IXE) (IL-17A antagonist), with an effective weight loss therapy, tirzepatide (TZP) (GIP/GLP-1 receptor agonist) may offer additional clinical benefits by addressing the interplay of obesity, systemic inflammation, and PsA disease activity.
- Two TOGETHER studies have been designed for PsA (NCT06588296) and PsO (NCT06588283): the focus of this presentation is PsA.

1. Eder L, Thavaneswaran A, Chandran V, et al. *Ann Rheum Dis.* 2015;74(5):813-7. 2. Curtis J, Rodriguez P, Probst J, et al. *presented at RCWS 2026 on 11-24 February 2026 in Maui, Hawaii, USA*. 3. Singh JA, Guyatt G, Ogdie A, et al. *Arthritis Rheumatol*. 2019;71(1):5-32. 4. Mease PJ, Armstrong AW. *Drugs*. 2014;74(4):423-41. 5. Kharouf F, Gladman DD. *BMJ*. 2024;387:e081860. 6. Panagiotopoulos A, Koutsianas C, Kougas N, et al. *Rheumatol Int.* 2023;43(5):969-973. 7. Kumthekar A, Ogdie A. *Rheumatol Ther.* 2020;7(3):447-56.

Abbreviations: GIP glucose-dependent insulinotropic polypeptide; GLP-1 glucagon-like peptide-1; IL interleukin; IXE ixekizumab; PsA psoriatic arthritis; PsO psoriasis; TZP tirzepatide

STUDY DESIGN: TOGETHER-PsA

- Phase 3b, randomized, 52-week trial.
- Participants ≥18 and ≤80 years with active PsA with overweight (BMI ≥27-<30kg/m^2) and ≥1 weight-related comorbidity or obesity (BMI ≥30kg/m^2).
- Primary outcome: week 36 simultaneous achievement of ACR50 and ≥10% weight reduction.
- Key secondary outcomes: achievement of ACR50, simultaneous achievement of ACR20 and ≥5% weight reduction, and achievement of ≥10% weight reduction at week 36.
  - ACR: composite endpoint that measures PsA disease activity (TJC 68, SJC 66, patient assessment of arthritis pain VAS, PaGADA NRS, PhGADA NRS, HAQ-DI, hsCRP).
- Additional secondary outcomes included PASI 75, PASI 90, and PASI 100.



1. Taltz [US PI]. Indianapolis, IN, USA: Eli Lilly USA LLC, 2024. 2. Zepbound [US PI]. Indianapolis, IN, USA: Eli Lilly USA LLC, 2024.

Abbreviations: ACR American College of Rheumatology; ACR20 at least 20% improvement in the ACR core set values; ACR50 at least 50% improvement in the ACR core set values; HAQ-DI Health Assessment Questionnaire-Disability Index; hsCRP high sensitivity C-Reactive Protein; IXE ixekizumab; MTD maximum tolerated dose; NRS numeric rating scale; PaGADA Patient's Global Assessment of Disease Activity; PASI Psoriasis Area and Severity Index; PhGADA Physician's Global Assessment of Disease Activity; PsA psoriatic arthritis; PsO psoriasis; QW once weekly; Q4W once every 4 weeks; SJC swollen joint counts; TJC tender joint counts; TZP tirzepatide; V visual analog scale; W week.

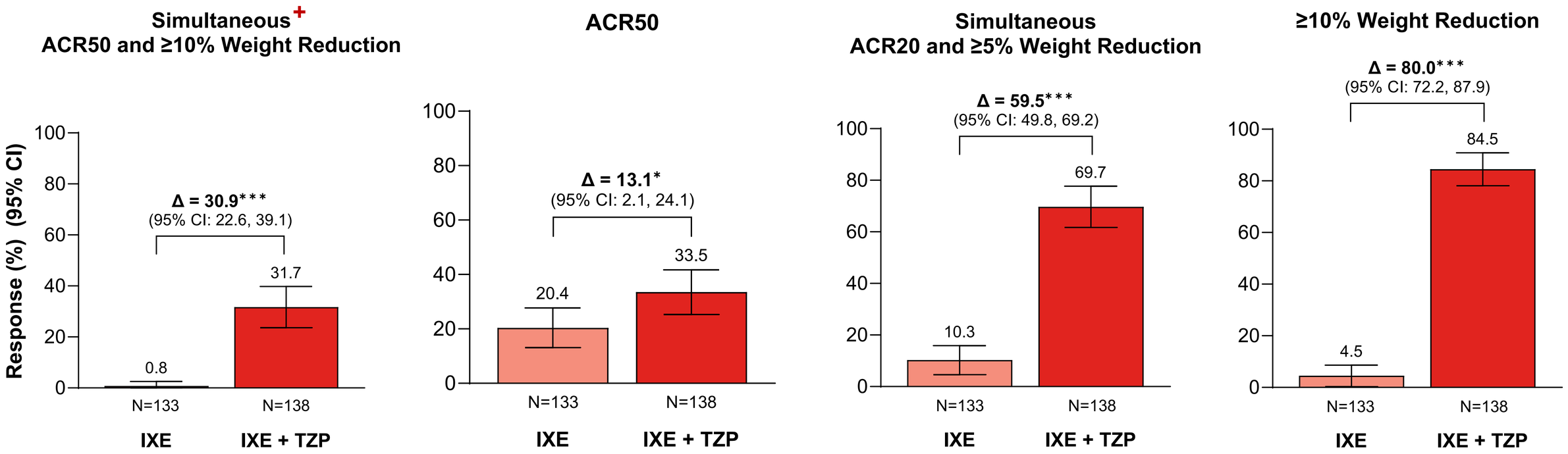
KEY BASELINE DEMOGRAPHICS & DISEASE CHARACTERISTICS Indicated a More Difficult-to-Treat PsA Population vs Historical Trials

Parameter	IXE (N=133)	IXE+TZP (N=138)	TOTAL (N=271)
Age, years	54.8 (11.9)	55.3 (11.8)	55.0 (11.9)
Female, n (%)	92 (69.2)	97 (70.3)	189 (69.7)
BMI, kg/m^2	38.3 (7.4)	37.0 (7.8)	37.6 (7.6)
BMI category, n (%)			
≥27 kg/m^2 to <30 kg/m^2	14 (10.5)	20 (14.5)	34 (12.5)
≥30 kg/m^2 to <35 kg/m^2	40 (30.1)	52 (37.7)	92 (33.9)
≥35 kg/m^2 to <40 kg/m^2	34 (25.6)	30 (21.7)	64 (23.6)
≥40 kg/m^2	45 (33.8)	36 (26.1)	81 (29.9)
PsO, n (%)	98 (73.7)	96 (69.6)	194 (71.6)
BSA ≥3%	75 (56.4)	76 (55.1)	151 (55.7)
Moderate-to-severe PsO	7 (5.3)	5 (3.6)	12 (4.4)
TJC based on 68 joints	27.9 (17.7)	25.5 (15.8)	26.7 (16.8)
SJC based on 66 joints	12.8 (10.6)	11.9 (9.0)	12.3 (9.8)
Treatment history - advanced therapy experienced, n (%)[a]	82 (61.7)	89 (64.5)	171 (63.1)
Number of prior advanced therapies categories, n (%)[b]			
1	60 (45.1)	60 (43.5)	120 (44.3)
≥2	22 (16.5)	29 (21.0)	51 (18.8)

Baseline demographics and disease characteristics shown for the mITT (efficacy) population, consisting of all randomly assigned participants with PsA and overweight with ≥1 weight related comorbidity or obesity. Values are mean (SD) unless otherwise indicated. a Inclusive of prior exposure to bDMARD and tsDMARD with the exception of apremilast. b Prior therapies categorized by drug class for stratification. Patients using >1 drug of the same class were counted once.
Abbreviations: BMI body mass index; bDMARD biologic disease-modifying anti-rheumatic drug; tsDMARD targeted synthetic disease-modifying anti-rheumatic drug; IXE ixekizumab; mITT modified intent-to-treat; N number of patients in the analysis population; n number of patients in the specified category; PsA psoriatic arthritis; PsO psoriasis; SD standard deviation; SJC swollen joint count; TJC tender joint count; TZP tirzepatide.

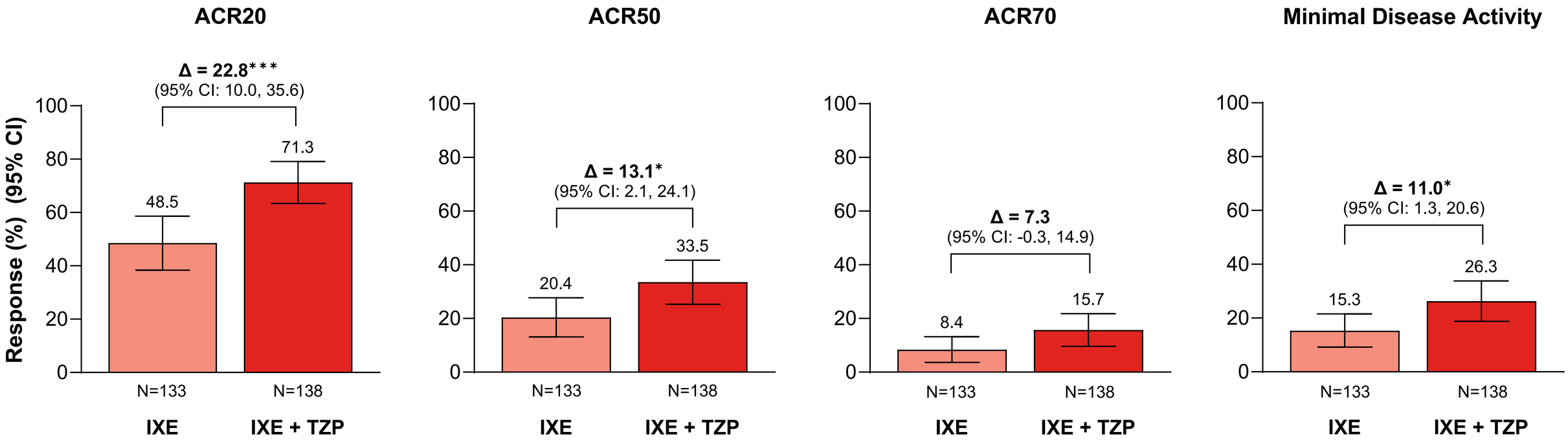
RESULTS: Multiplicity Controlled Primary and Key Secondary Outcomes at Week 36

Primary and key secondary outcomes were all statistically significant and clinically meaningful



vs. IXE: *p<0.05; ***p<0.001. Δ designates treatment difference between treatment arms. + primary endpoint.
Outcomes are shown for the mITT population. **Intercurrent events were the use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation for data handling. Logistic regression was used as working model to estimate unconditional risk difference.**
Abbreviations: ACR50 50% improvement in American College of Rheumatology response; CI confidence interval; IXE ixekizumab; mITT modified intent-to-treat; N number of patients in the analysis population; TZP tirzepatide

RESULTS:
Other Secondary Outcomes at Week 36



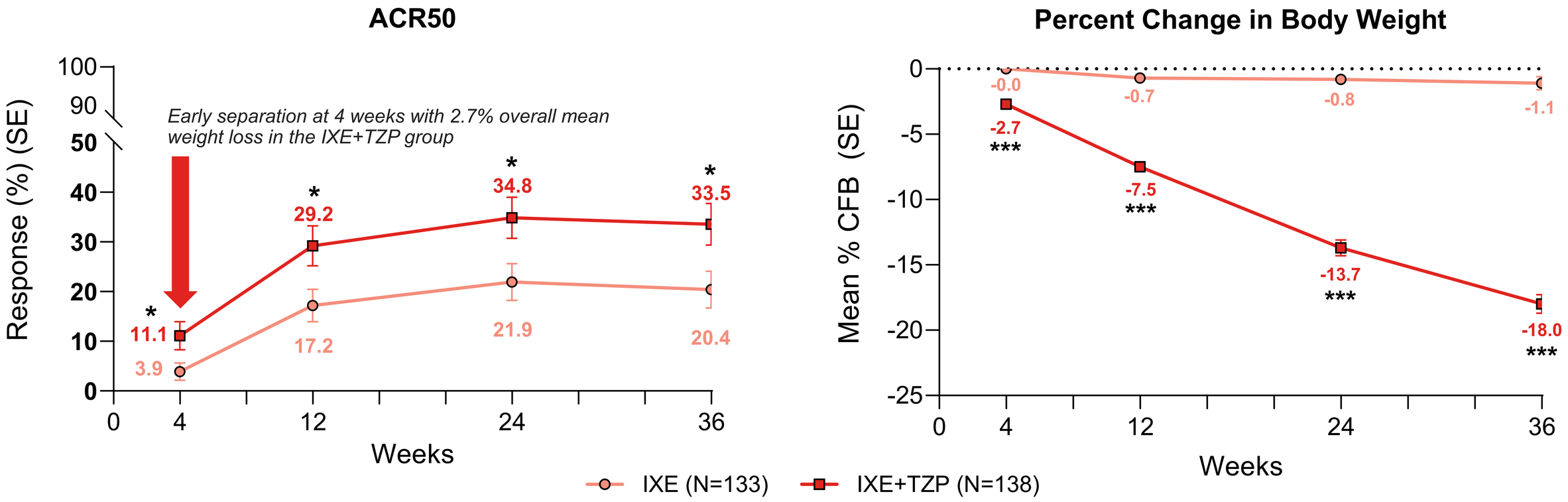
vs. IXE: *p<0.05; ***p<0.001. ACR50 at Week 36 was a key secondary endpoint and was multiplicity controlled; other endpoints show nominal p-value. Δ designates treatment difference between treatment arms.

Outcomes are shown for the mITT population. **Intercurrent events were the use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation for data handling. Logistic regression was used as working model to estimate unconditional risk difference.**

Abbreviations: ACR20 20% improvement in American College of Rheumatology response; ACR70 70% improvement in American College of Rheumatology response; CI confidence interval; IXE ixekizumab; MDA minimal disease activity; mITT modified intent-to-treat; N number of patients in the analysis population; TZP tirzepatide

RESULTS:
ACR50 and Change in Bodyweight Through Week 36

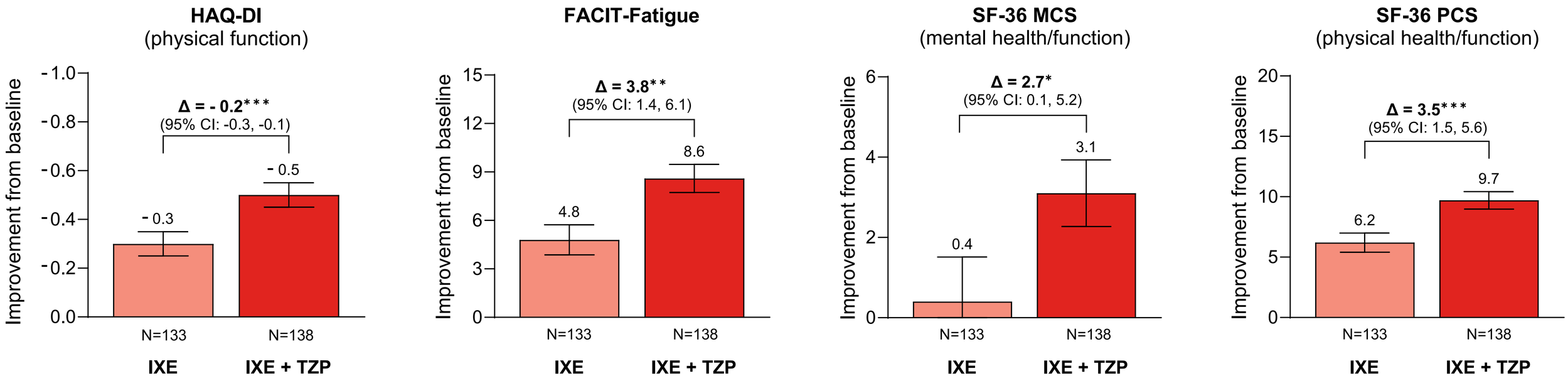
A meaningful difference in ACR50 was observed in IXE+TZP (33.5%) versus IXE alone (20.4%) (multiplicity-controlled p=0.020) with a significant improvement (p<0.05) seen as early as Week 4.



vs. IXE: *p<0.05; ***p<0.001. ACR50 at Week 36 was the only multiplicity controlled timepoint. For ACR50 over time, y-axis was scaled to data range (0-50; 90-100%) for clarity. All values are percentages. Outcomes are shown for the mITT population. **Intercurrent events were the use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation for data handling. Logistic regression (ACR50) or linear model (percent change in body weight) was used as working model to estimate unconditional treatment difference**.

Abbreviations: ACR50 50% improvement in American College of Rheumatology response; CFB change from baseline; CI confidence interval; IXE ixekizumab; mITT modified intent-to-treat; N number of patients in the analysis population; SE standard error; TZP tirzepatide.

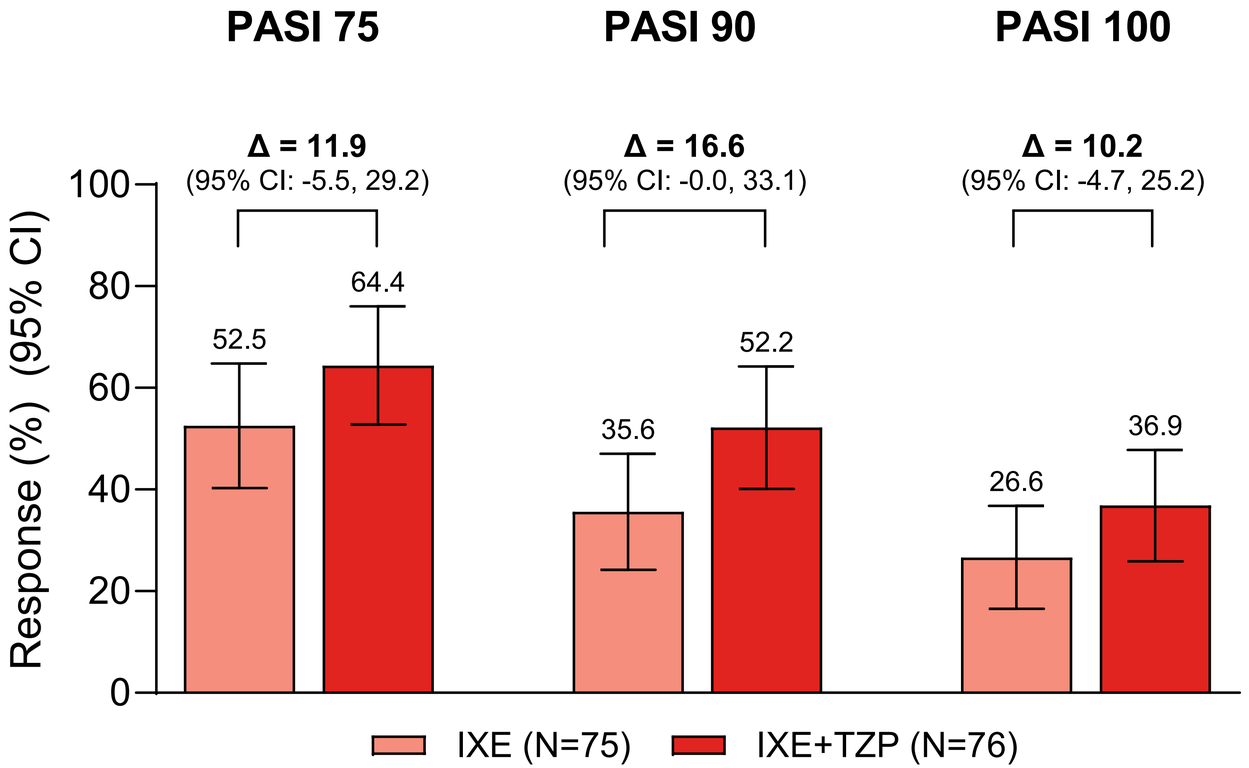
RESULTS:
Improvement in Patient Reported Outcomes at Week 36



vs. IXE: * p<0.05; ** p<0.01; *** p<0.001 Nominal p-values were reported. Δ designates treatment difference between treatment arms.
Outcomes are shown for the mITT population. **Intercurrent events were the use of prohibited medication or discontinuation of treatment. For HAQ-DI, linear model with multiple imputation was used. For other outcomes, linear model with last observation carried forward was used.**
Abbreviations: CFB change from baseline; CI confidence interval; FACIT-F Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI Health Assessment Questionnaire–Disability Index; IXE ixekizumab; MCS mental component summary; mITT modified intent-to-treat; N number of participants in the analysis population; PCS physical component summary; SF-36 36-Item Short Form Health Survey; TZP tirzepatide

RESULTS:
Psoriasis Outcomes at Week 36

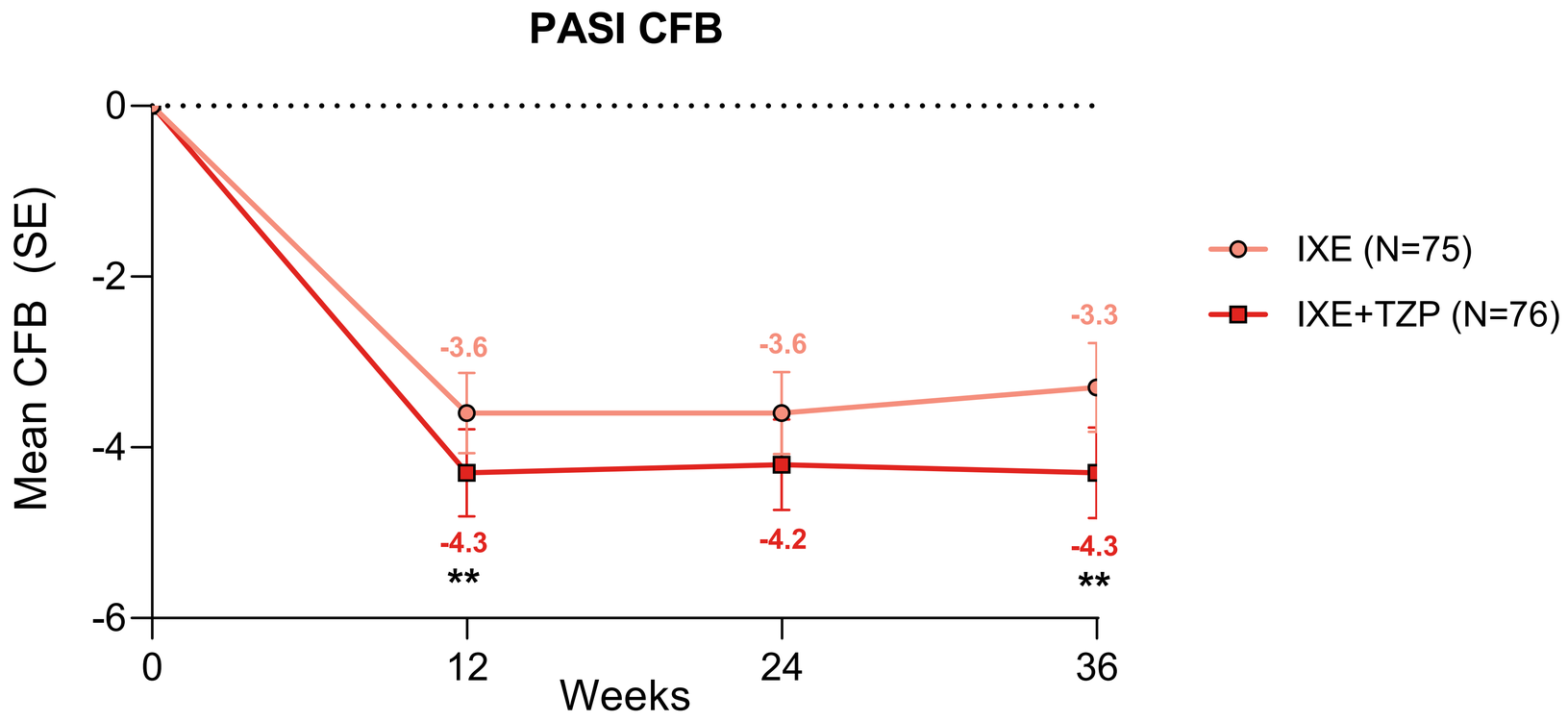
Numeric improvements were demonstrated in PASI 75/90/100 for IXE+TZP and IXE alone.



Δ designates treatment difference between treatment arms. Dermatologic outcomes were assessed in participants with ≥3% BSA at baseline. Mean (SD) baseline PASI total scores were 3.3 (5.9) for IXE; 3.2 (4.7) for IXE+TZP.
Outcomes are shown for the mITT population. **Intercurrent events were the use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation for data handling. Logistic regression was used as working model to estimate unconditional treatment difference.**
Abbreviations: CI confidence interval; IXE ixekizumab; mITT modified intent-to-treat; N number of participants in the analysis population; PASI Psoriasis Area and Severity Index; SD standard deviation; TZP tirzepatide

RESULTS:
Psoriasis: Absolute Change from Baseline

IXE+TZP demonstrated a significant difference in absolute PASI change from baseline (p<0.01).



vs. IXE: ** p<0.01. Nominal p-values were reported. Dermatologic outcomes were assessed in participants with ≥3% BSA at baseline. Mean (SD) baseline PASI total scores were 3.3 (5.9) for IXE; 3.2 (4.7) for IXE+TZP. PASI CFB was a post-hoc outcome.
Outcomes are shown for the mITT population. **Intercurrent events were the use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation for data handling. Linear model was used as working model to estimate unconditional treatment difference.**
Abbreviations: CFB change from baseline; CI confidence interval; IXE ixekizumab; mITT modified intent-to-treat; N number of participants in the analysis population; PASI Psoriasis Area and Severity Index; SD standard deviation; SE standard error; TZP tirzepatide

RESULTS:
Safety Outcomes in TOGETHER-PsA

Outcome	IXE (N=132)[a] n (%)	IXE + TZP (N=138) n (%)
TEAEs	95 (72.0)	104 (75.4)
Mild	40 (30.3)	42 (30.4)
Moderate	49 (37.1)	58 (42.0)
Severe	6 (4.5)	4 (2.9)
Most frequent TEAEs by preferred term[b]		
Nausea	4 (3.0)	41 (29.7)
Diarrhea	5 (3.8)	25 (18.1)
Constipation	4 (3.0)	23 (16.7)
Injection site reaction	22 (16.7)	21 (15.2)
Vomiting	1 (0.8)	15 (10.9)
Sinusitis	3 (2.3)	9 (6.5)
Urinary tract infection	4 (3.0)	9 (6.5)
Dizziness	1 (0.8)	8 (5.8)
Headache	1 (0.8)	8 (5.8)
Upper respiratory tract infection	7 (5.3)	5 (3.6)
SAEs	10 (7.6)	5 (3.6)
Deaths	0 (0)	0 (0)
Discontinuations from study treatment due to an AE	7 (5.3)	7 (5.1)
Discontinuations from study treatment due to gastrointestinal AEs	1 (0.8)	4 (2.9)

- Adverse events (AEs) generally aligned with established drug profiles.
- Treatment discontinuations due to AEs were comparable among treatment groups.

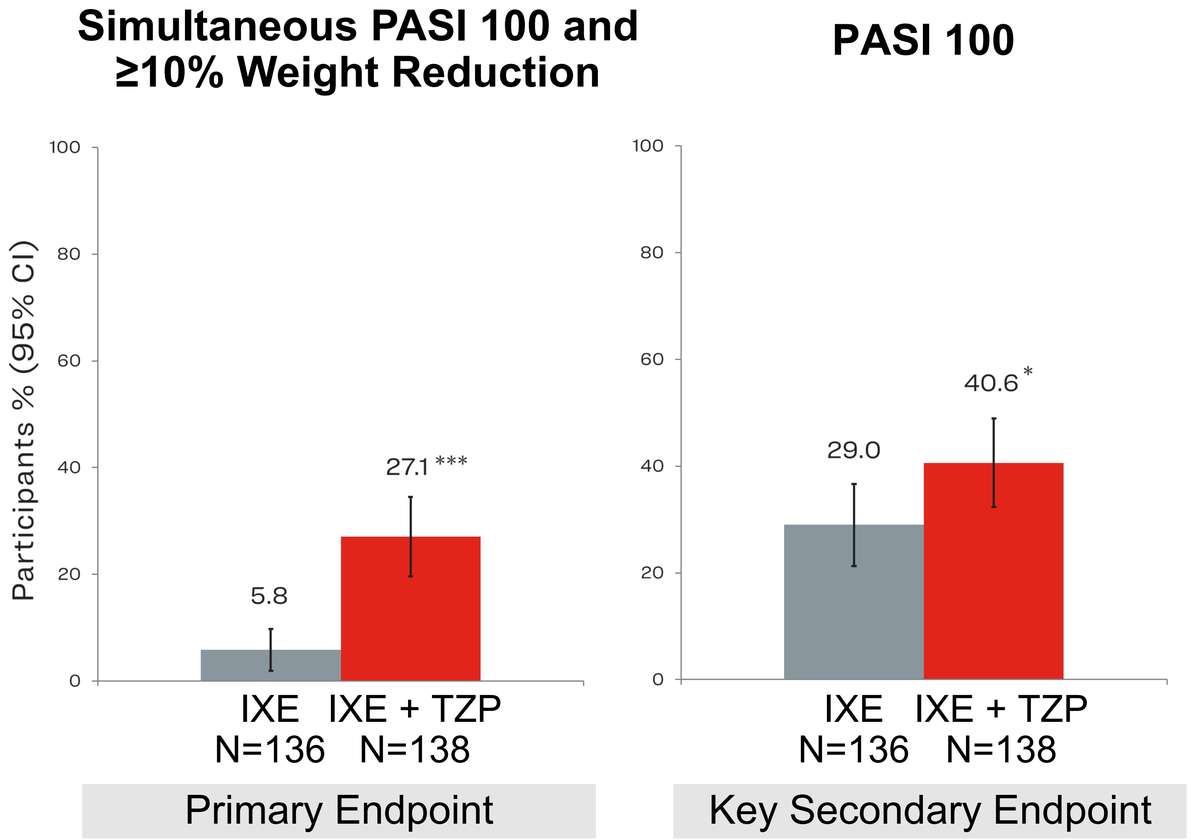
Modified Safety Population consisted of all randomly assigned participants with obesity or with overweight in the presence of at least 1 weight-related comorbid condition who are exposed to at least 1 dose of any of the study drugs. a One participant was randomized but did not receive study treatment b AEs occurring in ≥5% participants

Abbreviations: AE adverse event; IXE ixekizumab; N number of participants in the analysis population; n number of patients in the specified category; PsA psoriatic arthritis; SAE serious adverse event; TEAE treatment emergent adverse event; TZP tirzepatide.

TOGETHER-PsO: Primary and Select Key Secondary Endpoints at Week 36 (PR)

- This study included patients with moderate-to-severe plaque psoriasis, BSA ≥10%, sPGA ≥3 and PASI ≥12, and overweight with ≥1 weight-related comorbidity or obesity.
- This patient population had:
  - Mean BMI of >39 kg/m^2 across both treatment arms
  - Approximately 25% of BSA affected
  - Nearly all (97%) had psoriasis affecting high-impact sites

- Primary and all key secondary endpoints were statistically significant[1]
- Safety was generally consistent with known risk profile for both drugs[1-4]
- **TOGETHER-PsO trial by M Lebwohl, et al.**



vs. IXE: *p<.05, ***p<.001. Multiplicity controlled.

Note: Hypothetical estimand; imputation method used was MI.

1. Eli Lilly USA (18 February, 2026) [Press release] https://lilly.mediaroom.com/2026-02-18-Lillys-Taltz-ixekizumab-and-Zepbound-tirzepatide-used-together-delivered-superior-efficacy-in-first-of-its-kind-Phase-3b-trial-for-adults-with-psoriasis-and-obesity-or-overweight?utm_source=li&utm_medium=organic&utm_campaign=imm_imli&utm_id=imm. 2. Gordon KB, et al. *N Engl J Med.* 2016;375(4):345-356. 3. Deodhar A, et al. *Arthritis Res Ther*. 2024;26(1):49. 4. Jastreboff AM, et al. *N Engl J Med*. 2022;387(3):205-216

Abbreviations: BSA body surface area; CI confidence interval; IXE ixekizumab; MI multiple imputation; mITT modified intent-to-treat; N number of patients in the analysis population; PASI 75 75% improvement in psoriasis area and severity index; PASI 100 100% improvement in Psoriasis Area and Severity Index; PsO psoriasis; PR press release; sPGA static Physician's Global Assessment; TZP tirzepatide.

CONCLUSIONS

- In patients with Psoriatic Arthritis and overweight or obesity, concomitant administration of ixekizumab and tirzepatide was statistically superior to ixekizumab in achieving the primary endpoint and all key secondary efficacy outcomes at 36 weeks.
- Consistent improvements were observed across PsA domains with efficacy demonstrated for joint inflammation, pain, function, health-related quality of life, as well as psoriasis endpoints.
- Early separation of ACR50 at Week 4 was observed, with only 2.7% overall mean weight loss in the IXE+TZP treatment arm at that time.
- There were no new safety concerns and safety was generally consistent with each known drug profile.
- Collectively, these data support the use of TZP in addition to IXE as an integrated approach to comprehensive PsA disease management.

- Complete data from the dedicated TOGETHER-PSO study in patients with psoriasis will be disclosed in the near future.

ACCEPTED ARTICLE

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American College of Rheumatology
Empowering Rheumatology Professionals

Ixekizumab With Tirzepatide Achieved Greater Disease Control Than Ixekizumab Alone in Adults With Psoriatic Arthritis and Overweight or Obesity: Results From a Randomized Clinical Trial

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Mark Lebwohl, MD[1], Andrew Blauvelt, MD, MBA[2], Cynthia E. Kartman, RN[3], Cianna Leatherwood, MD, MPH[3], Kenneth B. Gordon, MD[4], Naveed Sattar, MD[5], Luis Puig, MD, PhD[6], Joseph F. Merola, MD MMSc, FAAD FACR[7], Kimberly Siu, MD, MPH[3], Rona Wang, MD, MBA[3], Luna Sun, PhD[3], Ann Leung, MS[8], Najwa Somani, MD[3], Maria Jose Rueda, MD[3], Anabela Cardoso, MD[3], Mark C. Genovese, MD[3], April W. Armstrong, MD, MPH[9], Bruce Strober, MD, PhD[10]

DISCLOSURES

- **J. F. Merola** is a consultant and/or investigator for Amgen, Astra-Zeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Abbvie, Dermavant, Eli Lilly, Moonlake, Novartis, Janssen, Oruka, UCB, Sanofi, Regeneron, Sun Pharma, Galderma, Biogen and Pfizer.
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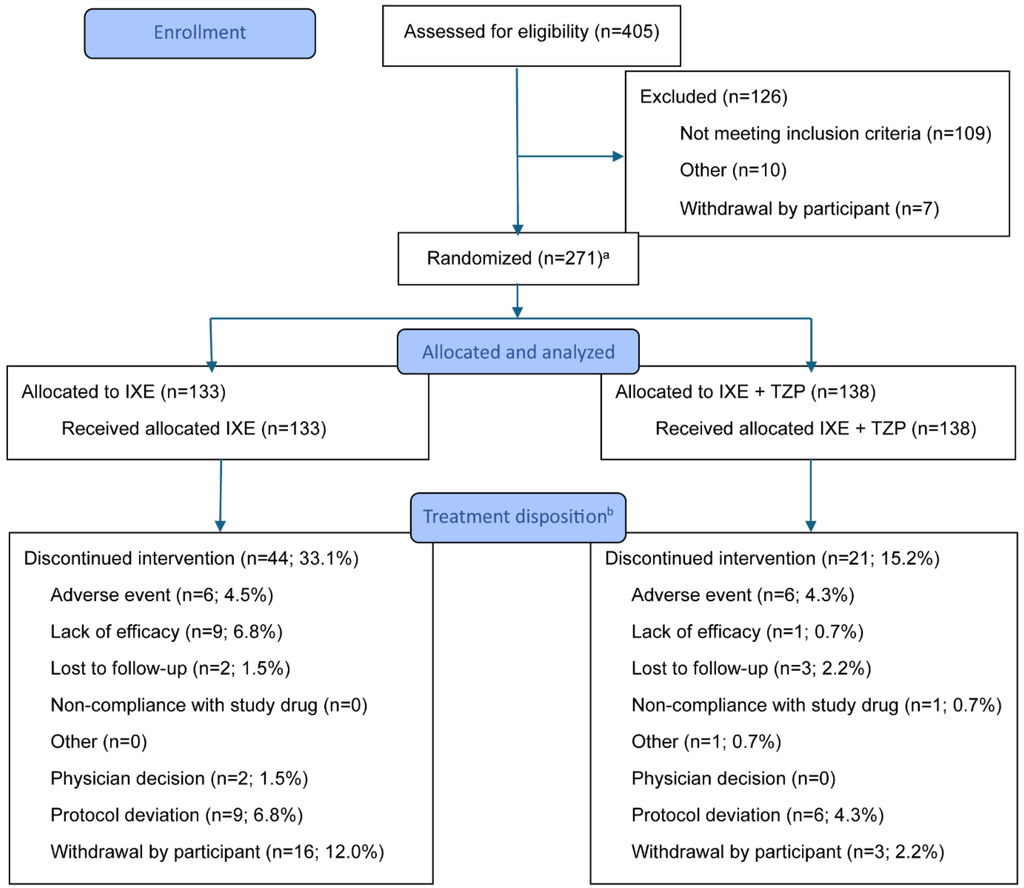
SUPPLEMENTARY SLIDES

PATIENT DISPOSITION



Data from modified intent-to-treat population up to Week 36 visit. [a]A total of 279 participants were randomized. Among them, 8 participants did not have weight-related comorbidity and were excluded from the modified intent-to-treat population and the modified safety population. [b] One participant ongoing in the IXE + TZP arm.

While more participants in the IXE alone arm discontinued study intervention due to lack of efficacy compared to the IXE+TZP arm, no consistent pattern of discontinuation was identified for withdrawal by participant. Reasons for withdrawal included: due to personal circumstances such as moving, scheduling conflicts, personal issues unrelated to trial, concern with study procedures, and wanted to pursue GLP1-1 RA therapy. Discontinuation due to lack of efficacy did not delineate if due to psoriatic disease activity or lack of weight loss.

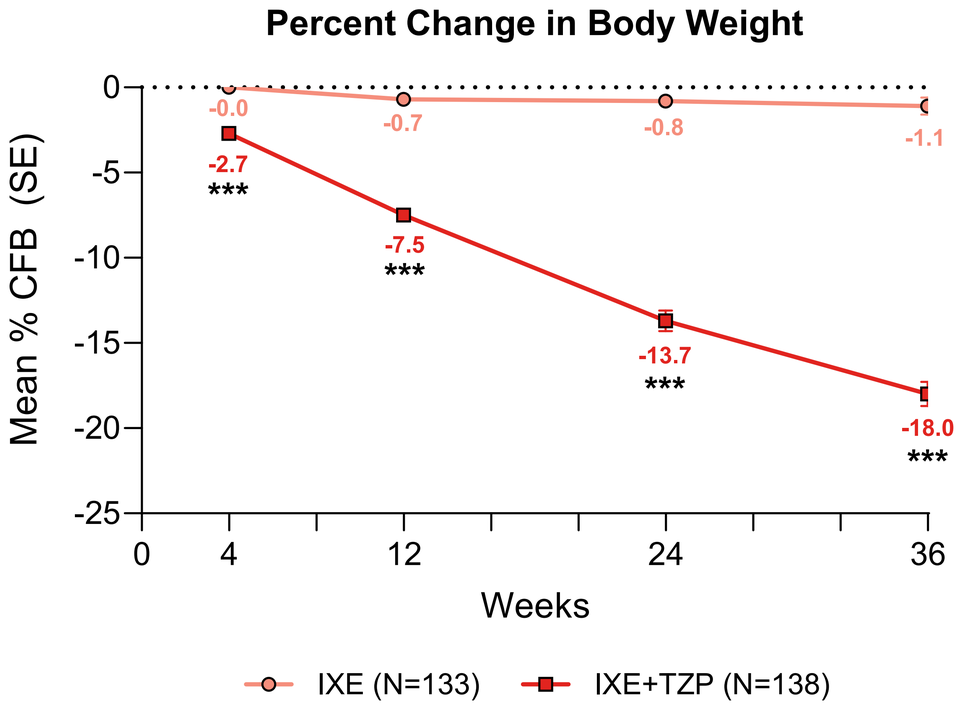
Abbreviations: IXE ixekizumab; GLP 1 RA glucagon-like peptide-1 receptor agonist; n number of patients in the specified category; TZP tirzepatide.

RESULTS: Effect on Weight and Metabolic Parameters Through Week 36

A meaningful difference in % change in body weight and metabolic parameters was demonstrated

Effect on Metabolic Parameters

- Metabolic outcomes assessed included BMI, body weight, glucose, HbA1c, lipids, namely, LDL-cholesterol, HDL-cholesterol, total cholesterol, triglycerides, and systolic and diastolic blood pressure.
- Nominally statistically significant improvements were observed in IXE+TZP compared with IXE in change from baseline for the following:
  - BMI, body weight,
  - systolic blood pressure,
  - glucose, HbA1c,
  - total cholesterol, and triglycerides



For percent change in body weight:
vs. IXE: ***p<0.001. Nominal p-values were reported.
Outcomes are shown for the mITT population. **Intercurrent events are use of prohibited medication or discontinuation of treatment, hypothetical estimand was used with multiple imputation for data handling. Linear model was used as working model to estimate unconditional treatment difference.**
Abbreviations: ACR50 50% improvement in American College of Rheumatology response; BMI, body mass index; CFB change from baseline; CI confidence interval; HbA1C, glycated hemoglobin; HDL, high density triglyceride; IXE ixekizumab; LDL, low density triglyceride; mITT modified intent-to-treat; N number of patients in the analysis population; SE standard error; TZP tirzepatide.