Icotrokinra, an IL-23 Receptor Targeted Oral Peptide, in Biologic-Naïve Participants With Active Psoriatic Arthritis: Results Through Week 24 of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study

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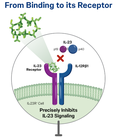
Key Takeaways

- **In biologic-naïve pts with active PsA, once-daily ICO 200 mg demonstrated both joint and skin improvements vs PBO at W16, with ICO 400 mg showing no additional benefit beyond the 200 mg dose**
- **Continued improvements were observed through W24 across both joint and skin responses**
- **AE profiles were comparable across groups, with no new safety signals identified through W24**

Background

Icotrokinra (ICO) is a first-in-class targeted oral peptide that:

- Precisely blocks the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling[1]
- Approved for the treatment of moderate-to-severe plaque psoriasis (PsO) in adult and pediatric patients (≥12 years of age; ≥40 kg) who are candidates for systemic therapy or phototherapy[2]
- Currently under investigation for the treatment of active psoriatic arthritis (PsA) in the 2 parallel phase 3 ICONIC-PsA 1 (biologic-naïve PsA) and ICONIC-PsA 2 (biologic-experienced and biologic-naïve PsA) studies[3-5]



IL-23R=interleukin-12 receptor beta 1.

Objective

To report ICO effects and safety findings through Week (W) 24 from the ongoing phase 3 ICONIC-PsA 1 study (NCT06878404) in biologic-naïve participants (pts) with active PsA

The ICONIC-PsA 1 Study Design

Key Eligibility Criteria

- Biologic-naïve
- ≥18 years of age
- Active PsA for ≥3 months (≥3 swollen joints, ≥3 tender joints, and CRP ≥0.1 mg/dL) despite prior or current csDMARD and/or apremilast treatment
- Active plaque PsO with ≥1 PsO plaque of ≥2 cm in diameter or nail changes consistent with PsO

Assessments

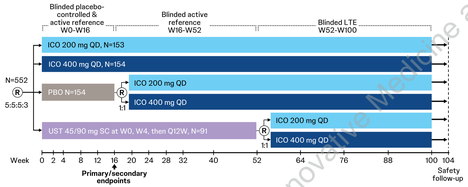
Primary Endpoint at W16:

- ACR20

Select Secondary Endpoints at W16:

- ACR50 and ACR70
- IGA 0/1[a] (score of 0/1 and ≥2-grade improvement from baseline)
- Change from baseline in HAQ-DI score

AEs Through W24



*Among pts with a baseline psoriasis BSA ≥3% and IGA score ≥2. **ACR20/50/70**=≥20%/50%/70% improvement in American College of Rheumatology response criteria; **AE**=adverse event; **BSA**=body surface area; **CRP**=C-reactive protein; **csDMARD**=conventional synthetic disease-modifying antirheumatic drug; **HAQ-DI**=Health Assessment Questionnaire Disability Index; **IGA**=Investigator's Global Assessment; **LTE**=long-term extension; **PBO**=placebo; **Q12W**=every 12 weeks; **QD**=once daily; **R**=randomization; **SC**=subcutaneous; **UST**=ustekinumab.

Statistical Analyses

- The primary endpoint and multiplicity-controlled secondary endpoints at W16 were tested (at the overall type I error rate of 5%) in a hierarchy order as follows: ACR20, IGA 0/1, HAQ-DI
  - For each endpoint, the testing began with ICO combined dose groups versus (vs) PBO, followed by dose-specific comparisons
  - Both ICO dose groups were required to be statistically significant before testing the next endpoint
- The UST arm is included to provide a safety reference through W52
  - It is not powered for formal statistical comparison with any other treatment arms
- For efficacy analyses through W24 for the data presented, pts with the following intercurrent events (ICEs) were considered nonresponders or to have no change from baseline:
  - Initiated or increased restricted medications (biologics, csDMARDs, apremilast, Janus kinase [JAK] inhibitors, tyrosine kinase [TYK] inhibitors, cytotoxics, oral corticosteroids, or investigational agents) for PsA
  - Discontinued treatment for any reason

Results

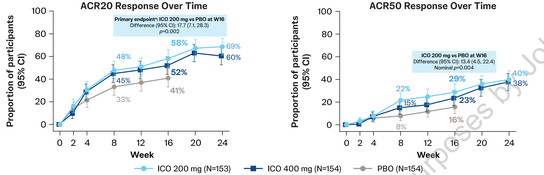
Baseline characteristics were balanced across treatment groups

Baseline Characteristics	ICO 200 mg (N=153)	ICO 400 mg (N=154)	PBO (N=154)	UST (N=91)
Demographics				
Age, years	49.0 (12.5)	49.0 (11.7)	48.9 (12.3)	48.7 (12.2)
Female	48%	45%	47%	54%
Race, Asian / Black / White	27% / 0% / 73%	26% / 0% / 74%	32% / 1% / 67%	26% / 0% / 74%
BMI, kg/m^2	29.5 (6.2)	29.1 (5.9)[a]	29.2 (6.0)	29.1 (5.7)
Region, Europe / Asia	67% / 27%	69% / 25%	65% / 32%	66% / 26%
PsA characteristics				
PsA duration, years	4.9 (5.3)	5.5 (7.0)	4.5 (4.6)	4.6 (5.1)
Swollen joint count (0-66)	9.1 (6.0)	9.2 (7.4)	8.4 (5.8)	9.6 (6.8)
Tender joint count (0-68)	16.0 (11.4)	15.5 (11.4)	14.8 (10.4)	14.4 (10.9)
HAQ-DI score (0-3)	1.04 (0.68)	1.10 (0.59)	1.09 (0.69)	1.02 (0.60)
CRP, mg/dL[b]	0.3 (0.1, 0.7)	0.4 (0.2, 0.6)	0.4 (0.1, 0.9)	0.3 (0.2, 0.7)
PsO BSA ≥3% and IGA score ≥2 (at least mild)	59%	58%	55%	49%
Baseline PsA therapy				
csDMARDs[c]	67%	68%	72%	68%
Methotrexate	58%	58%	57%	59%
NSAIDs	49%	44%	45%	43%
Oral corticosteroids	10%	10%	8%	5%
Apremilast	0%	2%	2%	1%

*Data shown are mean (SD), unless otherwise noted. [a]ICO 400 mg: N=153. [b]Values are median (IQR). [c]csDMARDs included hydroxychloroquine, leflunomide, methotrexate, and sulfasalazine. **BMI**=body mass index; **IQR**=interquartile range; **NSAID**=nonsteroidal anti-inflammatory drug; **SD**=standard deviation.*

Primary endpoint: A significantly higher proportion of ICO 200 mg-treated pts achieved ACR20 response vs PBO-treated pts at W16

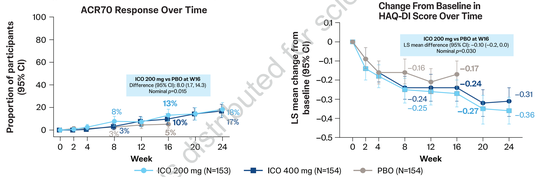
- A higher proportion of ICO 200 mg- vs PBO-treated pts achieved ACR50 response at W16



*The p-values were based on the Cochran-Mantel-Haenszel test stratified by csDMARD and/or apremilast use and the presence of dactylitis at baseline. [a]ACR20 response at W16. **CI**=confidence interval.*

A higher proportion of ICO 200 mg- vs PBO-treated pts achieved ACR70 response at W16; rates were increased from W16 to W24

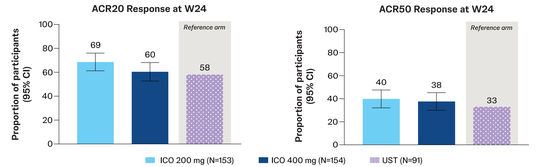
- ICO 200 mg-treated pts reported greater improvement from baseline in HAQ-DI score at W16



*The p-value for ACR70 was based on the Cochran-Mantel-Haenszel test stratified by csDMARD and/or apremilast use and the presence of dactylitis at baseline. The p-value for HAQ-DI was performed for each multiple imputation dataset using an analysis of covariance model, with treatment group, baseline score, and csDMARD and/or apremilast use and the presence of dactylitis at baseline as explanatory variables. **LS**=least-squares.*

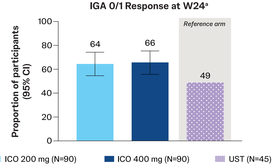
For ICO 200 mg-treated pts, ACR20 and ACR50 response rates were increased from W16 to W24

- ACR20 and ACR50 response rates also increased from W16 to W24 with ICO 400 mg



A higher proportion of ICO 200 mg- vs PBO-treated pts achieved IGA 0/1 response at W16 (57% vs 14%; nominal p<0.001); rates increased at W24

- IGA 0/1 results were similar for ICO 400 mg at W16 (57% vs 14%; nominal *p*<0.001); rates increased at W24



The p-values were based on the Cochran-Mantel-Haenszel test stratified by csDMARD and/or apremilast use and the presence of dactylitis at baseline. [a]Among pts with a baseline psoriasis BSA ≥3% and IGA score ≥2.

AE profiles were comparable across groups through W24

Safety in Pts Through W24	PBO-Controlled (W0-W16) ICO 200 mg (N=153)	PBO-Controlled (W0-W16) ICO 400 mg (N=154)	PBO-Controlled (W0-W16) PBO (N=154)	Active Reference (W0-W24) ICO 200 mg (N=153)	Active Reference (W0-W24) ICO 400 mg (N=154)	Active Reference (W0-W24) UST (N=91)	PBO Crossover (W16-W24) PBO → ICO 200 mg (N=72)	PBO Crossover (W16-W24) PBO → ICO 400 mg (N=74)
Mean weeks of follow-up	16.0	16.1	15.9	23.8	23.9	23.8	8.0	8.1
Any AE	67 (44%)	80 (52%)	63 (41%)	86 (56%)	100 (65%)	63 (69%)	28 (39%)	25 (34%)
Most common AEs (≥5%)								
Nasopharyngitis	10 (7%)	11 (7%)	8 (5%)	12 (8%)	19 (12%)	7 (8%)	2 (3%)	1 (1%)
Upper respiratory tract infection	7 (5%)	12 (8%)	13 (8%)	11 (7%)	14 (9%)	7 (8%)	1 (1%)	6 (8%)
Nausea	1 (1%)	7 (5%)	1 (1%)	2 (1%)	8 (5%)	1 (1%)	0	0
Headache	4 (3%)	3 (2%)	4 (3%)	5 (3%)	3 (2%)	5 (5%)	0	1 (1%)
Diarrhea	3 (2%)	5 (3%)	2 (1%)	4 (3%)	8 (5%)	1 (1%)	1 (1%)	1 (1%)
AEs leading to discontinuation	2 (1%)	2 (1%)	1 (1%)	2 (1%)	4 (3%)	2 (2%)	1 (1%)	1 (1%)
Serious AEs	1 (1%)	4 (3%)	3 (2%)	2 (1%)	5 (3%)	6 (7%)	1 (1%)	3 (4%)
Infections	32 (21%)	42 (27%)	37 (24%)	45 (29%)	55 (36%)	22 (24%)	11 (15%)	11 (15%)

Data shown are n (%) unless otherwise noted. Safety analysis set includes all randomized pts who received at dose of study intervention.

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REFERENCES: 1. Fourie AM, et al. *Sci Rep*. 2024;14:17515. **2.** Janssen Biotech, Inc. ICOTYDE™ (icotrokinra) tablets, for oral use. Revised 3/2026 (prescribing information). https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/ICOTYDE-pi.pdf. **3.** Merola JF. Poster presented at: European Alliance of Associations for Rheumatology (EULAR) Congress; June 11-14, 2025; Barcelona, Spain. **4.** ClinicalTrials.gov identifier: NCT06878404. https://clinicaltrials.gov/study/NCT06878404. Accessed October 13, 2026. **5.** ClinicalTrials.gov identifier: NCT06807424. https://clinicaltrials.gov/study/NCT06807424. Accessed October 13, 2026.
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