P2900

Durability of Icotrokinra Effect in Participants With Moderate-to-Severe Plaque Psoriasis and Psoriatic Arthritis: Pooled Analysis of One-Year Outcomes From the Phase 3 ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2 Trials

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Key Takeaways

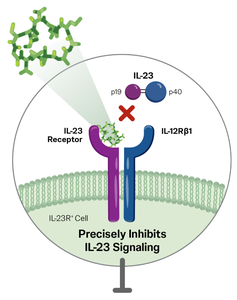
- **In a pooled cohort of adults with moderate-to-severe plaque PsO and a self-reported medical history of PsA, pts who were treated with ICO demonstrated:**
 - ✓ **Substantial improvements in PsA disease activity and pain, overall PsO, nail and scalp PsO, as well as HRQoL that were durable through W52**
- **ICO safety profile through W52 was consistent with that observed through W16**
- **Acknowledging the inherent limitations of post hoc subgroup analyses, these findings further support the potential of ICO as a targeted oral treatment option for active PsA**

Background

Icotrokinra (ICO), the first and only targeted oral peptide:

- 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 adults and pediatric patients (≥12 years, ≥40 kg) who are candidates for systemic therapy or phototherapy[2]
- Demonstrated substantial improvements in psoriatic arthritis (PsA) disease activity/pain and nail PsO, and high rates of scalp PsO clearance vs placebo (PBO) at Week (W)16 in a pooled cohort of participants (pts) with moderate-to-severe plaque PsO and a self-reported medical history of PsA across three phase 3 PsO studies[3]
- Currently under investigation for the treatment of active PsA in parallel phase 3 studies[4-6]

Icotrokinra Blocks IL-23 From Binding to its Receptor



Inhibits IL-17A, IL-17F, and IL-22 Production

IL-12Rβ1*=interleukin-12 receptor beta 1.*

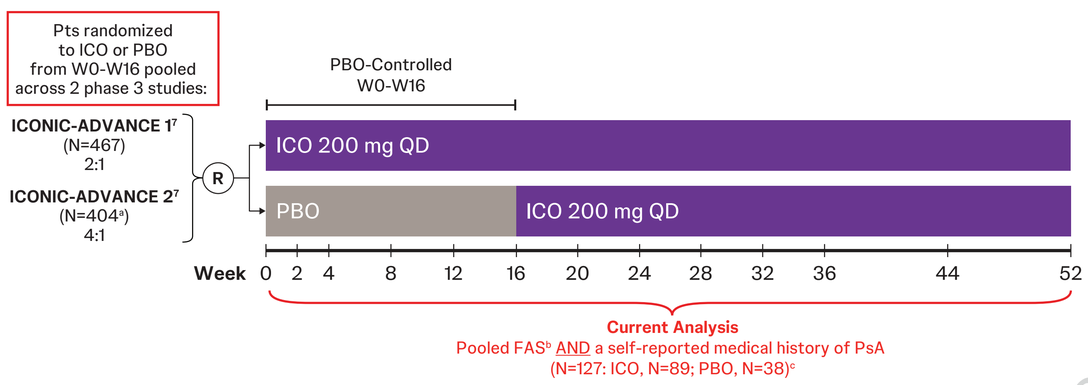
Objectives

Evaluate the durability of ICO effects through W52 in a pooled cohort of pts with moderate-to-severe plaque PsO and a self-reported medical history of PsA (PsO+PsA) in the two phase 3 ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2 studies

Pooled ICONIC-ADVANCE 1 & -ADVANCE 2: ICO and PBO→ICO Through W52

Key inclusion criteria

- ≥18 years
- Plaque PsO for ≥26 weeks
- Body surface area (BSA) ≥10%
- Psoriasis Area and Severity Index (PASI) score ≥12
- Investigator's Global Assessment (IGA) score ≥3
- Candidate for phototherapy or systemic therapy for plaque PsO



[a]ICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of whom 401 were evaluable for efficacy. [b]Includes pooled ICO- and PBO-randomized pts from the phase 3 ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2 studies. [c]Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. ***FAS****=full analysis set,* ***QD****=once daily,* ***R****=randomization.*

Outcomes & Analyses Through W52

PsA-Specific PROs (VAS):

- Mean change from baseline in PtGA of PsA disease activity and in PsA Patient Pain[a,c]
- ≥50% improvement from baseline in PtGA of PsA disease activity and in PsA Patient Pain[b,d,e]

Overall/High-Impact Site PsO:

- Mean/median percent improvement from baseline in PASI[a,c]
- Mean percent improvement from baseline in mNAPSI (among pts with a baseline mNAPSI score >0)[a,c]
- f-PGA 0/1 and 0 (among pts with a baseline f-PGA score ≥2)[b,d]
- ss-IGA 0/1 and 0 (among pts with a baseline ss-IGA score ≥2)[b,d]

HRQoL:

- DLQI 0/1 (among pts with a baseline DLQI score >1)[b,d]

AEs:

- Safety assessments through W16 and through W52

ss-IGA 0/1 reflects score 0/1 and ≥2-grade improvement from baseline. [c]No improvement from baseline / [e]Nonresponder imputation assigned after pts discontinued study drug due to a lack of efficacy or an AE of worsening PsO, or initiated prohibited medication that could impact PsO. Observed data were used for pts who discontinued study drug for other reasons. [d]The remaining missing data were not imputed. [d]After accounting for the intercurrent events, pts with missing data were considered nonresponders. [e]The ≥50% improvement from baseline in PtGA of PsA disease activity and PsA Patient Pain represent components of American College of Rheumatology 50% (ACR50) response criteria, a stringent, clinically relevant measure of improvement in PsA.[8,9] ***AE****=adverse event,* ***f-PGA****=Fingernail Physician's Global Assessment,* ***HRQoL****=health-related quality of life,* ***mNAPSI****=modified Nail Psoriasis Severity Index,* ***PRO****=participant-reported outcome,* ***PsA Patient Pain****=Patient's Assessment of PsA Pain,* ***PtGA****=Patient's Global Assessment,* ***ss-IGA****=scalp-specific Investigator's Global Assessment,* ***VAS****=visual analog scale.*

Results

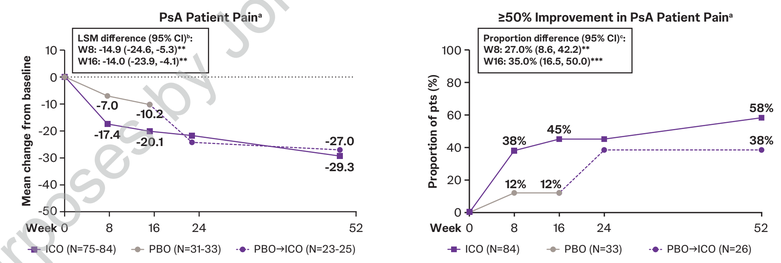
Baseline characteristics of pts with PsO+PsA reflected substantial skin PsO and moderate PsA disease activity/pain

Baseline Characteristics	ICO (N=89)	PBO (N=38)
Demographics		
Age, yrs	50.5 (12.2)	47.4 (12.4)
Female	34%	45%
Race, Asian/Black/White	20% / 3%/ 72%	13% / 5% / 82%
BMI, kg/m^2	31.0 (7.8)	28.4 (7.4)
PsA Characteristics		
PtGA of PsA disease activity[a] (0-100)	48.3 (27.2)	52.0 (29.4)
PsA Patient Pain[a] (0-100)	49.4 (28.0)	54.9 (30.4)
PsO Characteristics		
PsO disease duration, yrs	18.1 (11.9)	18.9 (13.4)
% of BSA with PsO	25.5 (14.6)	25.4 (15.1)
IGA score Moderate (3)/Severe (4)	84% / 16%	71% / 29%
PASI (0-72)	19.7 (6.8)	19.8 (8.0)
High-Impact Site PsO Characteristics		
mNAPSI score[b] (0-130)	24.5 (21.3)	23.6 (19.8)
f-PGA score[c] Mild (2)/Moderate (3)/Severe (4)	15% / 22% / 5%	16% / 24% / 0%
ss-IGA score[c] Mild (2)/Moderate (3)/Severe (4)	14% / 51% / 19%	13% / 45% / 21%
HRQoL		
DLQI (0-30)	13.5 (7.5)	15.8 (8.5)

Data shown are mean (SD), unless otherwise noted. [a]ICO N=86/PBO N=34. [b]Among pts with a baseline f-PGA score >0: ICO N=47/PBO N=19. [c]ICO N=88/PBO N=38. ***BMI****=body mass index,* ***SD****=standard deviation.*

ICO-randomized pts reported greater mean improvement in PsA Patient Pain vs PBO at W16 that was durable through W52

- Nearly one-half of ICO-randomized pts reported ≥50% improvement in PsA Patient Pain at W16, with durable response rates through W52

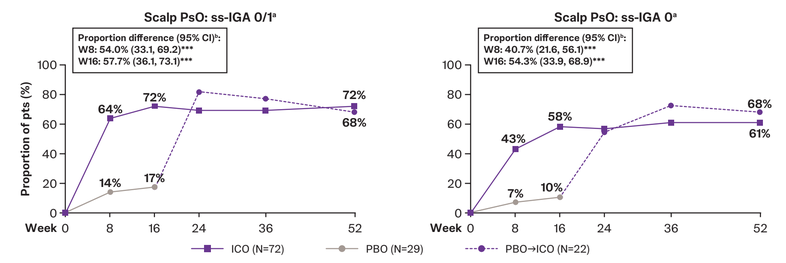


Nominal **p<0.01, *p<0.001 vs PBO**

Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. [a]Among pts with baseline PsA Patient Pain. [b]LSM differences and p-values were based on the MMRM model with treatment group, study, visit, treatment group by visit interaction, baseline PsA Patient Pain, and baseline PsA Patient Pain by visit interaction as covariates. [c]Proportion differences and 95% CIs (using Miettinen-Nurminen method) were calculated adjusting for study, baseline weight category (≤90 kg, >90 kg), and geographic region using Mantel-Haenszel weights; p-values were based on Cochran-Mantel-Haenszel chi-square test stratified by study, baseline weight category (≤90 kg, >90 kg), and geographic region.

ICO demonstrated high rates of scalp PsO clearance vs PBO at W16 that were durable through W52

- 72% of ICO-randomized pts achieved clear/almost clear scalp PsO at W52

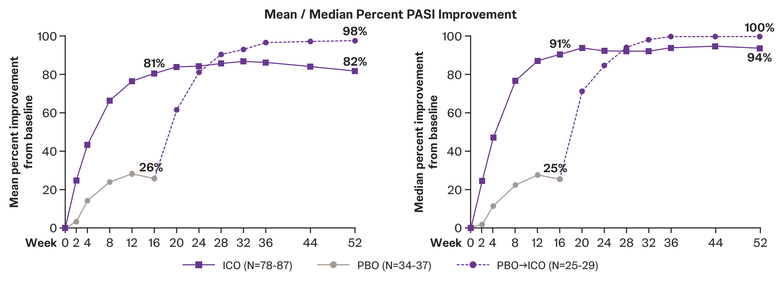


Nominal *p<0.001 vs PBO**

Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. [a]Among pts with a baseline ss-IGA score ≥2. [b]Proportion differences and 95% CIs (using Miettinen-Nurminen method) were calculated adjusting for study, baseline weight category (≤90 kg, >90 kg), and geographic region using Mantel-Haenszel weights; p-values were based on Cochran-Mantel-Haenszel chi-square test stratified by study, baseline weight category (≤90 kg, >90 kg), and geographic region. ***ss-IGA 0/1****=ss-IGA score 0/1 and ≥2-grade improvement from baseline.*

ICO-randomized pts exhibited greater percent PASI improvements vs PBO through W16, with durable improvements through W52

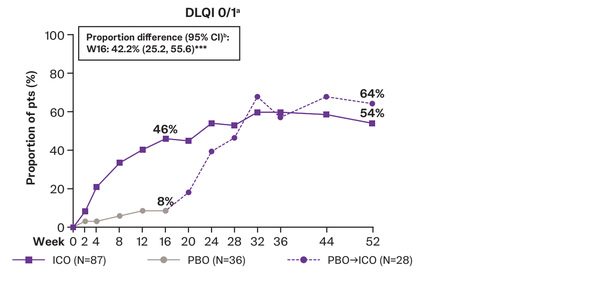
- ICO showed separation from PBO as early as W2 (LSM difference: 21.1 [95% CI: 12.6, 29.6]; nominal p<0.001[a])
- ICO demonstrated greater LSM percent PASI improvement from baseline vs PBO at W16 (81% vs 26%, respectively; LSM difference: 55.2 [95% CI: 42.8, 67.7]; nominal p<0.001[a])



Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. [a]LSMs, LSM differences, and p-values were based on the MMRM model with treatment group, study, visit, treatment group by visit interaction, baseline PASI total score, and baseline PASI total score by visit interaction as covariates.

ICO demonstrated high rates of no PsO impact on HRQoL vs PBO at W16 that were durable through W52

- ICO showed separation from PBO as early as W4 (proportion difference: 19.8% [95% CI: 6.1, 31.9]; nominal p<0.01[b])

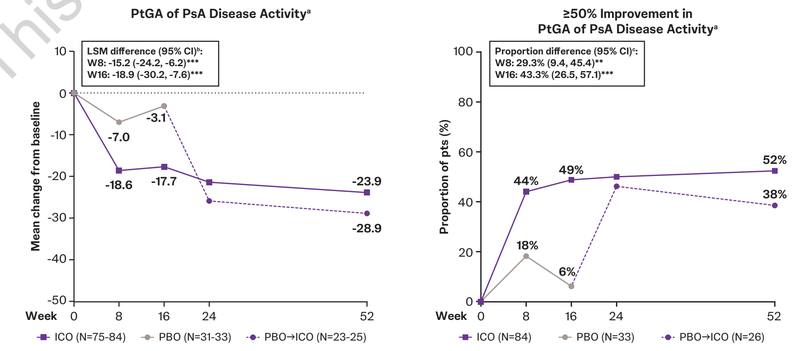


Nominal *p<0.001 vs PBO**

Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. [a]Among pts with a baseline DLQI score >1. [b]Proportion differences and 95% CIs (using Miettinen-Nurminen method) were calculated adjusting for study, baseline weight category (≤90 kg, >90 kg), and geographic region using Mantel-Haenszel weights; p-values were based on Cochran-Mantel-Haenszel chi-square test stratified by study, baseline weight category (≤90 kg, >90 kg), and geographic region.

ICO-randomized pts reported greater mean improvement in PsA disease activity vs PBO at W16 that was durable through W52

- ~50% of ICO-randomized pts reported ≥50% improvement in PsA disease activity at W16, with durable response rates through W52

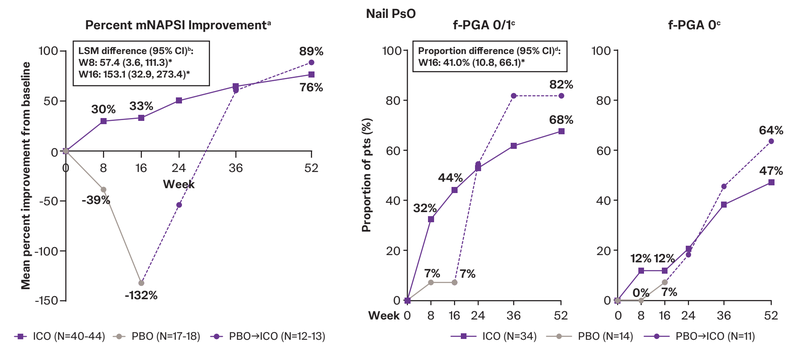


Nominal **p<0.01, *p≤0.001 vs PBO**

Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. [a]Among pts with baseline PtGA of PsA disease activity. [b]LSM differences and p-values were based on the MMRM model with treatment group, study, visit, treatment group by visit interaction, baseline PtGA of PsA disease activity, and baseline PtGA of PsA disease activity by visit interaction as covariates. [c]Proportion differences and 95% CIs (using Miettinen-Nurminen method) were calculated adjusting for study, baseline weight category (≤90 kg, >90 kg), and geographic region using Mantel-Haenszel weights; p-values were based on Cochran-Mantel-Haenszel chi-square test stratified by study, baseline weight category (≤90 kg, >90 kg), and geographic region. ***CI****=confidence interval,* ***LSM****=least squares mean,* ***MMRM****=mixed-effect model for repeated measures.*

ICO-randomized pts exhibited increasing mean percent mNAPSI improvement through W52

- Nearly 70% of ICO-randomized pts achieved clear/almost clear nail PsO at W52



Nominal *p<0.05

Among pts in the pooled FAS and with a self-reported medical history of PsA, 124 were evaluable for efficacy. [a]Among pts with a baseline mNAPSI score >0. [b]LSM differences and p-values were based on the MMRM model with treatment group, study, visit, treatment group by visit interaction, baseline mNAPSI score, and baseline mNAPSI score by visit interaction as covariates. [c]Among pts with a baseline f-PGA score ≥2. [d]Proportion difference and 95% CI (using Miettinen-Nurminen method) were calculated adjusting for study, baseline weight category (≤90 kg, >90 kg), and geographic region using Mantel-Haenszel weights; p-value was based on Cochran-Mantel-Haenszel chi-square test stratified by study, baseline weight category (≤90 kg, >90 kg), and geographic region.

ICO AE profile through W52 was consistent with that observed through W16

Pooled Safety in Pts With PsO+PsA[a]	Through W16: PBO (N=38)	Through W16: ICO (N=88)	Through W52: PBO→ICO[b] (N=30)	Through W52: ICO (N=88)
Mean weeks/total PY of follow-up	14.8 / 10.8	15.7 / 26.5	33.6 / 19.3	48.8 / 82.4
Any AE	24 (63%)	47 (53%)	24 (80%)	72 (82%)
Incidence/100 PY (95% CI)	370 (213, 503)	273 (194, 350)	272 (159, 379)	221 (170, 272)
Serious AE	2 (5%)	1 (1%)	1 (3%)	4 (5%)
Incidence/100 PY (95% CI)	20 (<1, 76)	4 (0, 25)	5 (0, 34)	5 (2, 14)
Infection	12 (32%)	19 (22%)	12 (40%)	49 (56%)
Incidence/100 PY (95% CI)	139 (59, 222)	82 (45, 119)	82 (37, 139)	91 (65, 115)
Serious infection	1 (3%)	0	0	1 (1%)
Incidence/100 PY (95% CI)	10 (0, 62)	0 (0, 18)	0 (0, 27)	1 (0, 8)
Gastrointestinal AE	2 (5%)	7 (8%)	2 (7%)	12 (14%)
Incidence/100 PY (95% CI)	19 (0, 84)	28 (12, 58)	11 (<1, 42)	16 (9, 28)
Malignancy	1 (3%)	0	0	1 (1%)
Incidence/100 PY (95% CI)	10 (0, 62)	0 (0, 18)	0 (0, 27)	1 (0, 8)

Data shown are n (%), unless otherwise noted. Safety analysis set includes all randomized and treated pts. Incidence/100 PY: (number of pts with AEs/total PY at risk [time to first event]) × 100; CI based on study-size adjusted Wald statistic. [a]Among pts in the pooled FAS and with a self-reported medical history of PsA. [b]Includes data after W16 for PBO-randomized pts who crossed over to receive ICO. ***PY****=participant-years.*

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PRESENTED AT: EADV Congress; September 30–October 3, 2026; Vienna, Austria. **REFERENCES: 1.** Fourie AM. *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.** McInnes IB. Poster presented at: EULAR; June 3–6, 2026; London, England. **4.** Merola JF. Poster presented at: EULAR; June 11–14, 2025; Barcelona, Spain. **5.** https://clinicaltrials.gov/study/NCT06878404. **6.** https://clinicaltrials.gov/study/NCT06807424. **7.** Stein Gold L. *Lancet.* 2025;406:1363-74. **8.** Felson DT. *Arthritis Rheum.* 1995;38:727-35. **9.** Chung CP. *Ann Rheum Dis.* 2006;65:1602-7. **ACKNOWLEDGMENTS:** Medical writing support was provided by R. Contento, PharmD of Johnson & Johnson under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298–1304). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: AWA:** Served as a speaker, consultant, and/or investigator for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Eli Lilly, Galderma, Incyte, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, Takeda, and UCB. **IBM:** Served as a consultant for AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Cabaletta Bio, Compugen, Dextera Biosciences, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, MoonLake, Novartis, Pfizer, Roche, Sanofi, and UCB; received grant/research support from Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, Roche, and UCB; is a share-option holder of Cabaletta Bio, Causeway Therapeutics, Compugen, Dextera Biosciences, and Montai Therapeutics; and is a trustee of Arthritis UK. **LSG:** Served as an investigator, advisor and/or speaker for AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Galderma, Johnson & Johnson, LEO Pharma, Pfizer, Regeneron, Sanofi, Takeda. **MGL:** Employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Oruka, Pfizer, Sanofi-Regeneron, and UCB Pharma; and has served as a consultant for AbbVie, Added Health, Aikium, Almirall, AltruBio, Alumis, Amgen, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres Therapeutics, Bausch, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, Dermavant Sciences, Dermsquared, Edesa Biotech, Eli Lilly, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, Johnson & Johnson, LEO Pharma, Mayne Pharmaceuticals, Meiji Seika Pharma, Mindera Health, Mirum Pharmaceuticals, MoonLake, Novartis, Oruka, Pfizer, PPD™ CorEvitas™ Clinical Registries, Revolo, Sanofi-Regeneron, Seanergy, Strata, Sun Pharma, Takeda, Thermo Fisher Scientific, Trevi, and Verrica. **OR-S, Y-WY, SDC, CI, KC, TS,** and **KL:** Employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson. **SO:** Former Johnson & Johnson employee and may own stock/stock options. **JFM:** Served as a consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Johnson & Johnson, MoonLake, Novartis, Oruka, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB.