

Consistency of Skin Clearance With the Targeted Oral Peptide Icotrokinra: Results From a Large Pooled Cohort of Phase 3 Study Participants With Moderate-to-Severe Plaque Psoriasis

Linda Stein Gold,¹ April W. Armstrong,² Jennifer Soung,³ Ronald B. Vender,⁴ Andrew E. Pink,⁵ Joseph Cafone,⁶ Bassey Effiom Edem,⁷ Ofelia Reyes-Servin,⁶ Shu Li,⁶ Ya-Wen Yang,⁸ Mark G. Lebwohl⁹

¹Henry Ford Health System, West Bloomfield, MI, USA; ²Department of Dermatology, University of California Los Angeles, Los Angeles, CA, USA; ³Southern California Clinical Research, Santa Ana, and Harbor University of California Los Angeles, CA, USA; ⁴McMaster University and Dermatrials Research Inc., Hamilton, ON, Canada; ⁵St. John's Institute of Dermatology, Guy's & St. Thomas' NHS Foundation Trust and King's College London, London, UK; ⁶Johnson & Johnson, Spring House, PA, USA; ⁷Johnson & Johnson, Leiden, The Netherlands; ⁸Johnson & Johnson, Horsham, PA, USA; ⁹Icahn School of Medicine at Mount Sinai, New York, NY, USA.

This presentation was sponsored by Johnson & Johnson.

PRESENTED AT: AAD Annual Meeting; March 27-31, 2026; Denver, CO, USA.

Disclosures

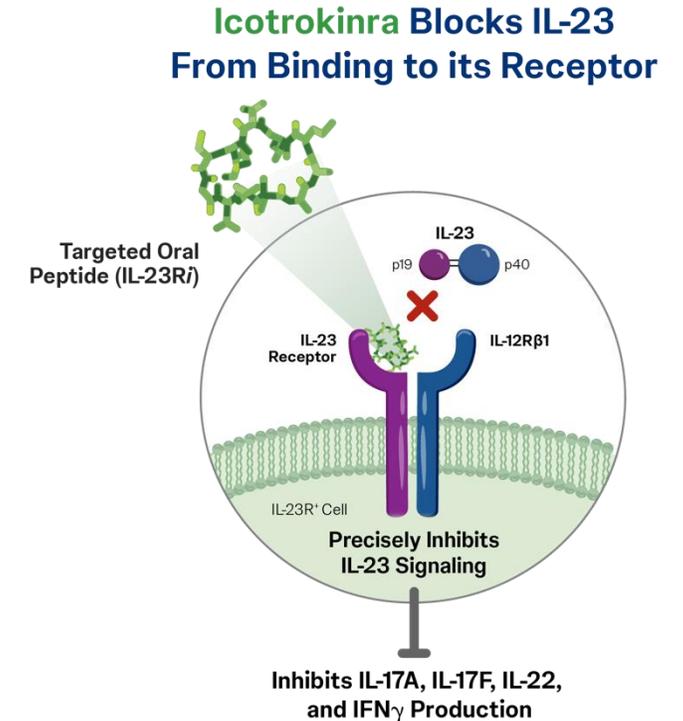
LSG: Served as an investigator, advisor, and/or speaker for AbbVie, Amgen, Bristol Myers Squibb, Galderma, Johnson & Johnson, LEO Pharma, Lilly, Pfizer, Regeneron, Sanofi, and Takeda. **AWA:** Served as a speaker, consultant, and/or investigator for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant Sciences, Eli Lilly and Company, Galderma, Incyte, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, Takeda, and UCB. **JS:** Served as a speaker, consultant, advisory board member, and/or investigator for AbbVie, Amgen, Arcutis, Aslan, Bristol Myers Squibb, Coval Biopharma, Dermavant Sciences, Eli Lilly, Johnson & Johnson, KoBioLabs, National Psoriasis Foundation, Novartis, Ortho Dermatologic, Oruka, Pfizer, Regeneron/Sanofi, and UCB. **RBV:** Received grants/research support and speakers bureau honoraria from: AbbVie, Alumis, Amgen, Arcutis, Bausch, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Dermavant Sciences, Dermira, DICE, Galderma, Incyte, JAMP, Johnson & Johnson, LEO Pharma, Lilly, Meiji, Nimbus, Novartis, Organon, Oruka, Pfizer, Sandoz, Sanofi, Sun, Takeda, UCB, and Zai. **AEP:** Served as an investigator, advisor and/or speaker and/or received educational support from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, Incyte, Johnson & Johnson, Leo Pharma, Novartis, Pfizer, Sanofi, and UCB. **JC, BEE, OR-S, SL, and Y-WY:** Employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson. **MGL:** Employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Oruka, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for AbbVie, Added Health, Aikium, Almirall, AltruBio Inc., Alumis, Amgen, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, Dermsquared, Edesa Biotech, Eli Lilly, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Johnson & Johnson, Incyte, LEO Pharma, Mayne Pharmaceuticals, Meiji Seika Pharma, Mindera, Mirium Pharmaceuticals, Moonlake, Oruka, Pfizer, Sanofi-Regeneron, Revolo, Seanergy, Strata, Sun Pharma, Takeda, Trevi, and Verrica.

Background



Icotrokinra (ICO) for Plaque Psoriasis (PsO)

- First and only targeted oral peptide that precisely blocks the interleukin-23 (IL-23) receptor and inhibits IL-23 pathway signaling¹
- Evaluated for the treatment of moderate-to-severe plaque PsO in the phase 3 ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2 studies^{2,3}
 - Co-primary endpoints of each study were met, with ICO demonstrating significantly higher rates of clear/almost clear skin versus placebo (PBO) at Week (W) 16



IFN=interferon, IL-12R β 1=interleukin-12 receptor beta 1, IL-23Ri=interleukin-23 receptor inhibitor.

Objective



Evaluate the consistency of ICO versus PBO skin clearance response at W16 across baseline subgroups of high clinical interest in a large pooled cohort of phase 3 study participants

This material is distributed for scientific purposes on J&J Medical Company and is not for promotional use

Pooled ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2: ICO Versus PBO Through W16 by Baseline Subgroups

Moderate-to-Severe Plaque PsO (N=1555)

Key inclusion criteria

- ≥12 yrs ICONIC-LEAD
- ≥18 yrs ICONIC-ADVANCE 1 & 2
- Plaque PsO ≥26 weeks
- BSA ≥10%, PASI score ≥12, IGA score ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO

Co-primary endpoints

- IGA score of 0/1 and ≥2-grade improvement from baseline (IGA 0/1) versus PBO at W16
- ≥90% reduction in PASI score from baseline (PASI 90) versus PBO at W16

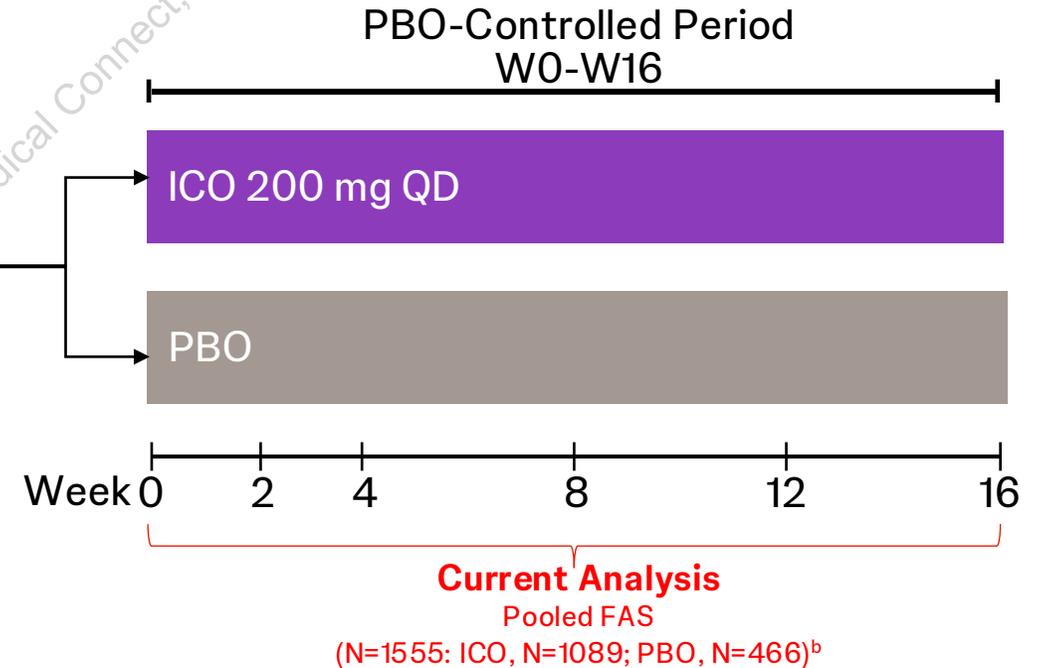
Participants randomized to ICO or PBO from W0-W16 across pooled phase 3 studies:

ICONIC-LEAD²
(N=684)^a
2:1

ICONIC-ADVANCE 1³
(N=467)
2:1

ICONIC-ADVANCE 2³
(N=404)
4:1

R



^aAdolescents, n=66. ^bIncludes participants who were randomized to ICO or PBO from the pooled phase 3 ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2 studies. **BSA**=body surface area, **FAS**=full analysis set, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **QD**=once daily, **R**=randomization.

Outcomes & Analyses

W16 IGA 0/1 Response^{a,c}

- Proportion difference (95% confidence interval [CI]) between ICO and PBO IGA 0/1 response
- Subgroups of high clinical interest:
 - Demographic characteristics (sex, age, body weight, body mass index)
 - PsO disease characteristics (PASI, IGA)
 - Prior PsO treatment (biologics, systemics)

W16 Percent PASI Improvement^{b,d}

- Least squares (LS) mean percent improvement from baseline in PASI score
- Subgroups of interest:
 - Body weight quartiles
 - Body mass index categories

^aNonresponder imputation / ^bNo improvement from baseline assigned after participants discontinued the study drug due to a lack of efficacy or an adverse event (AE) of worsening PsO, or initiated prohibited medication that could impact PsO. Observed data were used for participants who discontinued the study drug for other reasons. ^cAfter accounting for the intercurrent events, participants with missing data were considered nonresponders. ^dThe remaining missing data were not imputed.

ICO consistently demonstrated higher IGA 0/1 response rates versus PBO at W16 across subgroups defined by sex and age

Baseline Demographic Characteristics in the Pooled Phase 3 Cohort

| | ICO | PBO |
|-------------------|-----------|-----------|
| Pooled FAS | N=1089 | N=466 |
| Sex | | |
| Male | 732 (67%) | 316 (68%) |
| Female | 357 (33%) | 150 (32%) |
| Age, years | | |
| ≥12 to <18 | 44 (4%) | 22 (5%) |
| ≥18 to <45 | 505 (46%) | 197 (42%) |
| ≥45 to <65 | 435 (40%) | 194 (42%) |
| ≥65 | 105 (10%) | 53 (11%) |

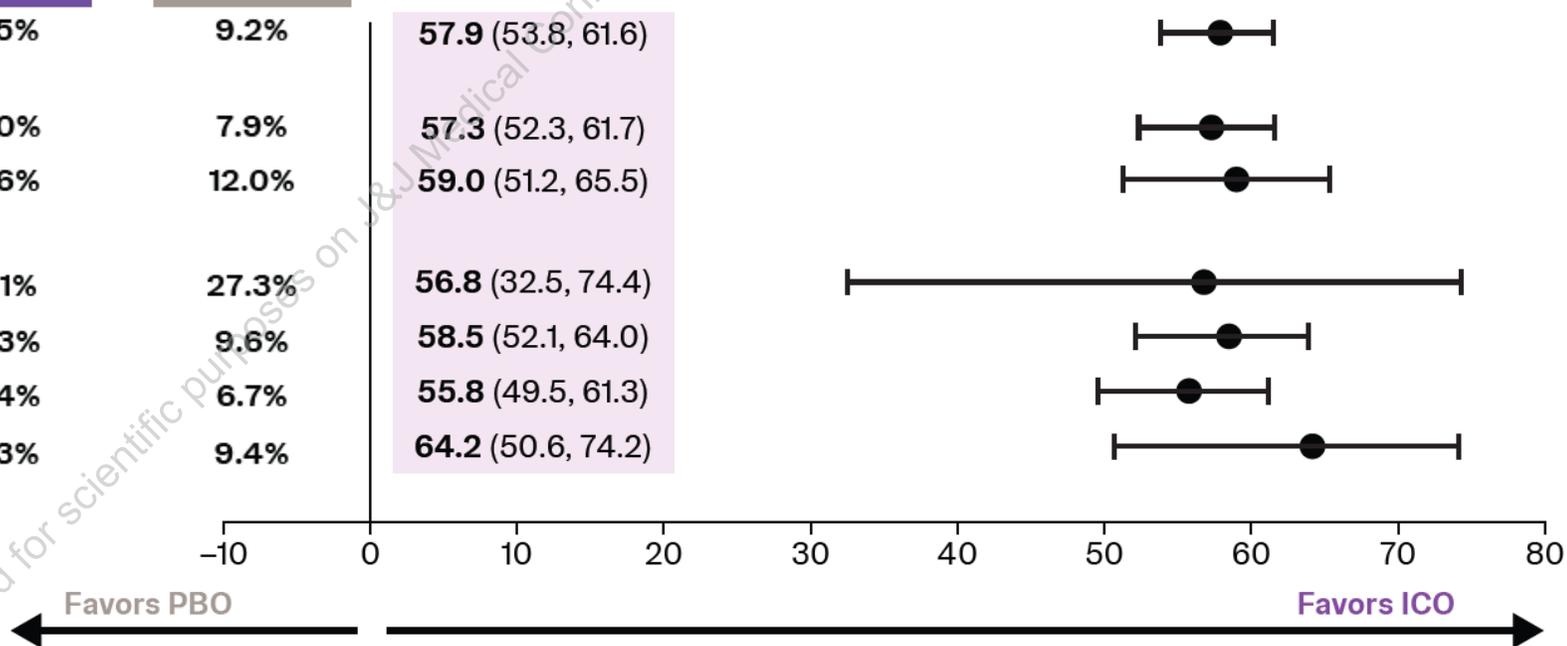
Data shown are mean (SD) or n (%).

Response Rate

| | ICO | PBO |
|-------------------|--------------|--------------|
| Pooled FAS | 67.5% | 9.2% |
| Sex | | |
| Male | 66.0% | 7.9% |
| Female | 70.6% | 12.0% |
| Age, years | | |
| ≥12 to <18 | 84.1% | 27.3% |
| ≥18 to <45 | 68.3% | 9.6% |
| ≥45 to <65 | 63.4% | 6.7% |
| ≥65 | 73.3% | 9.4% |

IGA 0/1 Response at W16 by Sex and Age at Baseline

Proportion Difference (95% CI)



Participant demographic characteristics were balanced across treatment groups

ICO consistently demonstrated higher IGA 0/1 response rates versus PBO at W16 across subgroups defined by weight and body mass index

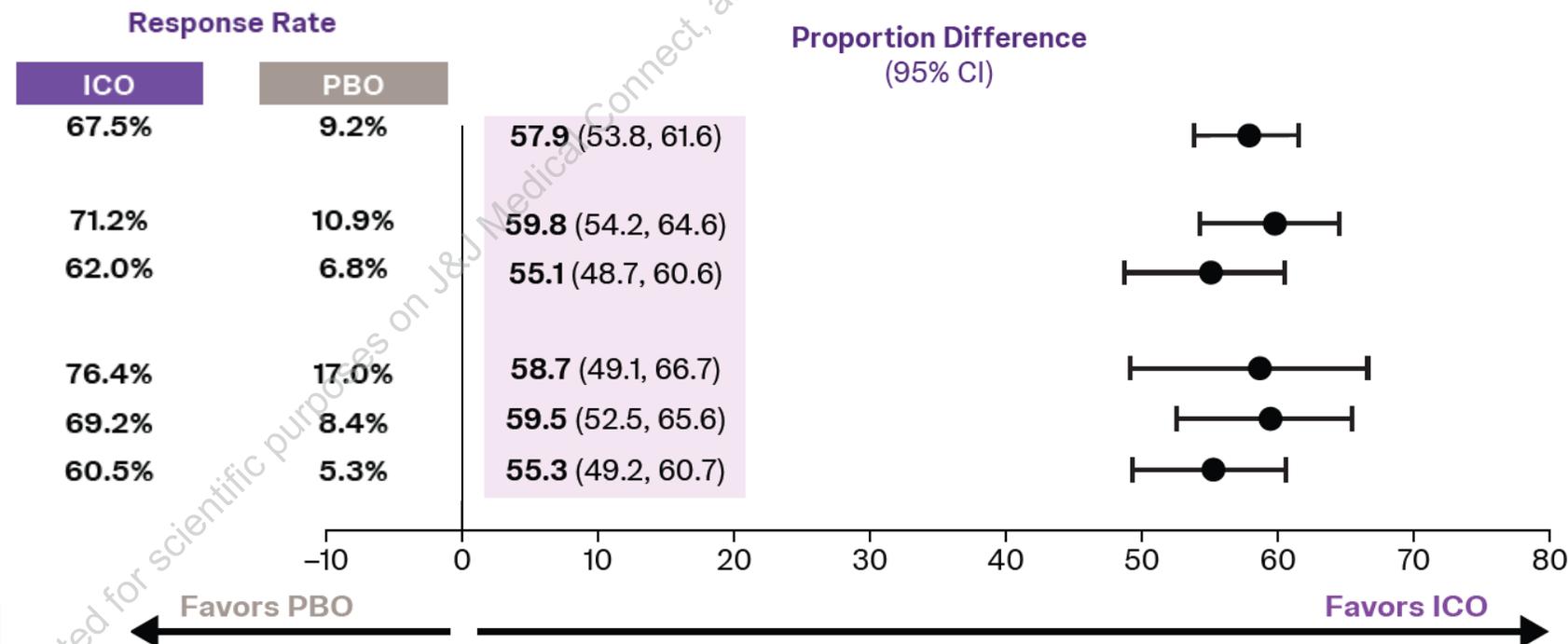
Baseline Demographic Characteristics in the Pooled Phase 3 Cohort

| | ICO | PBO |
|--|-------------|-------------|
| Pooled FAS | N=1089 | N=466 |
| Weight, kg | 87.1 (21.0) | 87.1 (23.2) |
| ≤90 | 649 (60%) | 276 (59%) |
| >90 | 440 (40%) | 190 (41%) |
| Body mass index,^a kg/m² | 29.4 (6.6) | 29.4 (7.2) |
| Normal (<25) | 276 (25%) | 112 (24%) |
| Overweight (≥25 to <30) | 377 (35%) | 166 (36%) |
| Obese (≥30) | 435 (40%) | 187 (40%) |

Data shown are mean (SD) or n (%).

Body size categories were balanced across treatment groups

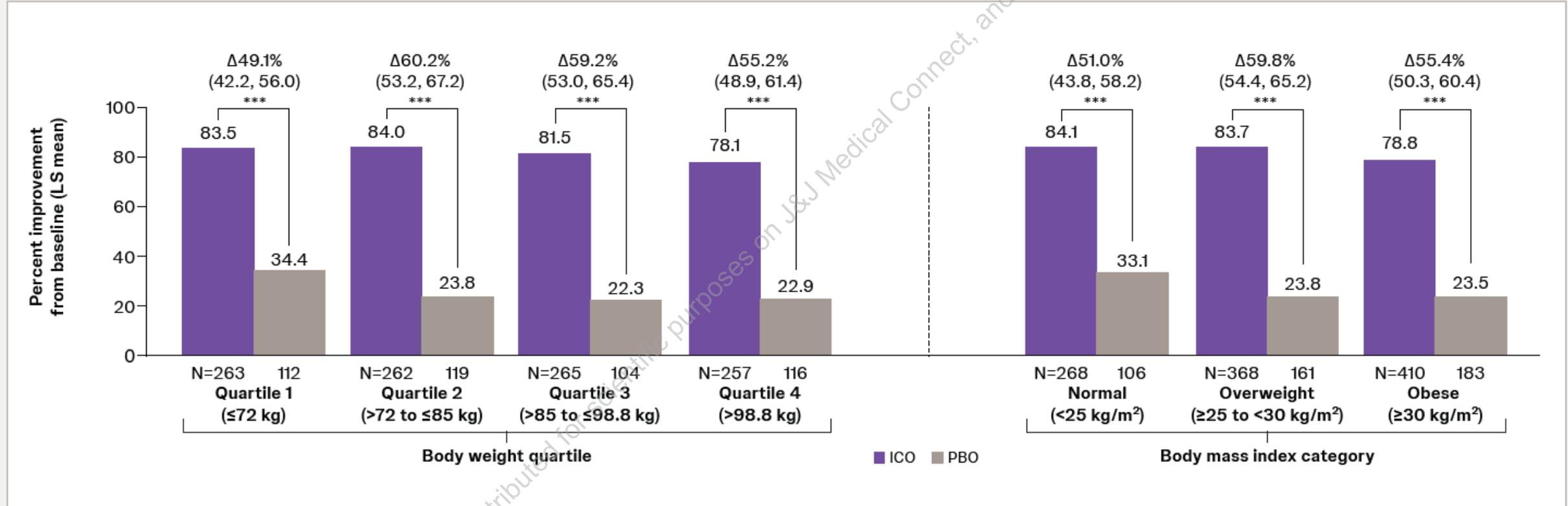
IGA 0/1 Response at W16 by Baseline Weight and Body Mass Index



^aICO, N=1088; PBO, N=465. 95% CI for difference in proportion is based on the Miettinen-Nurminen method using Mantel-Haenszel weights adjusted by study.

ICO consistently demonstrated greater mean percent PASI improvements versus PBO at W16 regardless of weight and body mass index

- In the overall pooled population, ICO provided substantially greater LS mean percent PASI improvement versus PBO at W16 (81.9% vs 25.8%, respectively; LS mean difference: 56.1% [95% CI: 52.8, 59.4]; nominal $P < 0.001$)



***Nominal $P < 0.001$ versus PBO. LS means, LS mean differences, and P values were based on the MMRM model, with treatment group, visit, study, baseline PASI total score, and treatment group by visit interaction as covariates. Participants with missing baseline body weight or body mass index were not included in the analysis. **MMRM**=mixed-effect model for repeated measures.

ICO consistently demonstrated higher IGA 0/1 response rates versus PBO at W16 across subgroups defined by baseline disease severity

Baseline Disease Severity in the Pooled Phase 3 Cohort

| | ICO | PBO |
|--------------------------|------------|------------|
| Pooled FAS | N=1089 | N=466 |
| PASI score (0-72) | 19.8 (7.0) | 20.1 (7.5) |
| <20 | 699 (64%) | 300 (64%) |
| ≥20 | 390 (36%) | 166 (36%) |
| IGA score (0-4) | | |
| 3 (moderate) | 844 (78%) | 363 (78%) |
| 4 (severe) | 245 (22%) | 103 (22%) |

Data shown are mean (SD) or n (%).

Disease characteristics were balanced across treatment groups

- Mean PsO duration: 17-18 years
- Mean PsO BSA: 26%

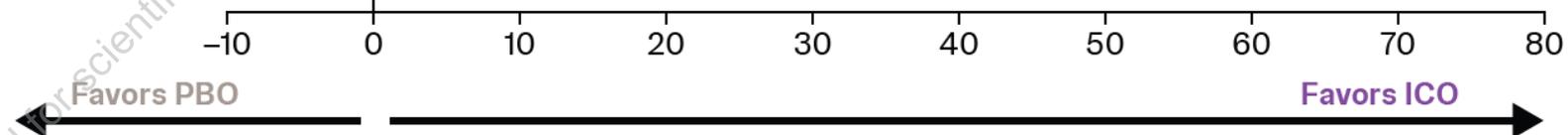
IGA 0/1 Response at W16 by Baseline PASI and IGA

Response Rate

| | ICO | PBO |
|--------------------------|--------------|--------------|
| Pooled FAS | 67.5% | 9.2% |
| PASI score (0-72) | | |
| <20 | 66.4% | 11.0% |
| ≥20 | 69.5% | 6.0% |
| IGA score (0-4) | | |
| 3 (moderate) | 70.7% | 10.5% |
| 4 (severe) | 56.3% | 4.9% |

Proportion Difference (95% CI)

| | |
|--------------------------|--------------------------|
| Pooled FAS | 57.9 (53.8, 61.6) |
| PASI score (0-72) | |
| <20 | 55.0 (49.6, 59.8) |
| ≥20 | 63.9 (57.4, 69.3) |
| IGA score (0-4) | |
| 3 (moderate) | 59.8 (55.0, 64.0) |
| 4 (severe) | 51.8 (43.5, 58.9) |



ICO consistently demonstrated higher IGA 0/1 response rates versus PBO at W16 across subgroups defined by prior biologic/systemic treatment

Prior PsO Treatments at Baseline in the Pooled Phase 3 Cohort

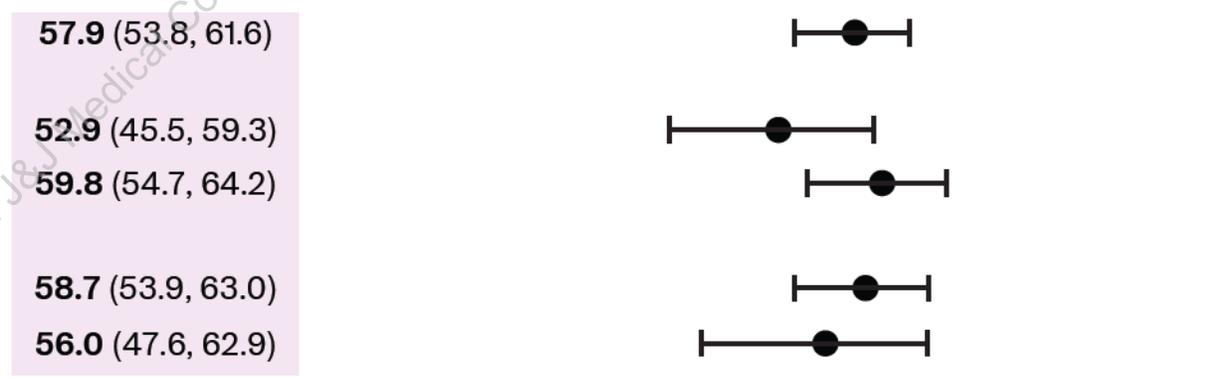
| | ICO | PBO |
|----------------------------|-----------|-----------|
| Pooled FAS | N=1089 | N=466 |
| Biologics ever used | | |
| Yes | 312 (29%) | 153 (33%) |
| No | 777 (71%) | 313 (67%) |
| Systemics ever used | | |
| Yes | 788 (72%) | 331 (71%) |
| No | 301 (28%) | 135 (29%) |

Response Rate

| | ICO | PBO |
|----------------------------|--------------|--------------|
| Pooled FAS | 67.5% | 9.2% |
| Biologics ever used | | |
| Yes | 59.9% | 6.5% |
| No | 70.5% | 10.5% |
| Systemics ever used | | |
| Yes | 67.6% | 8.2% |
| No | 67.1% | 11.9% |

IGA 0/1 Response at W16 by Prior PsO Treatments

Proportion Difference (95% CI)



Data shown are n (%).

PsO treatment history was similar between treatment groups

- 32% had previous phototherapy (PUVA or UVB)

In this large pooled cohort, the ICO AE profile was similar to PBO through W16

| Pooled safety through W16, ^a n (%) | ICO (N=1088) | PBO (N=465) |
|---|-----------------|----------------|
| Mean weeks of follow-up, n | 15.9 | 15.6 |
| Any AE | 531 (49%) | 249 (54%) |
| Most common AEs (≥5%) | | |
| Nasopharyngitis | 68 (6%) | 28 (6%) |
| Upper respiratory tract infection | 53 (5%) | 24 (5%) |
| Serious AEs | 20 (2%) | 10 (2%) |
| AEs leading to discontinuation | 20 (2%) | 13 (3%) |
| Infections | 252 (23%) | 125 (27%) |
| Serious infections | 2 (<1%) | 1 (<1%) |
| Gastrointestinal AEs | 71 (7%) | 27 (6%) |
| Malignancy | 5 (<1%) | 1 (<1%) |

^aSafety analysis set included all randomized and treated participants.

Key Takeaways



In a large pooled cohort of adults and adolescents with moderate-to-severe plaque PsO, the targeted oral peptide ICO demonstrated:

- ✓ **Robust rates of skin clearance at W16**
- ✓ **Consistent treatment effects regardless of:**
 - ✓ **Sex, age, weight, and body mass index**
 - ✓ **PsO disease severity**
 - ✓ **Prior PsO treatment**
- ✓ **An AE profile similar to PBO through W16**



Findings suggest that once-daily oral ICO provides high-level skin improvements across broad groups of participants with moderate-to-severe PsO

References

1. Fourie AM. *Sci Rep*. 2024;14:17515.
2. Bissonnette R. *N Engl J Med*. 2025;393:1784-95.
3. Stein Gold L. *Lancet*. 2025;406:1363-74.

This material is distributed for scientific purposes on J&J Medical Connect, and is not for promotional use

Acknowledgments

- > Medical writing support was provided by Kelly Koch, PharmD, of Johnson & Johnson, and Panita M. Trenor, PhD, of Lumanity Communications Inc. under the direction of the authors in accordance with Good Publication Practice guidelines (DeTora LM. *Ann Intern Med.* 2022;175:1298-1304).
- > This presentation was sponsored by Johnson & Johnson.