

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 S. Gold,¹ April W. Armstrong,² Jennifer Soung,³ Ronald B. Vender,⁴ Andrew E. Pink,^{5*} Joseph Cafone,⁶ Bassey E. 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.

*Presenting author



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Key Takeaways

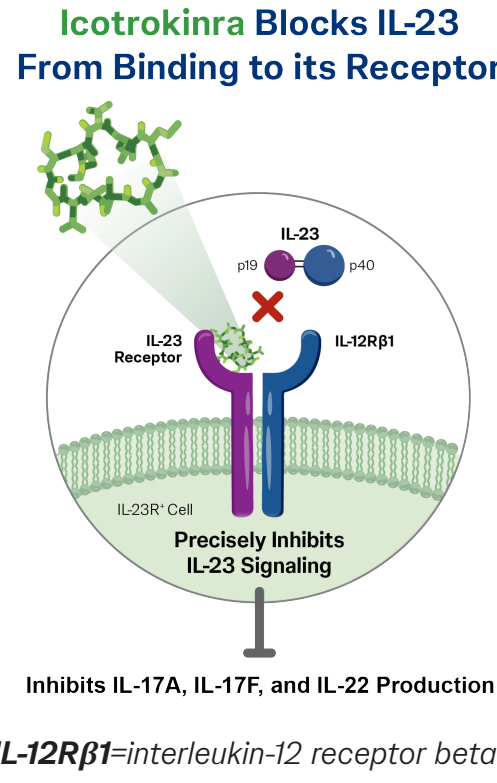
- In a large pooled cohort of adults and adolescents with moderate-to-severe plaque PsO, the targeted oral peptide ICO demonstrated:**
 - Robust rates of skin clearance at W16
 - Consistent treatment effects regardless of:
 - Sex, age, weight, and body mass index
 - PsO disease severity
 - Prior PsO 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**

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}

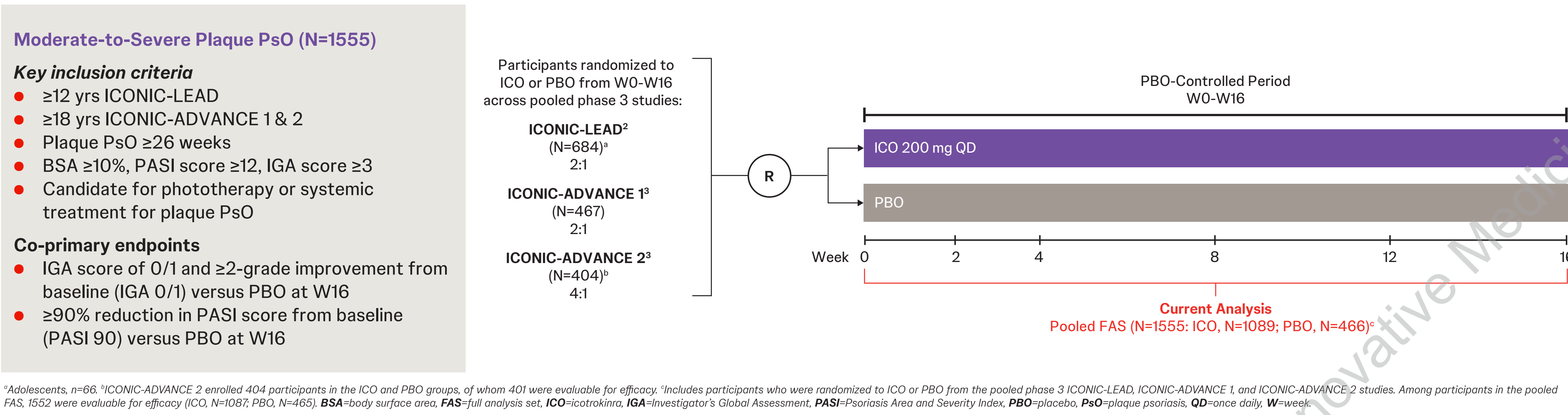
- Co-primary endpoints of each study were met, with ICO demonstrating significantly higher rates of clear/almost clear skin versus placebo (PBO) at Week (W) 16



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

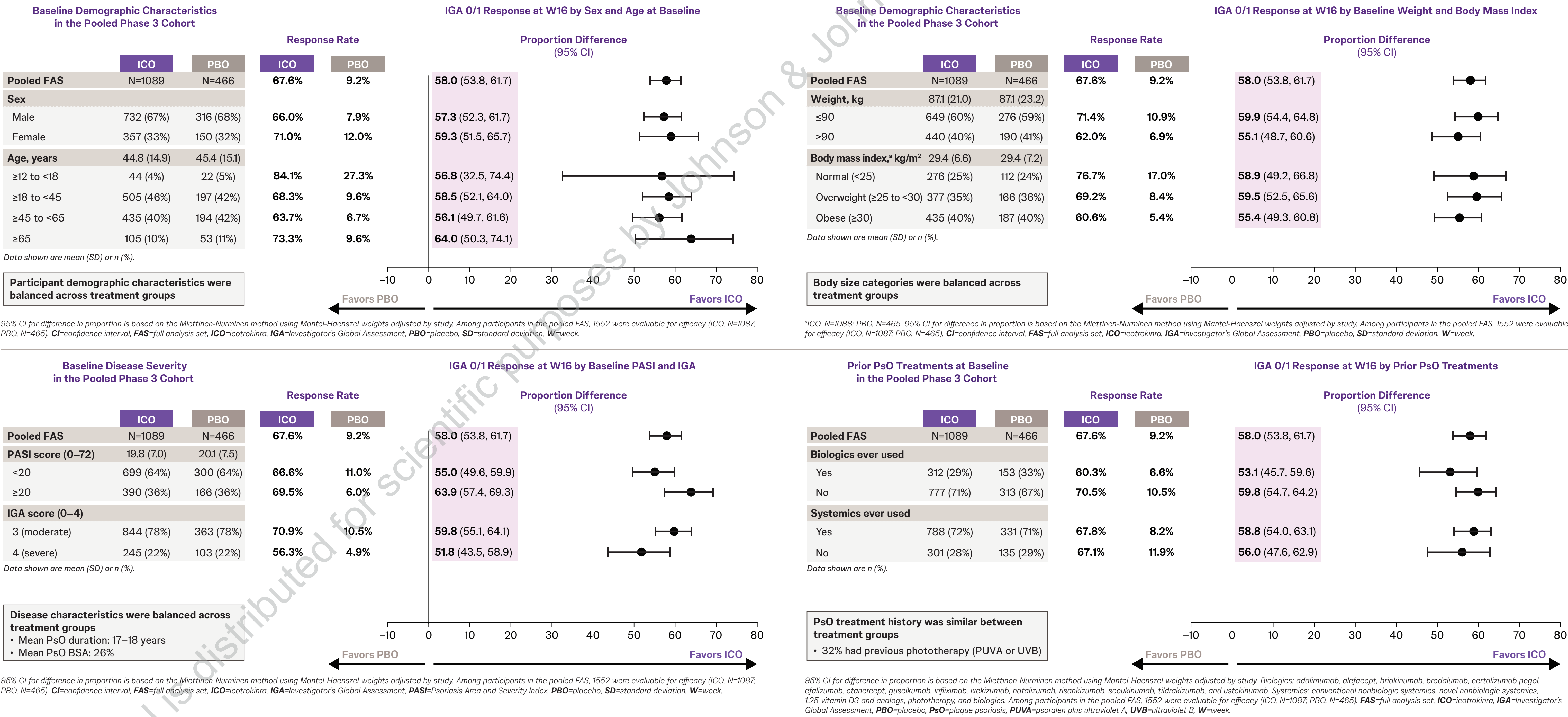
Pooled ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2: ICO Versus PBO Through W16 by Baseline Subgroups



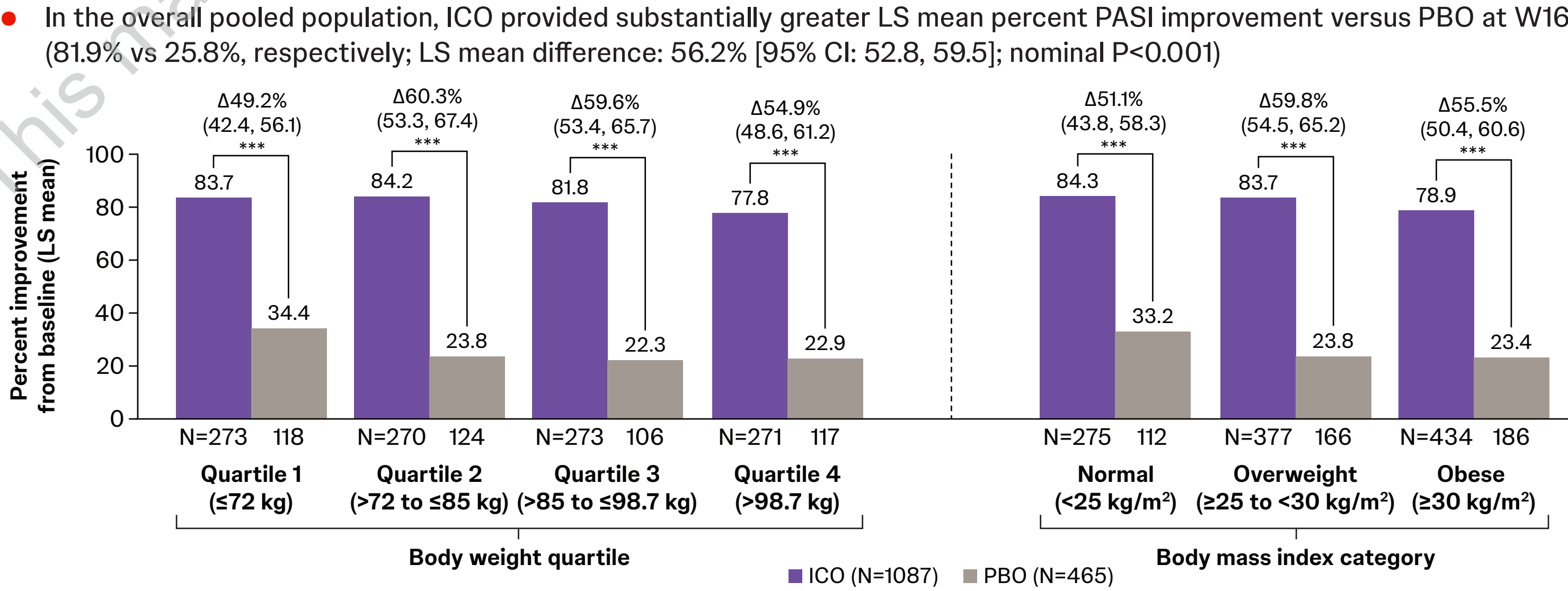
^aAdolescents, n=66. ^bICONIC-ADVANCE 2 enrolled 404 participants in the ICO and PBO groups, of whom 401 were evaluable for efficacy. ^cIncludes participants who were randomized to ICO or PBO from the pooled phase 3 ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2 studies. Among participants in the pooled FAS, 1552 were evaluable for efficacy (ICO, N=1087; PBO, N=465). ^dBSA=body surface area. ^eFAS=full analysis set. ^fICO=icotrokinra. ^gIGA=Investigator's Global Assessment. ^hPASI=Psoriasis Area and Severity Index. ⁱPBO=placebo. ^jPsO=plaque psoriasis. ^kQD=once daily. ^lW=week.

Results

ICO consistently demonstrated higher IGA 0/1 response rates versus PBO at W16 across subgroups defined by sex, age, weight, body mass index, baseline disease severity, and prior biologic/systemic treatment



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



***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. Among participants in the pooled FAS, 1552 were evaluable for efficacy (ICO, N=1087; PBO, N=465). CI=confidence interval. ICO=icotrokinra. LS=least squares. MMRM=mixed-effects model for repeated measures. PASI=Psoriasis Area and Severity Index. PBO=placebo. W=week.

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

Pooled safety through W16, 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%)

*Safety analysis set included all randomized and treated participants. AE=adverse event. ICO=icotrokinra. PBO=placebo. W=week.