Early and Durable Improvements in Patient-Reported Outcomes With the Targeted Oral Peptide Icotrokinra in Adolescents With Moderate-to-Severe Plaque Psoriasis:

One-Year Results From the ICONIC-LEAD Study

Jennifer Soung,[1] Mark G. Lebwohl,[2] Adelaide Hebert,[3] Andrew E. Pink,[4] H. Chih-ho Hong,[5,6] Charles Iaconangelo,[7] Joseph Cafone,[8] Jingzhi Jiang,[8] Shu Li,[8] Ya-Wen Yang,[9] Lawrence F. Eichenfield[10]

[1]Southern California Clinical Research, Santa Ana, and Harbor University of California Los Angeles, CA, USA; [2]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [3]UTHealth McGovern Medical School, Houston, TX, USA; [4]St. John's Institute of Dermatology, Guy's & St. Thomas' NHS Foundation Trust and King's College London, London, UK; [5]University of British Columbia, Department of Dermatology and Skin Science, Vancouver, BC, Canada; [6]Dr. Chih-ho Hong Medical Inc., a member of Probity Medical Research, Surrey, BC, Canada; [7]Johnson & Johnson, Malvern, PA, USA; [8]Johnson & Johnson, Spring House, PA, USA; [9]Johnson & Johnson, Horsham, PA, USA; [10]University of California, San Diego School of Medicine, and Rady Children's Hospital, San Diego, CA, USA

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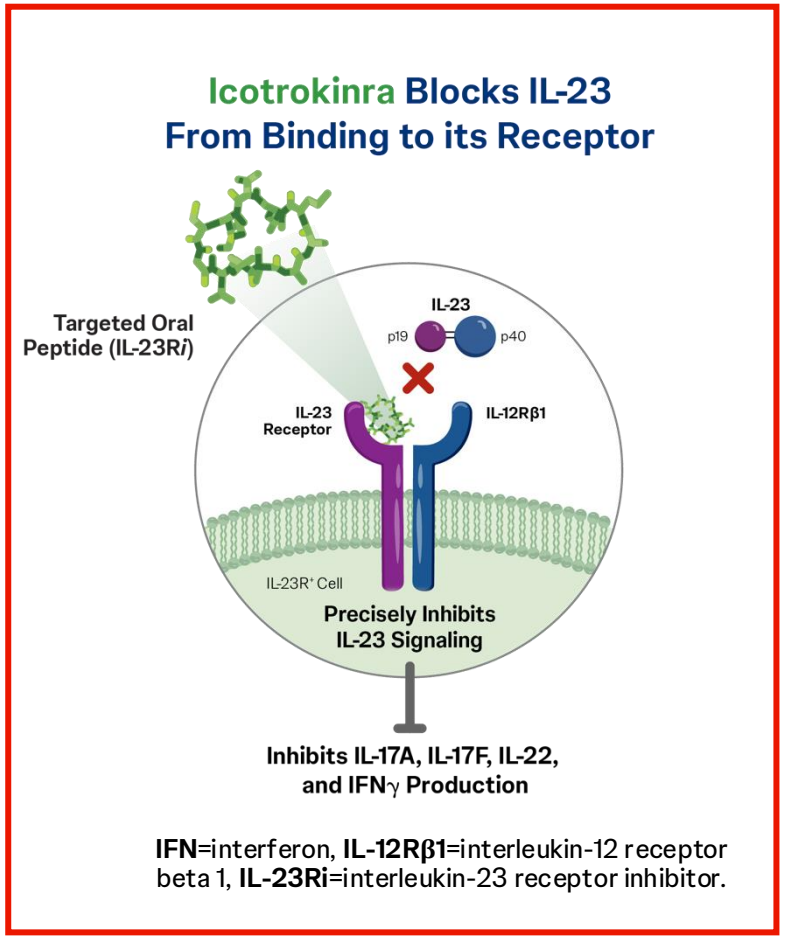
Background

Psoriasis (PsO) in Adolescents

- PsO onset commonly occurs in adolescence; stigmatization, mental health impacts, and diminished health-related quality of life (HRQoL) are major concerns for this age group[1,2]
- Patient-reported outcomes (PROs) measure bothersome PsO symptoms, such as itch and pain, and HRQoL
- Pediatric studies have shown a correlation between HRQoL scores and disease severity; HRQoL improves with successful treatment of PsO[2]

Icotrokinra (ICO)

- First and only targeted oral peptide that precisely blocks the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling[3]
- Demonstrated significantly higher skin clearance rates vs placebo (PBO) at Week (W)16, with increasing response rates and no safety signal through W24 among adults & adolescents with moderate-to-severe plaque PsO in the phase 3 ICONIC-LEAD study[4]
  - Consistent with overall study results, adolescents demonstrated higher rates of skin clearance with ICO vs PBO at W16, with increased response rates and a favorable safety profile through W24[5]



IFN=interferon, **IL-12Rβ1**=interleukin-12 receptor beta 1, **IL-23Ri**=interleukin-23 receptor inhibitor.

Objective

Assess ICO effects on PRO measures of PsO manifestations and HRQoL in ICONIC-LEAD adolescents with moderate-to-severe plaque PsO through W52

ICONIC-LEAD – Study Design & Adolescent Subgroup

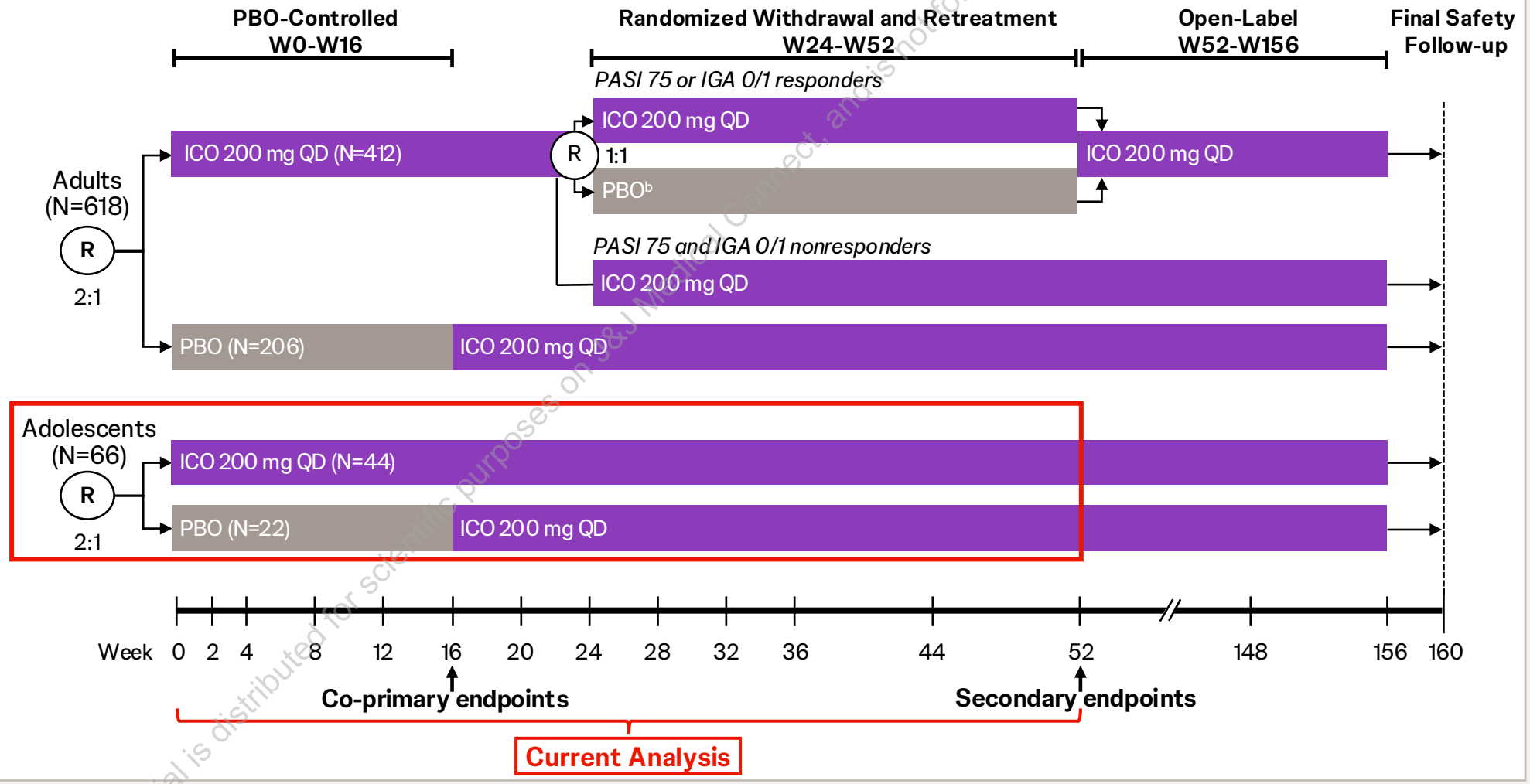
Moderate-to-Severe Plaque PsO (N=684)

Key inclusion criteria

- ≥12 years
  - Adults (≥18 years)
  - Adolescents (12-<18 years)
- Plaque PsO for ≥26 weeks
- BSA ≥10%, PASI score ≥12, IGA score ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO

Adolescent-specific inclusion criteria:

- Body weight ≥40 kg[a]



[a]Weight limit was set to ensure similar exposures between adults and adolescents. [b]Participants (pts) retreated with ICO upon loss of ≥50% PASI improvement observed at W24. **BSA**=body surface area, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **QD**=once daily, **R**=randomization.

Assessments & Analyses

Psoriasis Symptoms and Signs Diary (PSSD)[6]

- **5 Symptoms**
  - Itch, Skin tightness, Burning, Stinging, Pain
- **6 Signs**
  - Dryness, Cracking, Scaling, Shedding/Flaking, Redness, Bleeding

- PSSD symptoms and signs summary scores range: 0-100
- Individual item scores range: 0 (absent)-10 (worst imaginable)
- Clinically meaningful improvement (CMI): cut-offs range from ≥3 to ≥5-point improvement from baseline in individual item scores

Children's Dermatology Life Quality Index (CDLQI)[7]

- Questionnaire for children designed to measure the impact of skin disease on HRQoL
- Scores range: 0-30; higher scores indicate greater impact on HRQoL

Improvement From Baseline in PROs at W16[a,c]

- PSSD Symptom score
- PSSD Sign score
- CDLQI score

PROs Through W52[b,d]

- CMI in PSSD Itch score (≥4-point improvement from baseline)
- PSSD Symptom score 0
- PSSD Sign score 0
- CDLQI score 0/1

[a]No improvement from baseline / [b]Nonresponder imputation assigned after pts discontinued 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 pts who discontinued study drug for other reasons. [c]The remaining missing data were not imputed. [d]After accounting for the intercurrent events, pts with missing data were considered nonresponders.

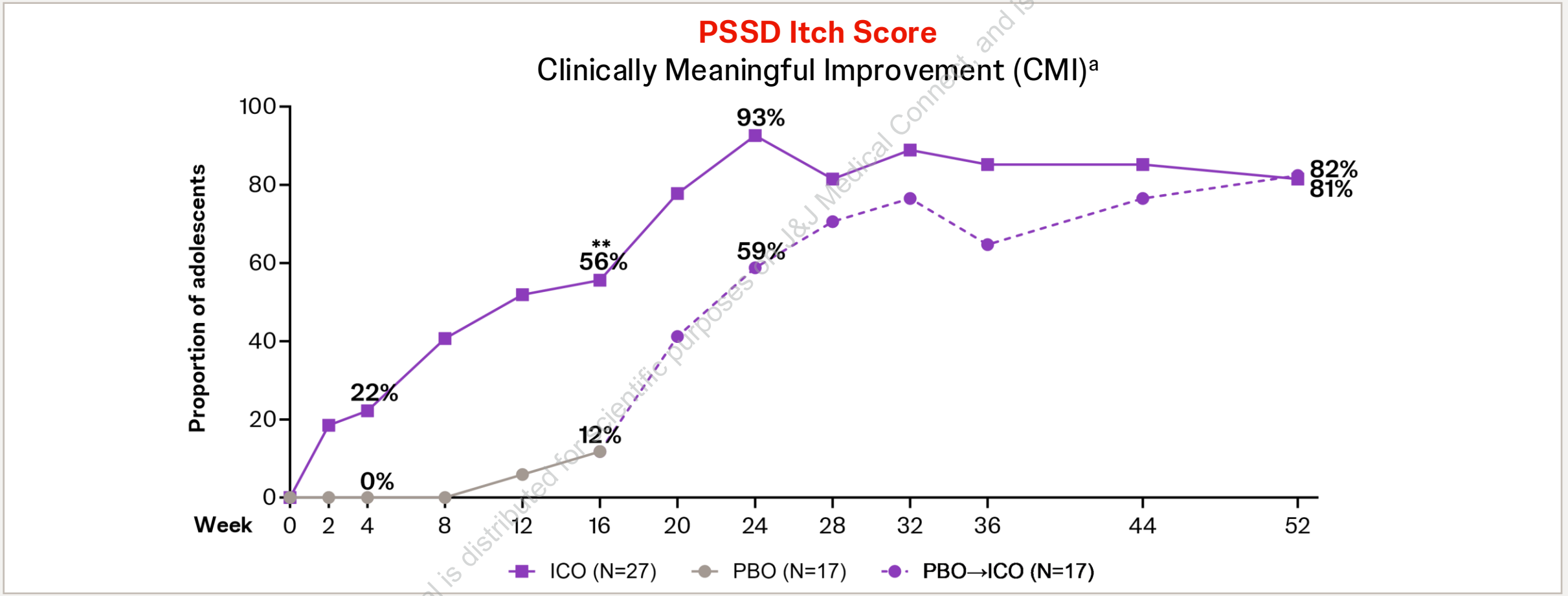
Most adolescent pts reported moderate-to-severe PsO manifestations impacted their HRQoL at baseline

Baseline Characteristics		ICO (N=44)	PBO (N=22)
Demographics			
	Age, yrs	15.0 (1.8)	15.0 (1.5)
	Female	52%	64%
	Race, Asian / Black / White	23% / 5% / 70%	23% / 0% / 77%
	BMI, kg/m^2	26.0 (7.1)	24.4 (7.9)
Disease Characteristics			
	PsO disease duration, yrs	4.9 (4.0)	5.8 (3.4)
	% of BSA with PsO	26.1 (15.6)	27.1 (14.0)
	IGA score Moderate (3) / Severe (4)	70% / 30%	82% / 18%
	PASI (0-72)	19.8 (8.2)	18.6 (4.0)
PROs			
	CDLQI score [0–30][a]	6.8 (5.6)	6.5 (4.6)
	CDLQI score >1	93%	86%
	PSSD symptom score [0–100][b]	35.4 (26.6)	29.9 (12.4)
	PSSD symptom score >0	100%	100%
	PSSD itch score ≥4	73%	85%
	PSSD sign score [0–100][b]	46.2 (26.0)	46.7 (17.8)
	PSSD sign score >0	100%	100%

Data shown are mean (SD), unless otherwise noted. [a]Adolescents with non-missing CDLQI scores at baseline: ICO N=43, PBO N=22. [b]Adolescents with non-missing PSSD symptom/sign scores at baseline: ICO N=37, PBO N=20. **BMI**=body mass index, **SD**=standard deviation.

Following early ICO vs PBO separation, >80% of ICO-randomized adolescents reported meaningful itch improvement during W24-52

- A comparable proportion of PBO-randomized pts who transitioned to ICO at W16 reported meaningful improvement in PsO itch at W52



Nominal **$p<0.01$ vs PBO[b]

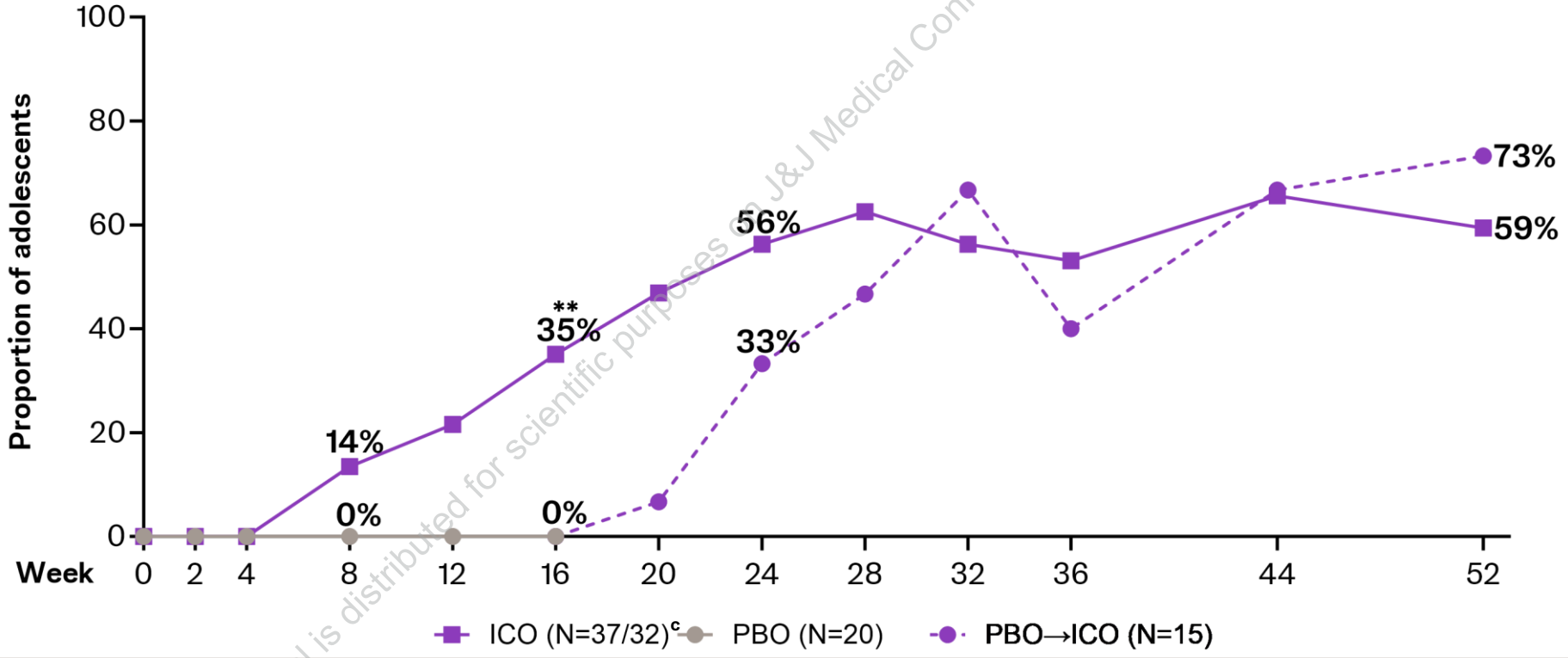
[a]Among adolescents with a baseline PSSD itch score ≥4. [b]Nominal p-value calculated adjusting for geographic region. **CMI**=clinically meaningful improvement (≥4-point improvement from baseline).

ICO-randomized adolescents reported PsO symptom resolution by W8, with >50% reporting no PsO symptoms from W24-52

- PBO-randomized pts demonstrated a similar pattern of PSSD symptom score 0 response after transitioning to ICO at W16
- ICO demonstrated greater PSSD symptom score improvement from baseline vs PBO at W16 (LS mean: 32.9 vs 5.8, respectively; difference: 27.1 [95% CI: 23.6, 30.5][a])

PSSD Symptom Score 0[b]

[Itch, Skin tightness, Burning, Stinging, Pain]



Nominal **$p<0.01$ vs PBO[d]

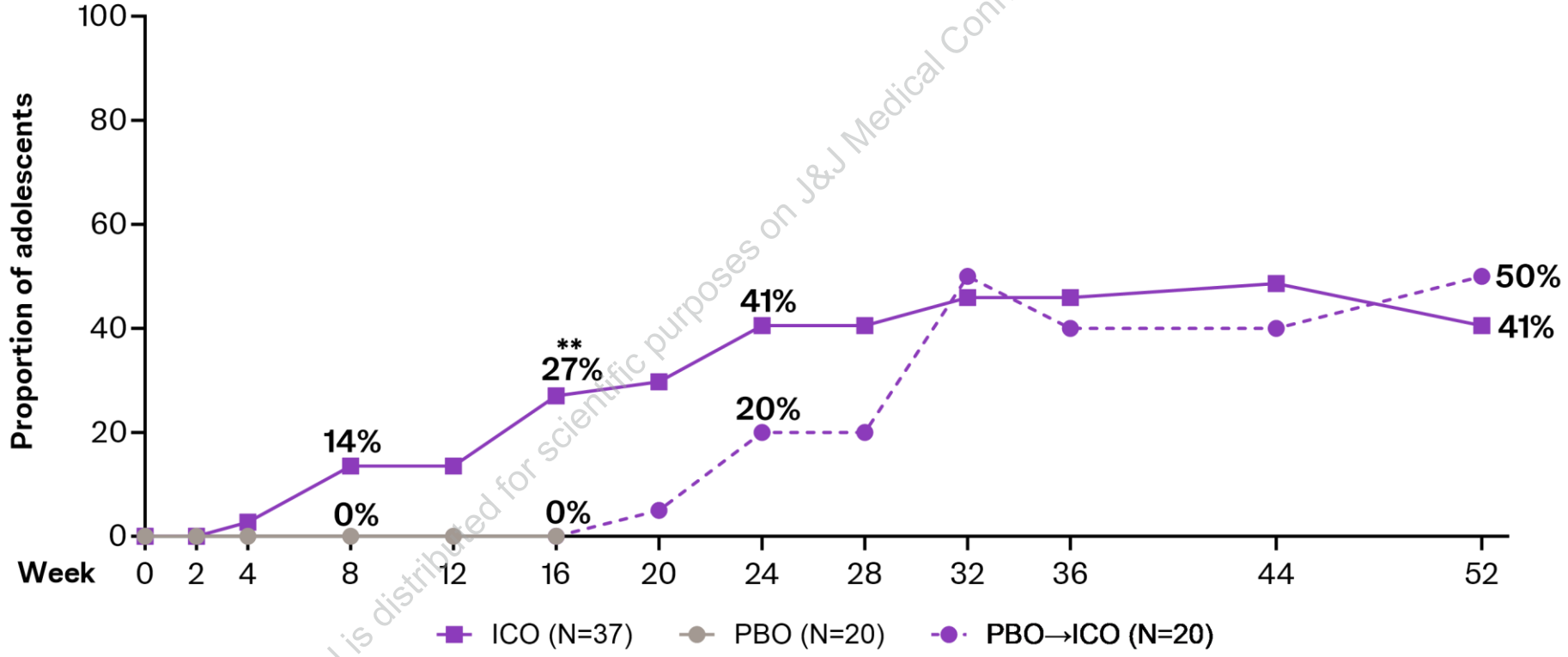
[a]LS mean and LS mean difference based on MMRM model with treatment group, visit, treatment group by visit interaction, geographic region, baseline PSSD symptom score, and baseline PSSD symptom score by visit interaction as covariates. [b]Among adolescents with a baseline PSSD Symptom score >0. [c]Data impacted by a translation error in the German 7-day recall version of the PSSD after W16 were excluded. [d]Nominal p-value calculated adjusting for geographic region. **CI**=confidence interval, **LS**=least squares, **MMRM**=mixed-effect model for repeated measures.

ICO-randomized adolescents reported PsO sign resolution by W8, with ~40% reporting no signs of PsO from W24-52

- PBO-randomized pts demonstrated consistent PSSD sign score 0 responses after transitioning to ICO at W16
- ICO demonstrated greater PSSD sign score improvement from baseline vs PBO at W16 (LS mean: 36.4 vs 7.2, respectively; difference: 29.2 [95% CI: 25.7, 32.7][a])

PSSD Sign Score 0[b]

[Dryness, Cracking, Scaling, Shedding/Flaking, Redness, Bleeding]

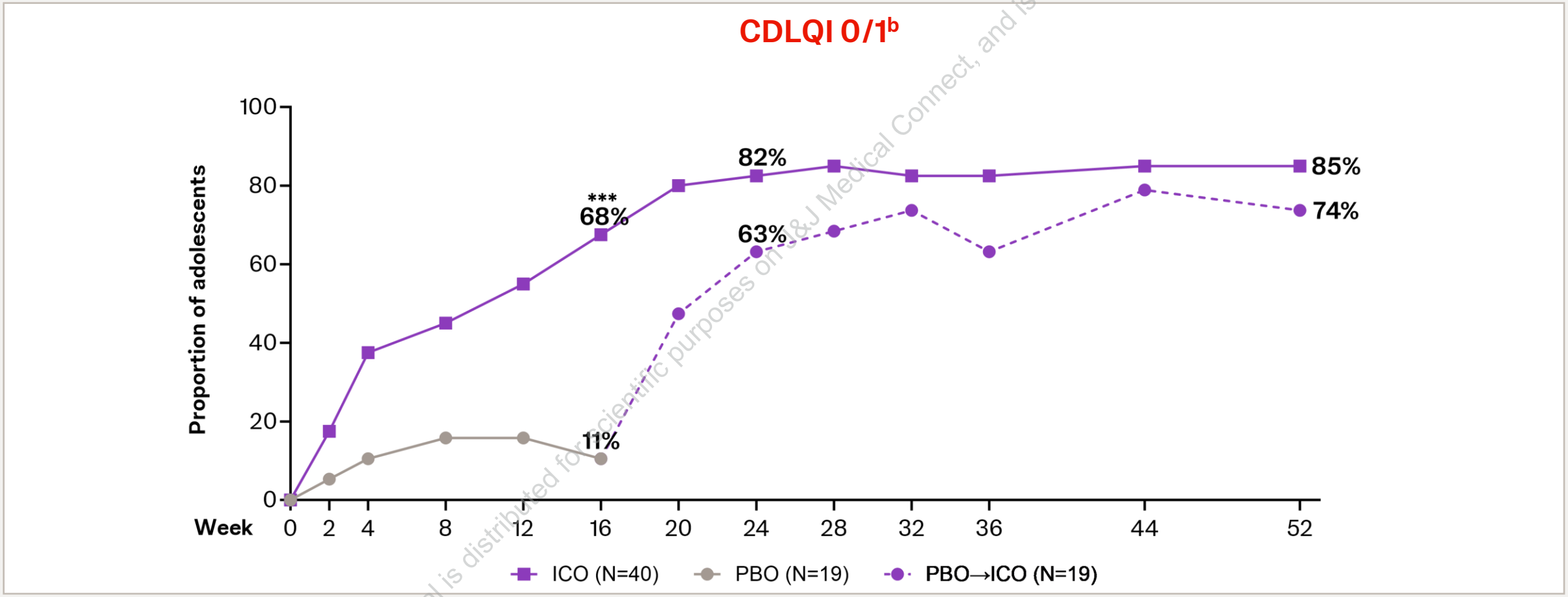


Nominal **p=0.01 vs PBO[c]

[a]LS mean and LS mean difference based on MMRM model with treatment group, visit, treatment group by visit interaction, geographic region, baseline PSSD sign score, and baseline PSSD sign score by visit interaction as covariates. [b]Among adolescents with a baseline PSSD Sign score >0. [c]Nominal p-value based on exact method.

ICO-randomized adolescents reported no impact of PsO on their HRQoL as early as W2; >80% reported no impact during W24-52

- PBO-randomized pts demonstrated a similar pattern of CDLQI 0/1 response after transitioning to ICO at W16
- ICO demonstrated greater CDLQI score improvement from baseline vs PBO at W16 (LS mean: 5.3 vs 2.5, respectively; difference: 2.8 [95% CI: 1.4, 4.1][a])



Nominal ***$p<0.001$ vs PBO[c]

[a]LS mean and LS mean difference based on MMRM model with treatment group, visit, treatment group by visit interaction, geographic region, baseline CDLQI score, and baseline CDLQI score by visit interaction as covariates. [b]Among adolescents with a baseline CDLQI score >1. [c]Nominal p-value based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region.

Key Takeaways

- **In the phase 3 ICONIC-LEAD study, adolescents with moderate-to-severe plaque PsO receiving ICO reported improvements/resolution of PsO symptoms, signs, and HRQoL at early timepoints**
- **Adolescent response rates increased through W24 and were durable through W52:**
  - ✓ **>80% reported clinically meaningful itch relief**
  - ✓ **>50%/~40% reported PsO symptom/sign resolution**
  - ✓ **>80% reported PsO no longer impacted HRQoL**
- Beyond clinical outcomes, assessing PROs is essential to holistic care of patients with plaque PsO, particularly during adolescence when patients may experience unique disease-related psychosocial challenges

For clinical and safety outcomes of the ICONIC-LEAD adolescent cohort through W52, please visit our companion AAD poster (ID: 73600)

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