

Durability of Icotrokinra (Targeted Oral Peptide) Effects in Adolescents With Moderate-to-Severe Plaque Psoriasis: One-Year Results From the ICONIC-LEAD Study



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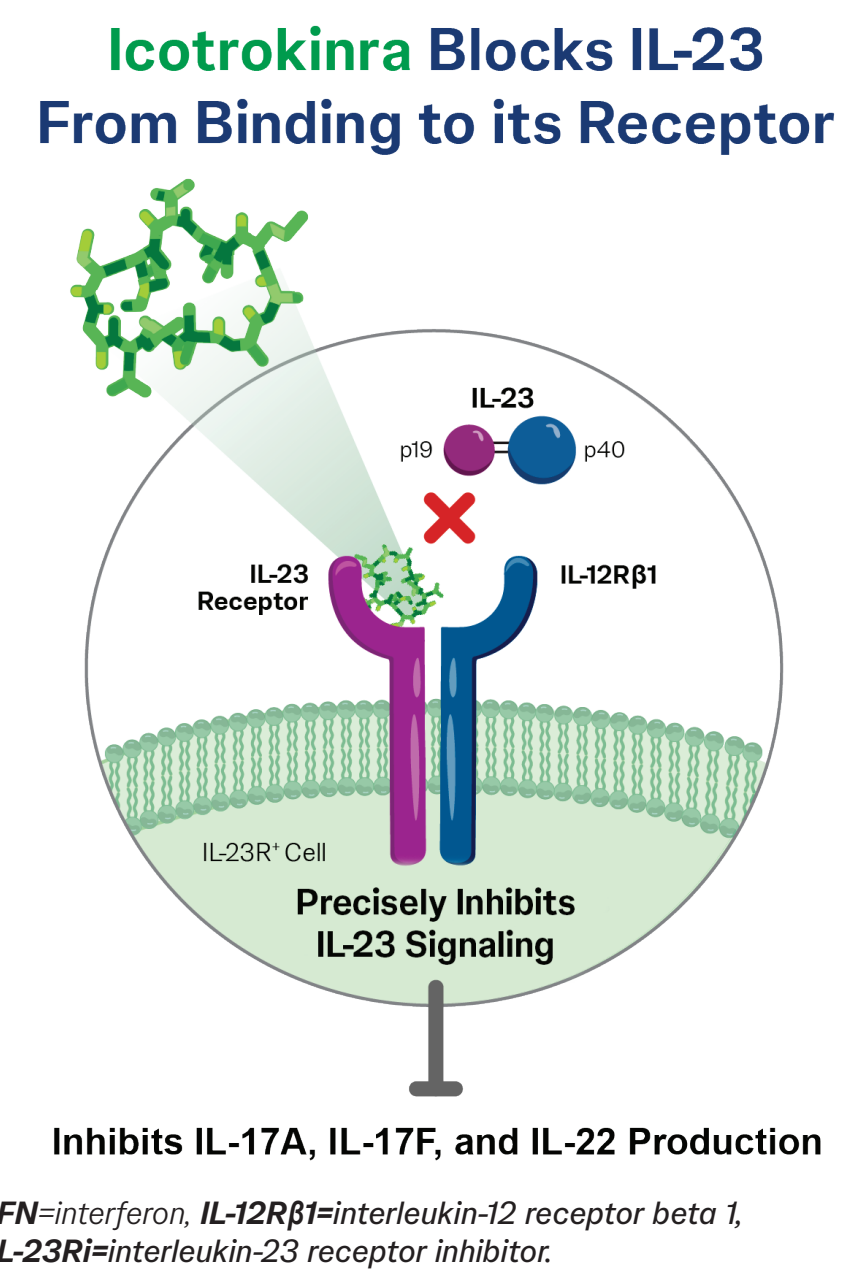
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Synopsis

Pediatric plaque psoriasis
 Approximately one-third of patients with plaque psoriasis (PsO) report onset before adulthood; however, few advanced treatment options are available¹

Icotrokinra
 Patients with moderate-to-severe plaque PsO are limited to injectable therapies to achieve high-level efficacy with a favorable safety profile

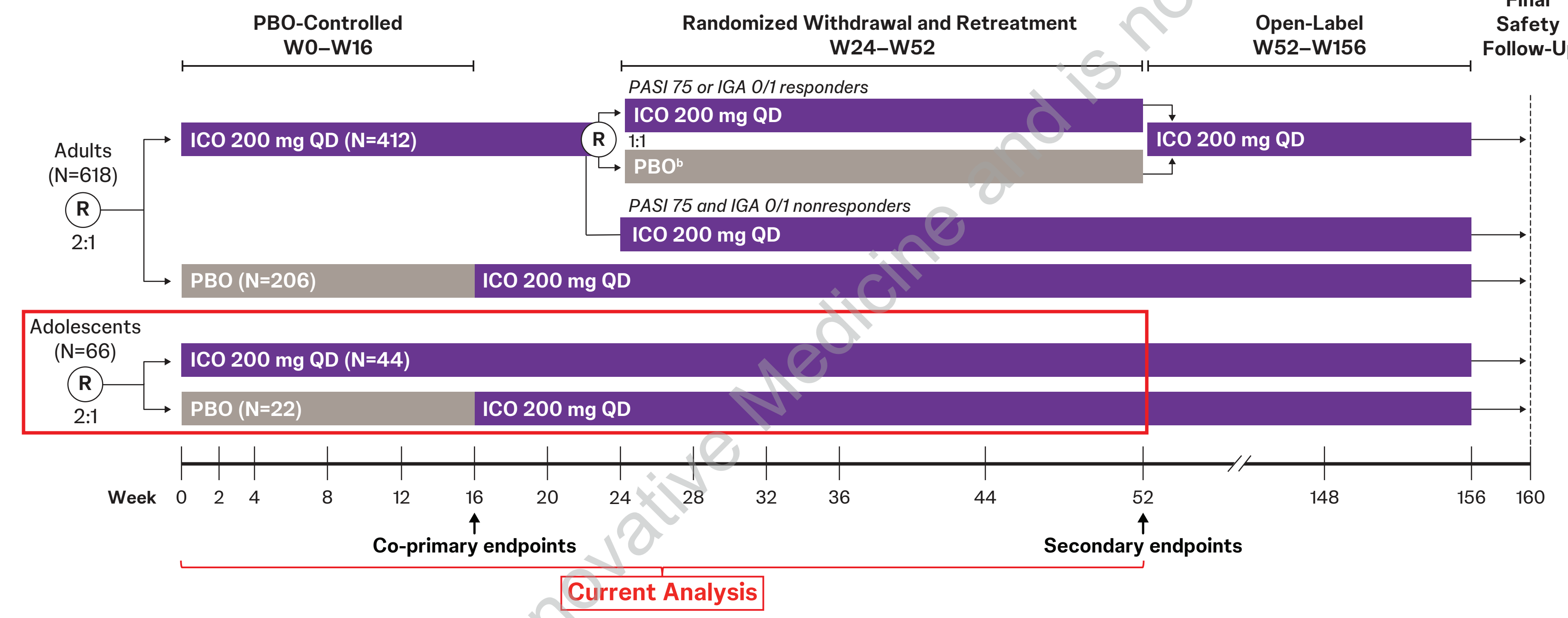
- Icotrokinra (ICO), the first and only targeted oral peptide:
- Precisely blocks the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling²
 - Demonstrated significantly higher rates of skin clearance vs placebo (PBO) at Week (W)16, with increasing response rates and no safety signal through W24 among all adult and adolescent participants (pts) with moderate-to-severe plaque PsO in the phase 3 ICONIC-LEAD study³
 - ICO showed higher skin clearance rates vs PBO at W16 in the adolescent subgroup, with increased response rates and a favorable safety profile through W24⁴



Methods

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 $\geq 10\%$, PASI score ≥ 12 , IGA score ≥ 3
 - Candidate for phototherapy or systemic treatment for plaque PsO
- Adolescent-specific inclusion criteria:**
- Body weight ≥ 40 kg⁵



Objective

Assess longer-term ICO effects and safety in ICONIC-LEAD adolescents through W52

Results

Through W52

- IGA 0/1 & ≥ 2 -grade improvement from baseline (IGA 0/1), PASI 90
- IGA 0, PASI 100
- AEs: Number (%) of adolescents and exposure-adjusted incidence rates (per 100 PY)

At W52

- IGA 0/1 among W24 IGA 0/1 responders
- PASI 90 among W24 PASI 90 responders

- Analyses**
- Nonresponder imputation: Pts who 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: Pts who discontinued study drug for other reasons
 - After accounting for the intercurrent events, pts with missing data were considered nonresponders

AE=adverse event; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; pts=participants; PY=participant-years; W=weeks.

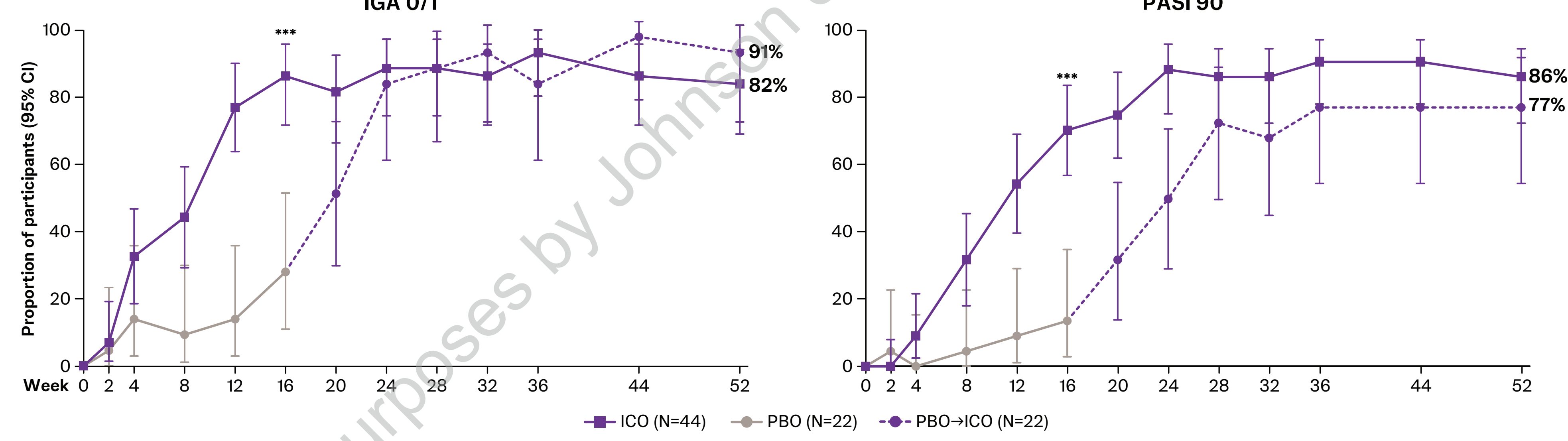
Adolescent characteristics were generally balanced between groups

Baseline Characteristics in Adolescents	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)	70%	82%
Severe (4)	30%	18%
PASI (0-72)	19.8 (8.2)	18.6 (4.0)
Prior PsO Treatments		
Phototherapy (PUVA or UVB)	23%	14%
Systemic therapy ^a	52%	50%
Biologic therapy ^b	14%	41%

Data shown are mean (SD), unless otherwise noted. ^aConventional nonbiologic systemic, novel nonbiologic systemic, L25-vitamin D3 and analogues, phototherapy, and biologics. ^bAdalimumab, abatacept, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, infliximab, ixekizumab, necotinzumab, risankizumab, secukinumab, ustekinumab, and ustekinumab. BMI=body mass index; BSA=body surface area; ICO=icotrokinra; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=placebo; PsO=psoriasis; PUVA=psoralen plus ultraviolet A; SD=standard deviation; UVB=ultraviolet B; Yrs=years.

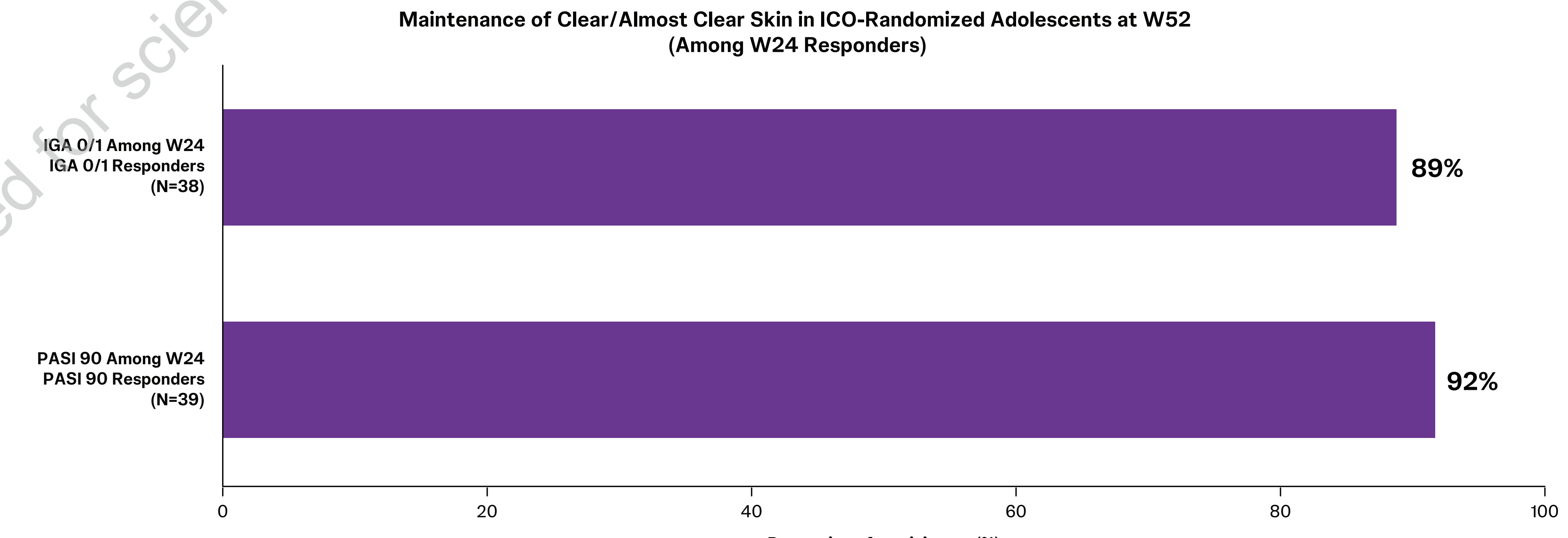
ICO demonstrated high rates of IGA 0/1 & PASI 90 by W24, with >80% of pts exhibiting clear/almost clear skin during W24-52

- After transitioning to ICO, PBO-randomized pts achieved IGA 0/1 and PASI 90 response rates at W52 that were consistent with those achieved by ICO-randomized pts



Nominal $*p < 0.05$, $**p < 0.01$, $***p < 0.001$ vs PBO
 P-values based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region. Known differences between IGA vs PASI score determinations likely account for differences in response rates. CI=confidence interval; ICO=icotrokinra; IGA 0/1=IGA score 0/1 & ≥ 2 -grade improvement from baseline; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=psoriasis; W=weeks.

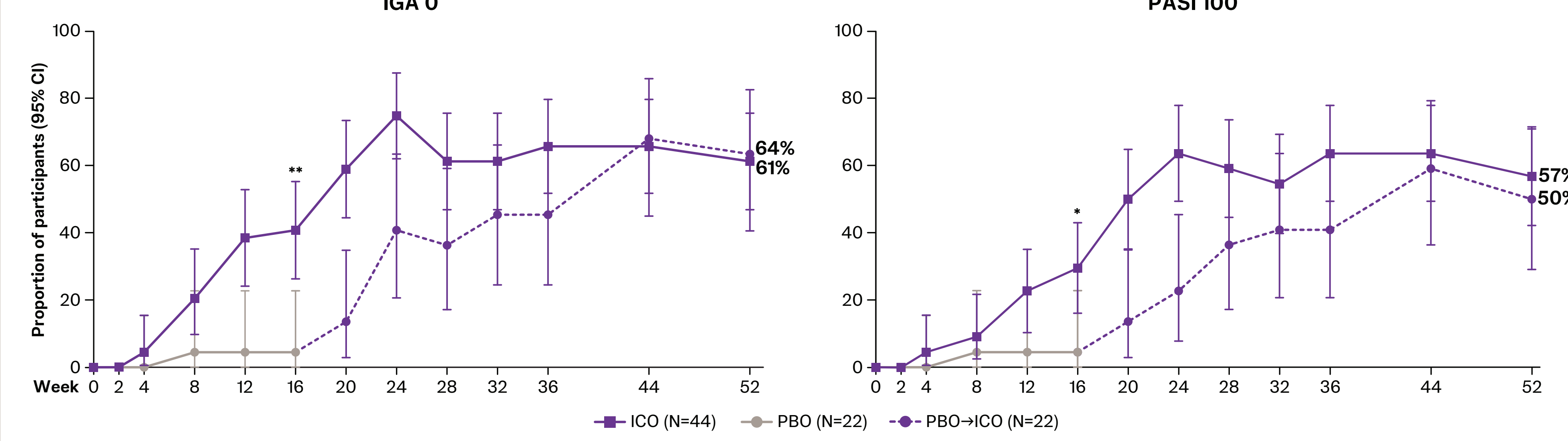
>90% of ICO-randomized adolescents achieving clear/almost clear skin at W24 maintained response at W52



Known differences between IGA vs PASI score determinations likely account for differences in response rates. ICO=icotrokinra; IGA 0/1=IGA score 0/1 & ≥ 2 -grade improvement from baseline; PASI=Psoriasis Area and Severity Index; W=weeks.

ICO demonstrated high rates of IGA 0 & PASI 100 by W24, with ~60% of pts exhibiting complete skin clearance during W24-52

- After transitioning to ICO, PBO-randomized pts achieved IGA 0 and PASI 100 response rates at W52 that were consistent with those achieved by ICO-randomized pts



Nominal $*p < 0.05$, $**p < 0.01$, $***p < 0.001$ vs PBO
 P-values based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region. Known differences between IGA vs PASI score determinations likely account for differences in response rates. CI=Confidence Interval; ICO=icotrokinra; PASI=Psoriasis Area and Severity Index; PBO=Placebo; W=weeks.

The ICO AE profile in adolescents was similar to PBO through W16, and consistent between W16 & W52

AEs Through W52: Adolescents ^a	PBO (N=22)	ICO (N=44)	Through W52 ICO Combined (N=66) ^a
Mean weeks / total PY of follow-up	16.2 / 6.8	16.2 / 13.7	46.3 / 58.6
Any AE	16 (73%)	22 (50%)	46 (70%)
Incidence/100 PY (95% CI) ^{b,c}	521 (266, 776)	238 (139, 338)	164 (117, 212)
Serious AE	0	2 (5%)	4 (6%)
Incidence/100 PY (95% CI) ^{b,d}	0 (0, 44)	15 (2, 54)	7 (2, 18)
AE leading to discontinuation	0	0	0
Incidence/100 PY (95% CI) ^{b,d}	0 (0, 44)	0 (0, 22)	0 (0, 5)
Infection	6 (27%)	14 (32%)	31 (47%)
Incidence/100 PY (95% CI) ^{b,c}	116 (23, 209)	130 (62, 198)	78 (50, 105)
Serious infection	0	0	0
Incidence/100 PY (95% CI) ^{b,d}	0 (0, 44)	0 (0, 22)	0 (0, 5)
Gastrointestinal AE	1 (5%)	2 (5%)	5 (8%)
Incidence/100 PY (95% CI) ^{b,d}	15 (<1, 85)	15 (2, 53)	9 (3, 21)
Malignancy	0	0	0
Incidence/100 PY (95% CI) ^{b,d}	0 (0, 44)	0 (0, 22)	0 (0, 5)

Data shown are n (%), unless otherwise noted. Safety analysis set included all randomized and treated pts. ^aIncludes pts receiving ICO through W52 and data after W16 for pts receiving PBO who transitioned to ICO. ^bIncidence/100 PY (number of pts with AE/total PY at risk) $\times 100$. ^cCIs were based on a Wald statistic using the normal assumption. ^dCIs were based on an exact method assuming that the observed number of events follows a Poisson distribution. AE=adverse event; CI=Confidence Interval; ICO=icotrokinra; PBO=Placebo; Pts=participants; PY=participant-years; W=weeks.

PRESENTED AT: PAMP360 Scottsdale, May 29-31, 2026; Scottsdale, AZ. REFERENCES: 1. Diotallevi F. *Int J Mol Sci*. 2022;23:1128. 2. Fourie AM. *Sci Rep*. 2024;14:17515. 3. Bissonnette R. *N Engl J Med*. 2025;393:1784-95. 4. Eichenfield L. World Congress of Pediatric Dermatology; April 8-11, 2025; Buenos Aires, Argentina. 5. Soung J. Presented at: EADV Congress; September 17, 2025; Paris, France. 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). Layout design and formatting for this encore presentation were provided by Amit Kavel (SIRIO Medical Writing Pvt. Ltd., India). This presentation was sponsored by Johnson & Johnson. DISCLOSURES: JS: Served as a speaker, consultant, advisory board member and/or investigator for AbbVie, Amgen, Arcutis, Aslan, Bristol Myers Squibb, Covax Biopharma, Dermavant, Eli Lilly, Johnson & Johnson, Kobi Labs, National Psoriasis Foundation, Novartis, Ortho Dermatologic, Orluka, Pfizer, Regeneron/Sanofi, and UCB. MGL: Employee of Mount Sinai; receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Celixo, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Orluka, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for AbbVie, Added Health, Akum, Almiral, Attribio Inc., Alumis, Amgen, Apogee, Arcutis, AstraZeneca, Atomics, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Cellion, CorEvitas, Dermavant Sciences, Dermasquared, Edesa Biotech, Eli Lilly, Evumune, Facilitation of International Dermatology Education, Fortis Biociences, Galderma, Genentech, Johnson & Johnson, Incyte, LEO Pharma, Mayne Pharmaceuticals, Meji Seika Pharma, Mindera, Mirum Pharmaceuticals, Moonlake, Orluka, Pfizer, Sanofi-Regeneron, Revolve, Seangene, Strata, Sun Pharma, Takeda, Trevi, and Verrica. AH: Employee of UTHealth McGovern Medical School-Houston; research grants paid to medical school by AbbVie, Arcutis, Dermavant, Eli Lilly, Johnson & Johnson, Pfizer, and Takeda; receives honoraria from Almiral, Apogee, Arcutis, Castle Biosciences, Dermavant, Incyte, Johnson & Johnson, Pfizer, and Verrica; served on DSMB; Galderma, Genentech, Johnson & Johnson, LEO Pharma, Novartis, Ortho Dermatologic, and Sanofi-Regeneron. AEP: Served as an investigator, advisor and/or speaker and/or received educational support from AbbVie, Almiral, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celixo, Eli Lilly, Galderma, Incyte, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. YS: Reported no disclosures. MM-K, JG, JJ, SL, and Y-WY: Employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson. LFE: Served as an investigator, advisor, and/or speaker for AbbVie, Abema, Acrotech, Almiral, Amgen, Apogee, Arcutis, Attovia, Bristol Myers Squibb, Castle Biosciences, Chiesi, CorEvitas, Dermavant, Eli Lilly, Formulation Bio, Forte, Galderma, Incyte, Johnson & Johnson, Kenvue, Kymera, Krystal, LEO Pharma, Novartis, OrthoDerm, Pfizer, Regeneron, Sanofi, Genzyme, Takeda, Target RWE, T-Rex, UCB, and Verrica. PREVIOUSLY PRESENTED AT: AAD Annual Meeting; March 27-31, 2026; Denver, CO, USA.