

Treatment of Plaque Psoriasis Involving High-Impact Sites With Icotrokinra, a Targeted Oral Peptide: Pooled Analyses of Four Phase 3 Placebo-Controlled Trials

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Background

Plaque psoriasis (PsO) on high-impact sites (e.g., scalp, genitals, hands/feet, nails) can be difficult to treat and negatively impact patients' quality of life¹

Patients with high-impact site PsO are candidates for systemic therapy, regardless of their body surface area (BSA) affected, per the International Psoriasis Council consensus statement²

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

- Precisely blocks the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling³
- Evaluated for the treatment of moderate-to-severe plaque PsO in the phase 3 ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2 studies, and for plaque PsO involving high-impact sites in the phase 3 ICONIC-TOTAL study; primary/co-primary endpoints of each study were met, with no safety signals identified^{4–6}
 - In adults and adolescents with high-impact site PsO involvement, ICO demonstrated:
- Significantly higher scalp and genital PsO clearance rates vs placebo (PBO) at Week (W)16 (ICONIC-TOTAL)⁶
- Higher rates of scalp, genital, and hand/foot PsO clearance and substantially improved nail PsO vs PBO at W16 (ICONIC-LEAD)⁷

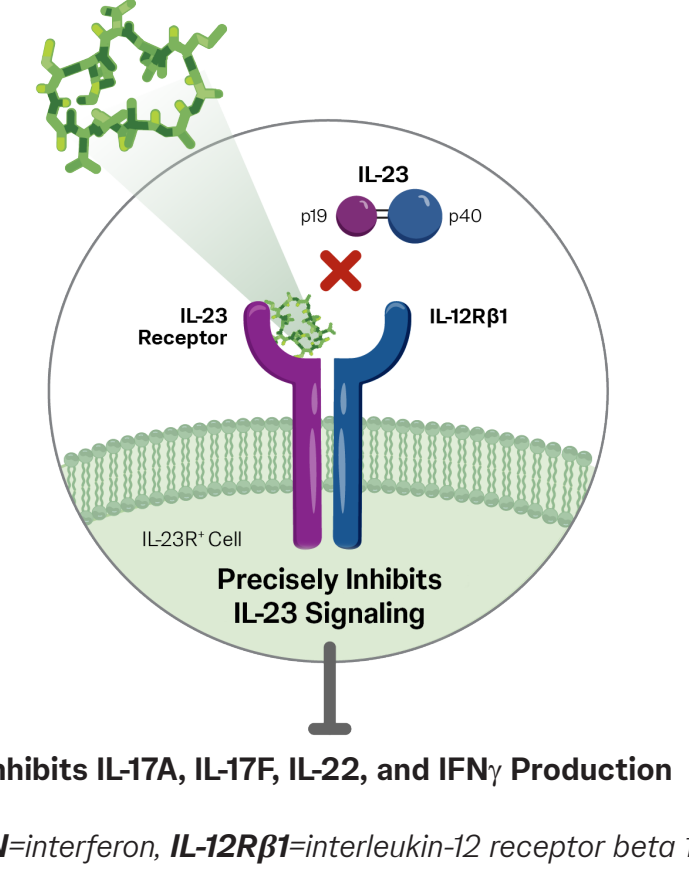
Objective

Evaluate ICO effects in pooled cohorts of participants (pts) with PsO involving high-impact sites, including the scalp, genitals, hands/feet, and/or nails, across 4 phase 3 studies

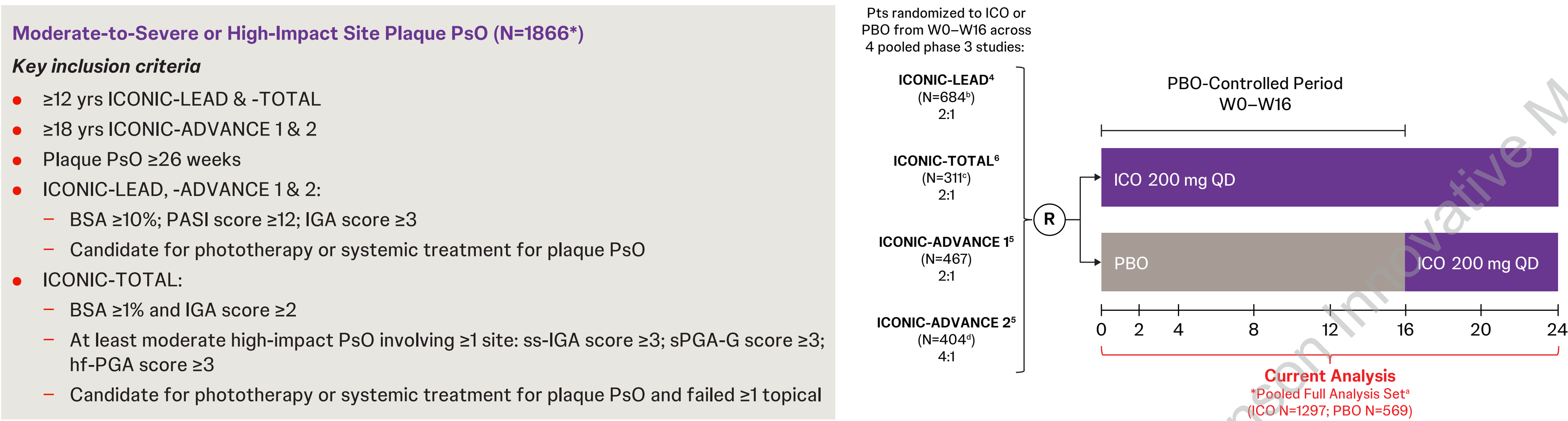


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Icotrokinra Blocks IL-23 From Binding to its Receptor

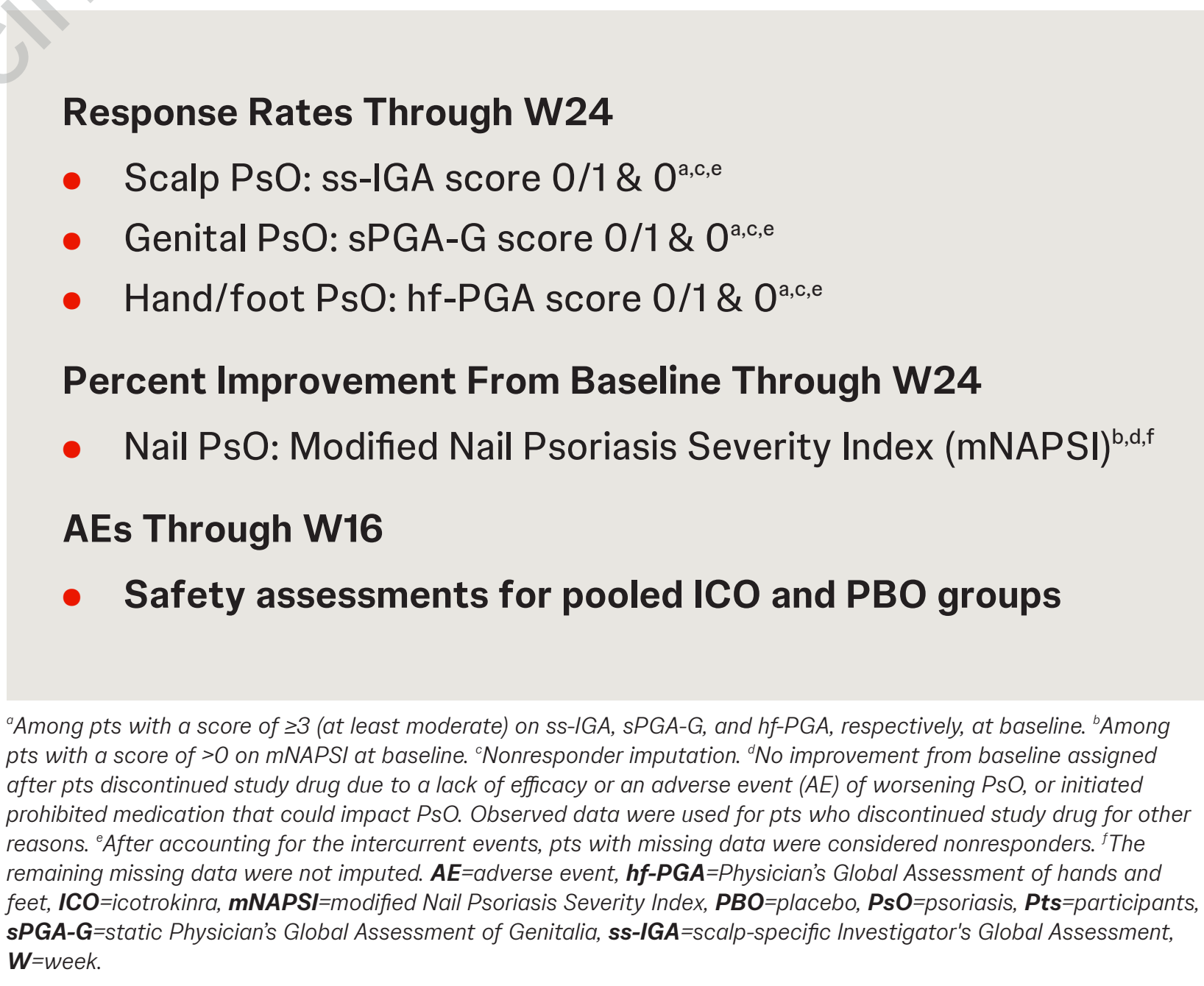


Pooled ICONIC-LEAD, -TOTAL, -ADVANCE 1 & 2: ICO vs PBO Through W16

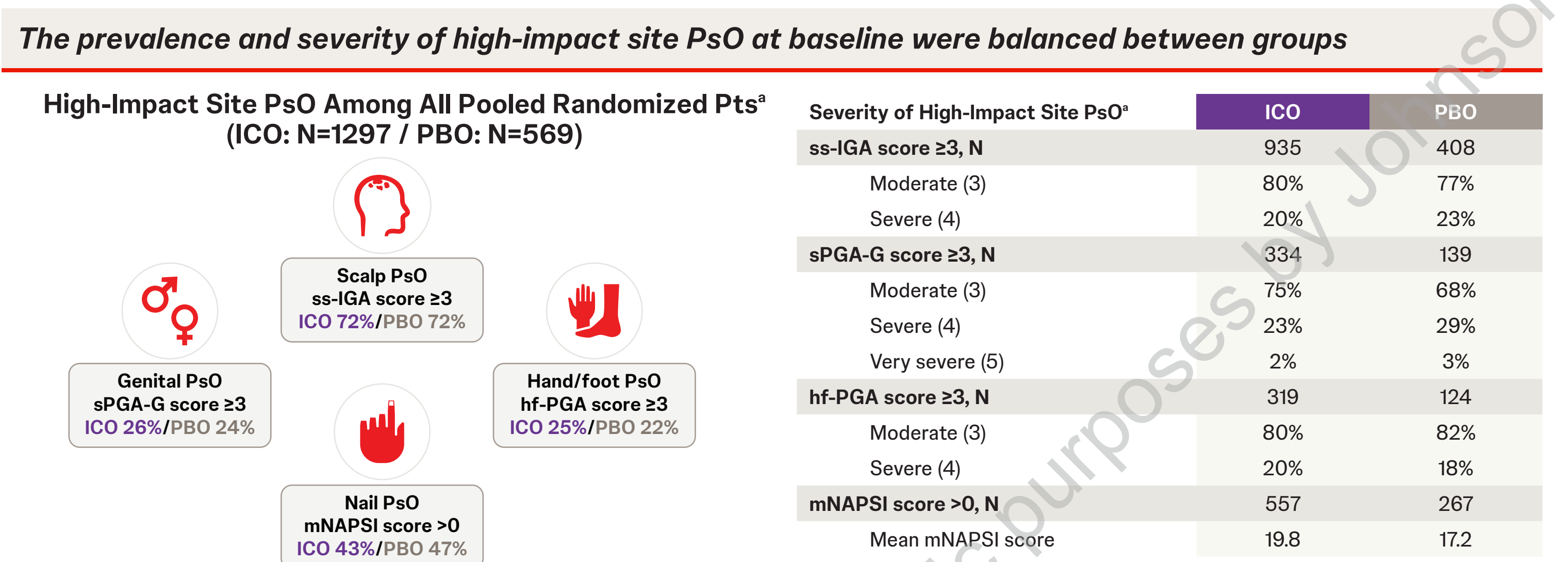


*Includes pooled ICO- and PBO-randomized pts from the phase 3 ICONIC-LEAD, ICONIC-TOTAL, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2 studies. ⁴Includes 66 adolescents. ⁵Includes 6 adolescents. ⁶ICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of which 401 were evaluable for efficacy. BSA=body surface area, hf-PGA=Physician's Global Assessment of hands and feet, ICO=icotrokinra, IGA=Investigator's Global Assessment, PASI=Psoriasis Area and Severity Index, PBO=placebo, PsO=psoriasis, Pts=participants, QD=once daily, R=randomization, sPGA-G=static Physician's Global Assessment of Genitalia, ss-IGA=scalp-specific IGA, W=week.

Outcomes & Analyses



Results



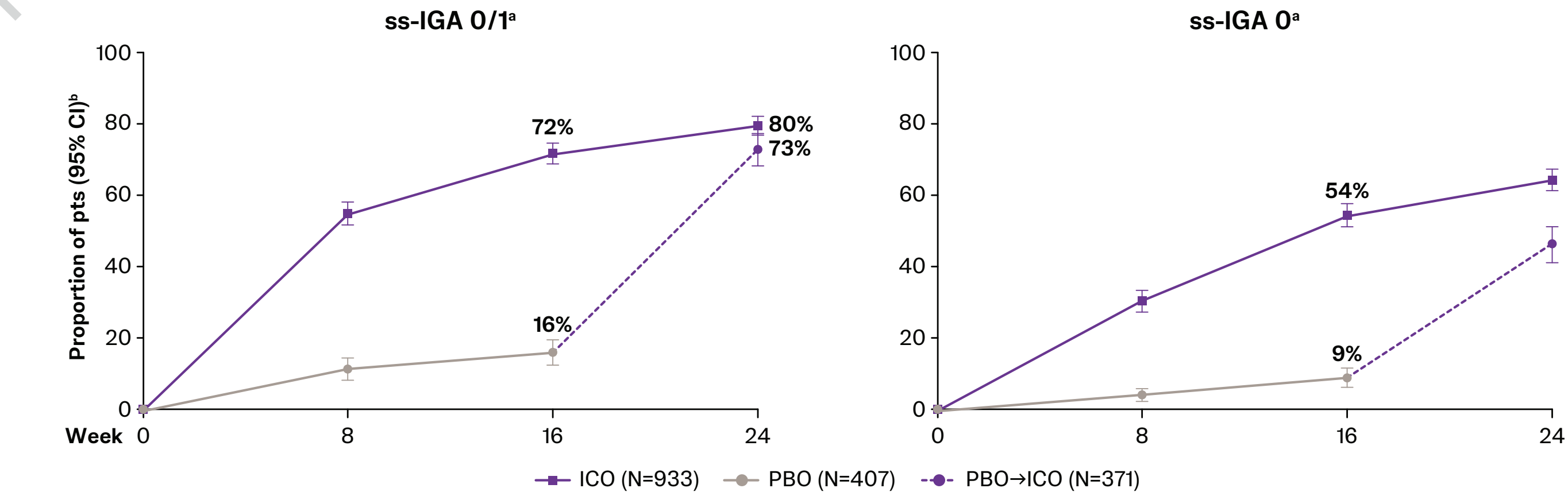
*PsO involving high-impact sites were not mutually exclusive. hf-PGA=Physician's Global Assessment of hands and feet, ICO=icotrokinra, mNAPSI=modified Nail Psoriasis Severity Index, PBO=placebo, PsO=psoriasis, Pts=participants, sPGA-G=static Physician's Global Assessment of Genitalia, ss-IGA=scalp-specific Investigator's Global Assessment.

Baseline characteristics were generally similar between treatment groups within each high-impact site PsO cohort						
Baseline Characteristics for Each Cohort of Pts With at Least Moderate High-Impact Site PsO	Scalp PsO: ss-IGA score ≥3		Genital PsO: sPGA-G score ≥3		Hand/foot PsO: hf-PGA score ≥3	
	ICO (N=935)	PBO (N=408)	ICO (N=334)	PBO (N=139)	ICO (N=319)	PBO (N=124)
Demographics						
Age, yrs	43.6 (14.9)	44.1 (14.6)	43.3 (13.8)	44.2 (15.0)	47.3 (14.2)	48.0 (13.6)
Female	318 (34%)	142 (35%)	103 (31%)	49 (35%)	100 (31%)	38 (31%)
Race, Asian / Black / White	21% / 2% / 75%	23% / 1% / 75%	19% / 1% / 77%	17% / 0% / 81%	22% / 3% / 72%	22% / 2% / 76%
BMI, kg/m ²	29.3 (6.5) ^a	29.3 (7.4) ^a	29.4 (6.6) ^a	29.6 (7.6) ^a	29.7 (6.6) ^a	30.2 (7.4) ^a
Disease Characteristics						
PsO duration, yrs	16.7 (12.8)	16.8 (12.7)	16.8 (13.0)	16.2 (11.3)	16.7 (12.1)	16.4 (13.1)
% of BSA with PsO	23.9 (14.9)	23.4 (15.0)	24.8 (14.7)	24.1 (15.2)	27.4 (17.7)	27.3 (17.5)
IGA score						
Moderate (3) / Severe (4)	74% / 25%	73% / 26%	73% / 26%	71% / 28%	69% / 31%	70% / 30%
PASI (0–72)	19.3 (7.7)	19.1 (7.9)	19.6 (7.6)	19.8 (7.9)	20.7 (8.9)	20.4 (9.4)
Prior PsO Treatments						
Phototherapy (PUVA and UVB)	34%	31%	35%	27%	33%	28%
Systemic therapy ^a	73%	71%	72%	75%	67%	68%
Biologic therapy ^a	30%	33%	31%	33%	26%	40%

Data shown are mean (SD), unless otherwise noted. ^aICO N=930/PBO N=405. ^bICO N=333/PBO N=138. ^cICO N=318/PBO N=123. ^dConventional nonbiologic systemics, novel nonbiologic systemics, 1,25-vitamin D3 and analogues, phototherapy, and biologics: ^eAdalimumab, alefacept, bimekizumab, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, infliximab, ixekizumab, natalizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab. BSA=body surface area, hf-PGA=Physician's Global Assessment of hands and feet, ICO=icotrokinra, IGA=Investigator's Global Assessment, mNAPSI=modified Nail Psoriasis Severity Index, PASI=Psoriasis Area and Severity Index, PBO=placebo, PsO=psoriasis, Pts=participants, PUVA=psoralen plus ultraviolet A, QD=once daily, R=randomization, SD=standard deviation, sPGA-G=static Physician's Global Assessment of Genitalia, ss-IGA=scalp-specific Investigator's Global Assessment, UVB=ultraviolet B, W=week.

Scalp PsO: ICO demonstrated high rates of clearance through W24

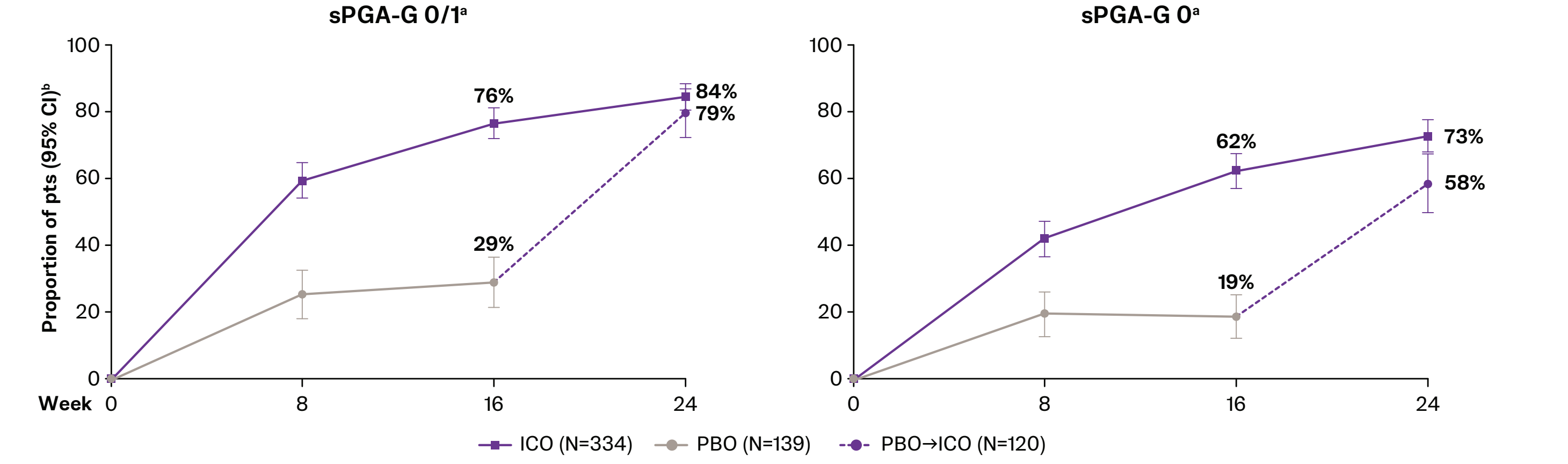
- After transitioning to ICO at W16, PBO-randomized pts demonstrated consistent patterns of response through W24



ICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of which 401 were evaluable for efficacy. ^aAmong pts with a baseline ss-IGA score ≥3. ^bNonresponder imputation. Confidence intervals based on the normal approximation confidence limits. CI=confidence interval, ICO=icotrokinra, PBO=placebo, PsO=psoriasis, Pts=participants, ss-IGA=scalp-specific Investigator's Global Assessment, W=week.

Genital PsO: ICO demonstrated high rates of clearance through W24

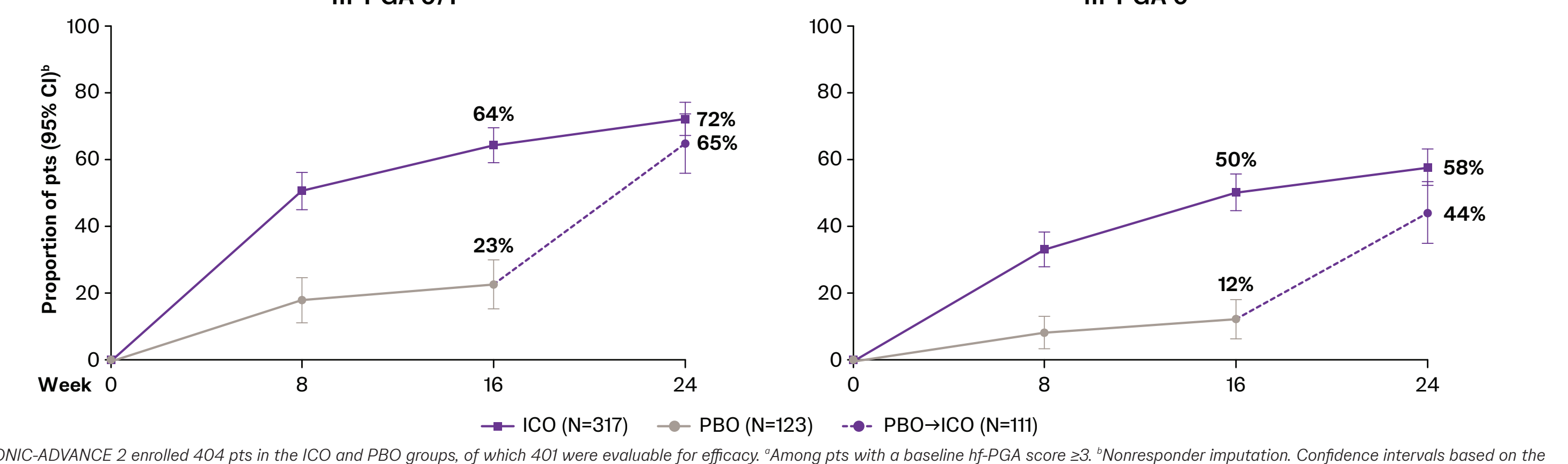
- After transitioning to ICO at W16, PBO-randomized pts demonstrated consistent patterns of response through W24



ICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of which 401 were evaluable for efficacy. ^aAmong pts with a baseline sPGA-G score ≥3. ^bNonresponder imputation. Confidence intervals based on the normal approximation confidence limits. CI=confidence interval, ICO=icotrokinra, PBO=placebo, PsO=psoriasis, Pts=participants, sPGA-G=static Physician's Global Assessment of Genitalia, W=week.

Hand/foot PsO: ICO demonstrated high rates of clearance through W24

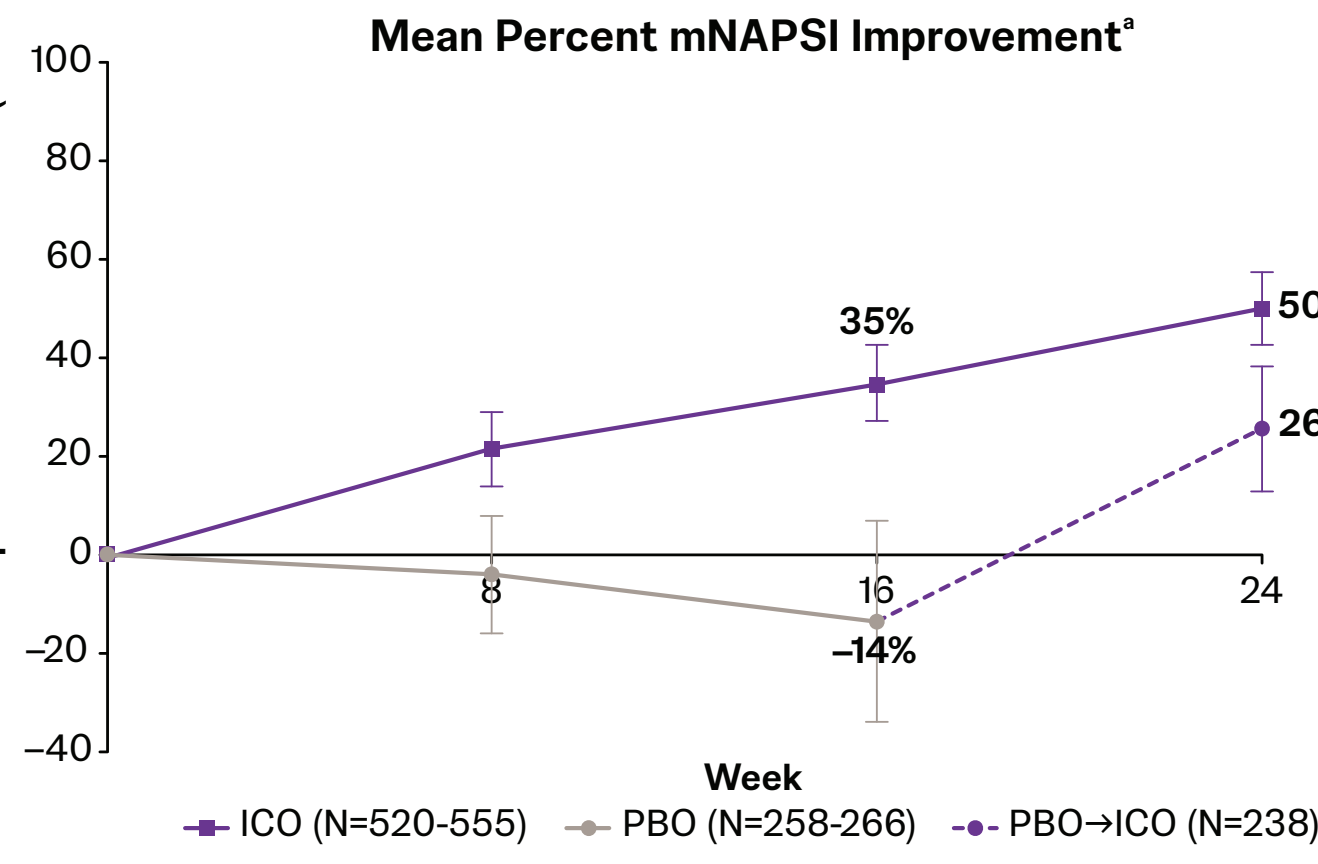
- After transitioning to ICO at W16, PBO-randomized pts demonstrated consistent patterns of response through W24



ICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of which 401 were evaluable for efficacy. ^aAmong pts with a baseline hf-PGA score ≥3. ^bNonresponder imputation. Confidence intervals based on the normal approximation confidence limits. CI=confidence interval, hf-PGA=Physician's Global Assessment of hands and feet, ICO=icotrokinra, PBO=placebo, PsO=psoriasis, Pts=participants, W=week.

Nail PsO: ICO-randomized pts exhibited increasing mean percent mNAPSI improvement through W24

- PBO-randomized pts demonstrated substantial improvement in nail PsO within 8 weeks of starting ICO



ICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of which 401 were evaluable for efficacy. ^aAmong pts with a baseline mNAPSI score >0. CI=confidence interval, ICO=icotrokinra, mNAPSI=modified Nail Psoriasis Severity Index, PBO=placebo, PsO=psoriasis, Pts=participants, W=week.

The ICO AE profile was similar to PBO through W16 in pts with at least moderate high-impact site PsO

Pooled Safety in Pts With at Least Moderate High-Impact Site PsO Through W16 ^a		ICO (N=1068)	PBO (N=460)
Mean weeks of follow-up		15.9	15.6
Any AE		516 (48%)	233 (51%)
Serious AE		15 (1%)	9 (2%)
AE leading to discontinuation		21 (2%)	15 (3%)
Infection		252 (24%)	114 (25%)
Serious infection		0%	1 (<1%)
Malignancy		5 (<1%)	1 (<1%)

^aSafety analysis set includes all randomized and treated pts. ^bPooled phase 3 cohort with at least moderate PsO (i.e., ss-IGA, sPGA-G, and/or hf-PGA score ≥3) at ≥1 high-impact site. AE=adverse event, hf-PGA=Physician's Global Assessment of hands and feet, ICO=icotrokinra, PBO=placebo, PsO=psoriasis, Pts=participants, SAE=serious adverse event, sPGA-G=static Physician's Global Assessment of Genitalia, ss-IGA=scalp-specific Investigator's Global Assessment, W=week.