

Durability and Safety of the Targeted Oral Peptide Icotrokinra for High-Impact Site Psoriasis: 2-Year ICONIC-TOTAL Findings

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Background

Plaque psoriasis (PsO) is a chronic inflammatory disease that may involve high-impact sites, such as the scalp, genitals, hands/feet, and nails

- High-impact site plaque PsO can be difficult to treat and has a significant impact on health-related quality of life¹

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

- Precisely targets the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling²
- Demonstrated robust efficacy and a favorable safety profile versus placebo (PBO) through Week (W) 16,^{3,4} with consistent results through 1 year⁵⁻⁸

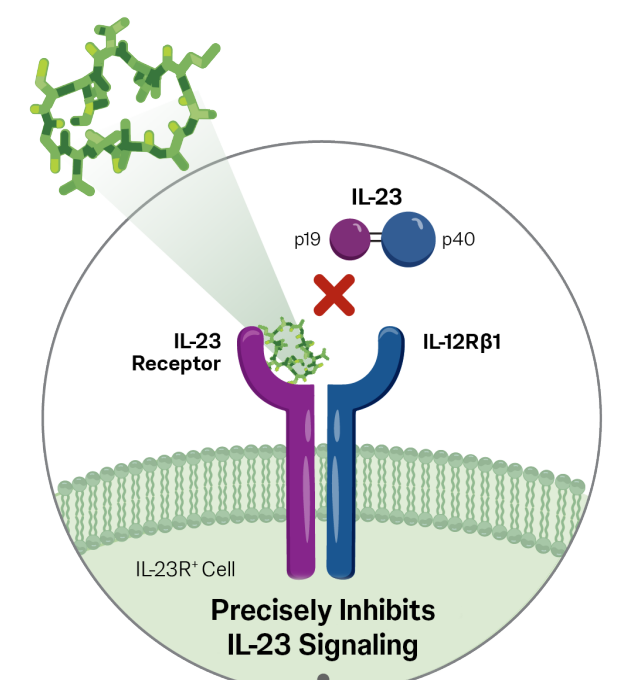
ICONIC-TOTAL (NCT06095102)

- Ongoing, phase 3, multicenter, randomized, double-blind, PBO-controlled trial in adult and adolescent participants (pts; ≥12 years of age)
- Long-term data on durability of response and safety will help inform treatment decisions

Objectives

Report clinical response rates and safety of ICO through 2 years in ICONIC-TOTAL study pts with high-impact site plaque PsO

Icotrokinra Blocks IL-23 From Binding to its Receptor



Inhibits IL-17A, IL-17F, and IL-22 Production
IL-12Rβ1=interleukin-12 receptor beta 1, IL-23R=interleukin-23 receptor

ICONIC-TOTAL Study Design

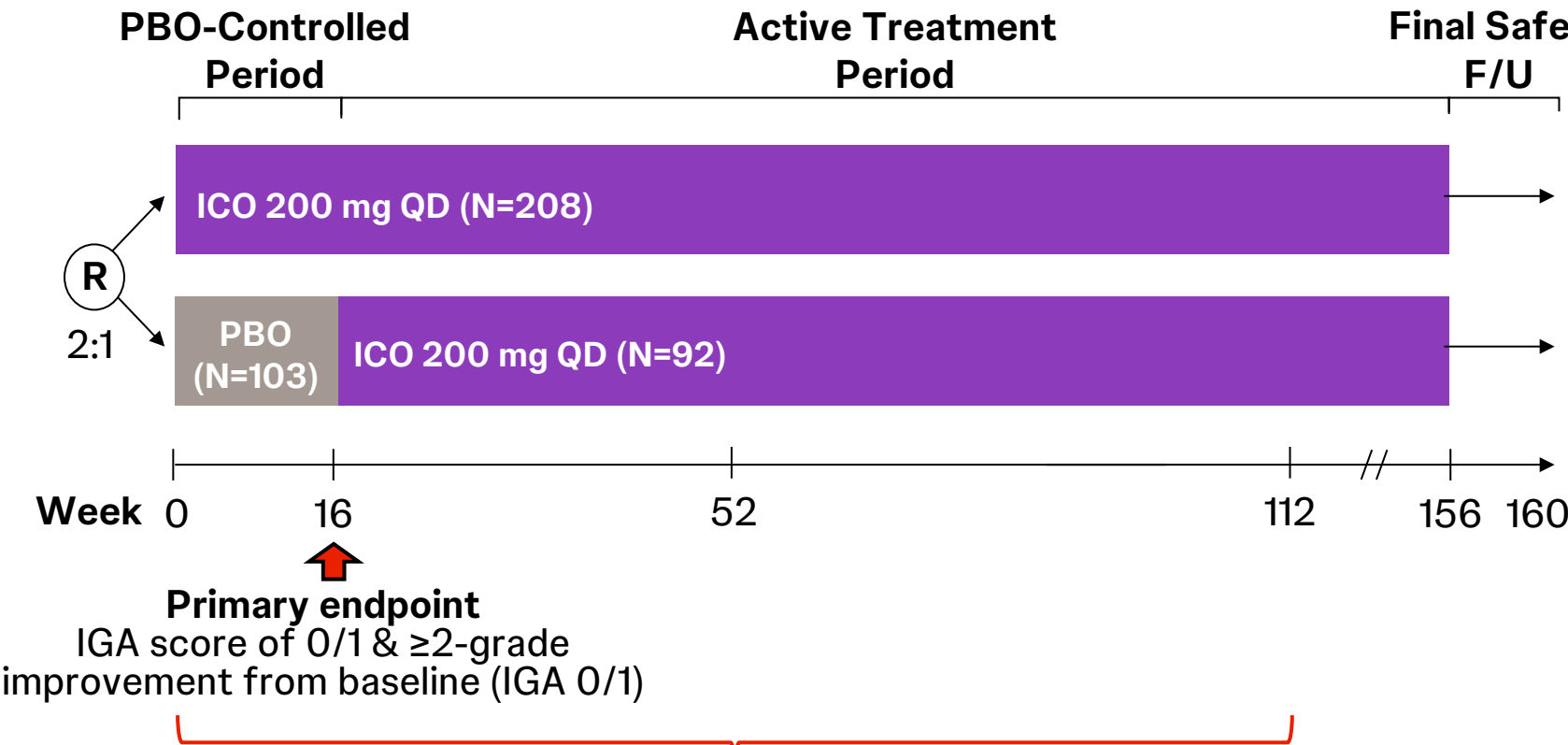
Adults and adolescents with plaque PsO involving high-impact sites (N=311)

Key inclusion criteria

- ≥12 years of age
- Plaque PsO for ≥26 weeks
- BSA ≥1% and IGA score ≥2
- At least moderate (score ≥3) high-impact PsO involving ≥1 site:

- Scalp: ss-IGA
- Genital: sPGA-G
- Hand/foot: hf-PGA

- Candidate for phototherapy or systemic treatment for plaque PsO and failed ≥1 topical treatment



Current analysis

Outcomes & Analyses

- Overall PsO: IGA 0/1 and 0^{a,c,e}
- Scalp PsO: ss-IGA 0/1 and 0^{a,c,e}
- Genital PsO: sPGA-G 0/1 and 0^{a,c,e}
- Hand/foot PsO: hf-PGA 0/1 and 0^{a,c,e}
- Nail PsO: mNAPSI % improvement^{b,d,f}
- AE: Number (%) of pts and exposure-adjusted incidence rates (/100 PY)

^aThrough W52 nonresponder imputation ^b0% improvement from baseline assigned after pts 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 were used for pts who discontinued study agent for other reasons. ^cAfter W52 nonresponder imputation ^d0% improvement from baseline assigned after pts who discontinued study drug due to a lack of efficacy or an AE of worsening PsO. ^eAfter accounting for these intercurrent events: through W52 pts with missing data were considered nonresponders and, after W52, other missing data were imputed using multiple imputation. ^fThe remaining missing data were not imputed.

Results

Baseline demographics and PsO characteristics were generally balanced between groups

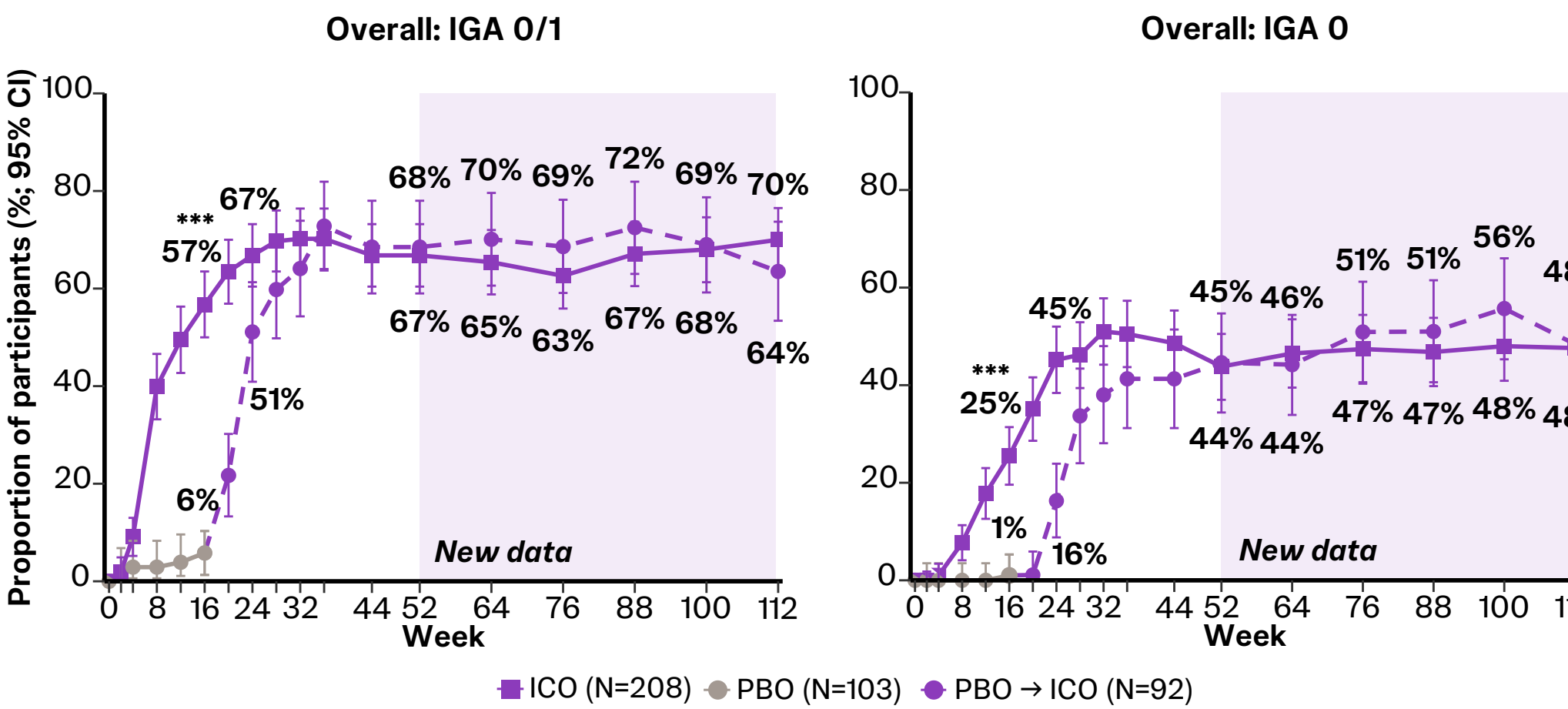
- Among pts with hand/foot PsO at baseline, greater proportions of pts in the ICO (35%) group had severe hand/foot PsO (hf-PGA=4) compared with PBO (17%)

Baseline Characteristics	ICO (N=208)	PBO (N=103)
Demographics		
Age, yrs	45.3 (14.6)	43.5 (13.8)
Female	34%	39%
Race, Asian/Black/White	20%/11%/ 77%	19%/0%/80%
BMI, kg/m ²	29.0 (6.6) ^a	29.4 (8.1) ^b
Disease Characteristics		
PsO disease duration, yrs	16.8 (13.3)	15.2 (10.5)
% BSA with PsO	16.6 (13.5)	14.8 (11.7)
IGA score		
Moderate (3)	74%	71%
Severe (4)	22%	21%
PASI (0-72)	14.6 (7.6)	14.0 (7.0)
Prior PsO treatments		
Phototherapy ^a	43%	31%
Systemic therapy ^d	73%	73%
Biologic therapy ^a	34%	31%

Data shown are mean (SD) unless otherwise noted. PsO involving high-impact sites was not mutually exclusive. ^aN=203. ^bN=101. ^cPUVA and UVB. ^dConventional nonbiologic systemics, novel nonbiologic systemics, 125-vitamin D3 and analogues, phototherapy, and biologics. ^aAdalimumab, defcixcept, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, infliximab, ixekizumab, natalizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab. BMI=body mass index, PASI=Psoriasis Area and Severity Index, PUVA=psoralen plus ultraviolet A, SD=standard deviation, UVB=ultraviolet B, yrs=years.

Overall PsO: IGA 0/1 response rates increased through W24 (67%) and remained stable through W112 (70%) among ICO-randomized pts

- IGA 0 response rates also increased through W24 (45%) and were consistent through W112 (48%) among ICO-randomized pts

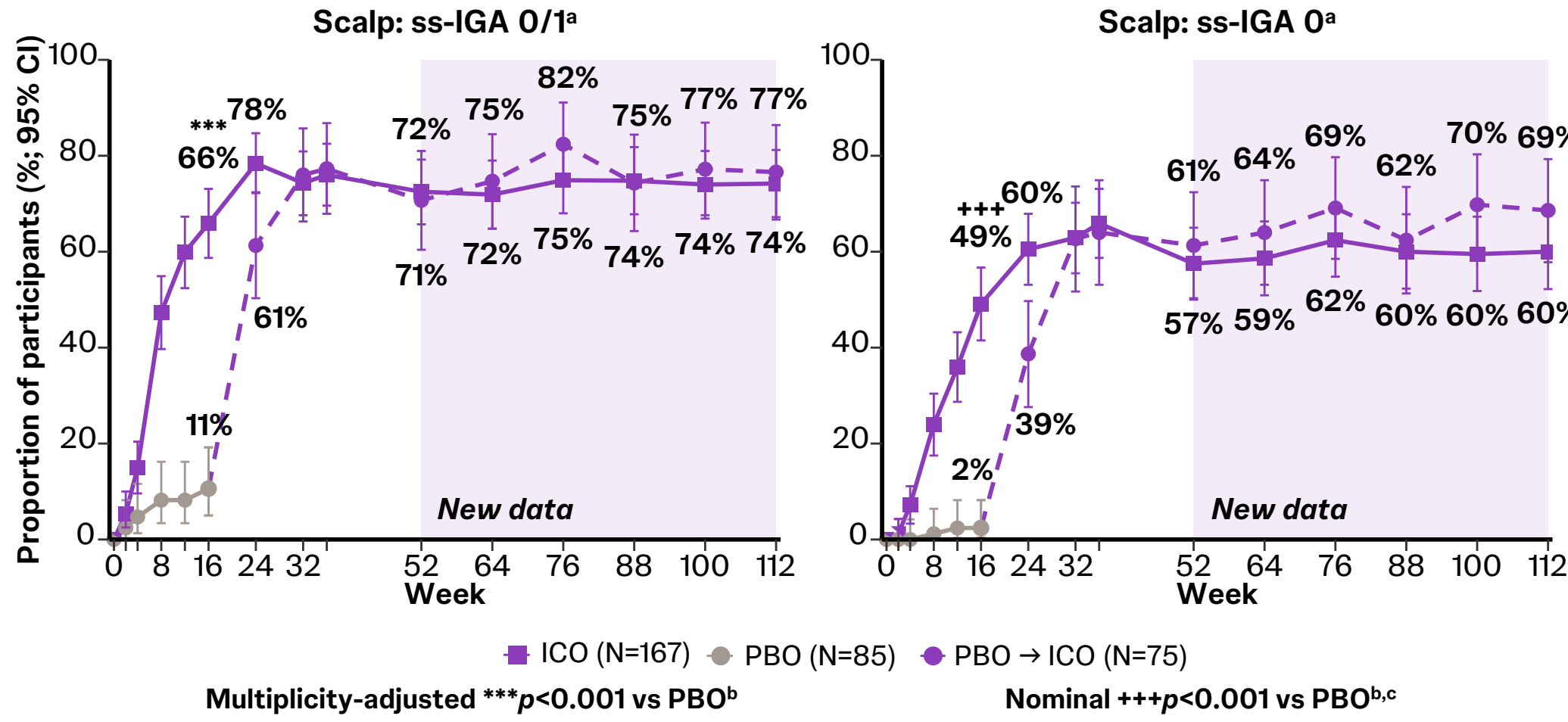


Multiplicity-adjusted ***p<0.001 vs PBO^a

^ap-values based on Cochran-Mantel-Haenszel chi-square test stratified by high-impact site involvement and BSA category.

Scalp PsO: ss-IGA 0/1 response rates increased through W24 (78%) and remained stable through W112 (74%) among ICO-randomized pts

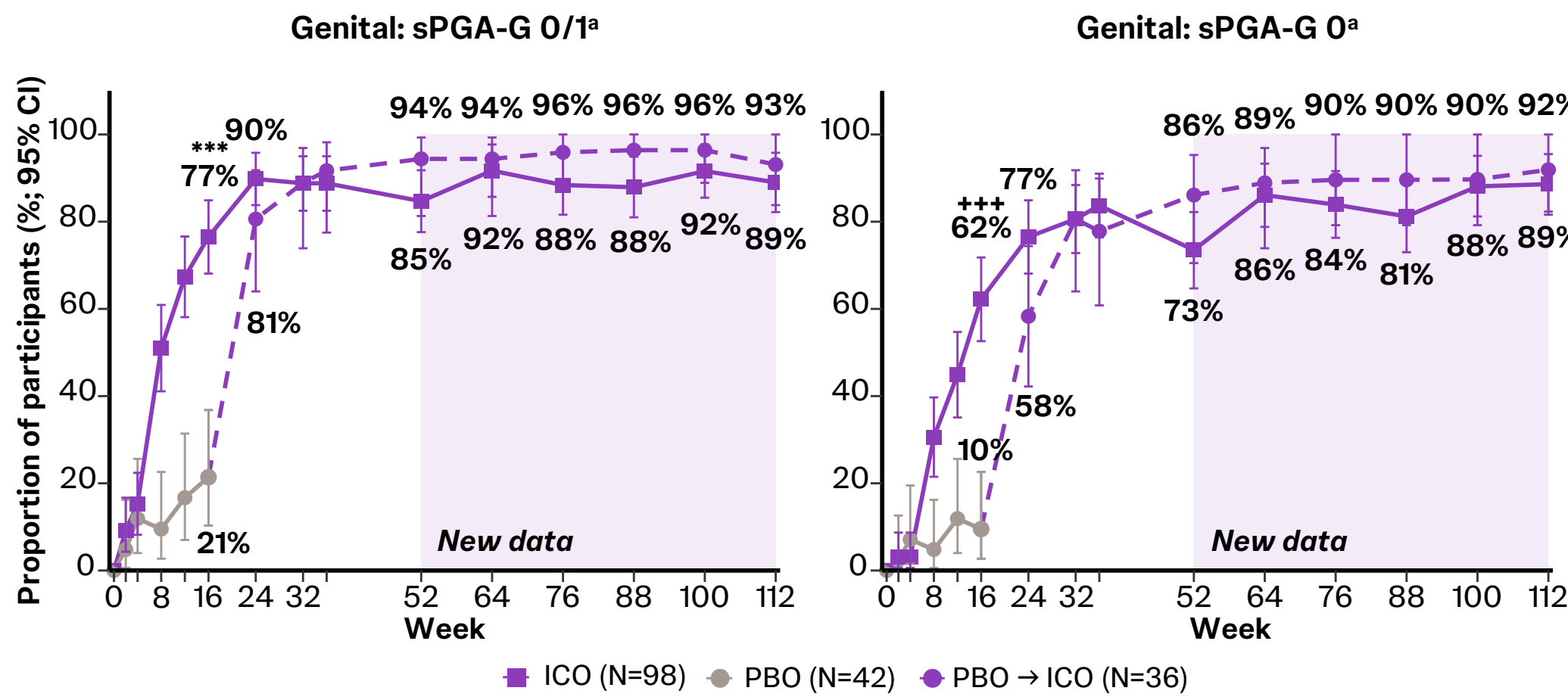
- ss-IGA 0 response rates also increased through W24 (60%) and were consistent through W112 (60%) among ICO-randomized pts



^aAmong pts with a baseline ss-IGA score ≥3. ^bp-values based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region and BSA category. ^cEndpoint was not included in the hierarchical testing strategy.

Genital PsO: sPGA-G 0/1 response rates increased through W24 (90%) and remained stable through W112 (89%) among ICO-randomized pts

- 89% of ICO-randomized pts achieved completely clear genital PsO (sPGA-G 0) at W112

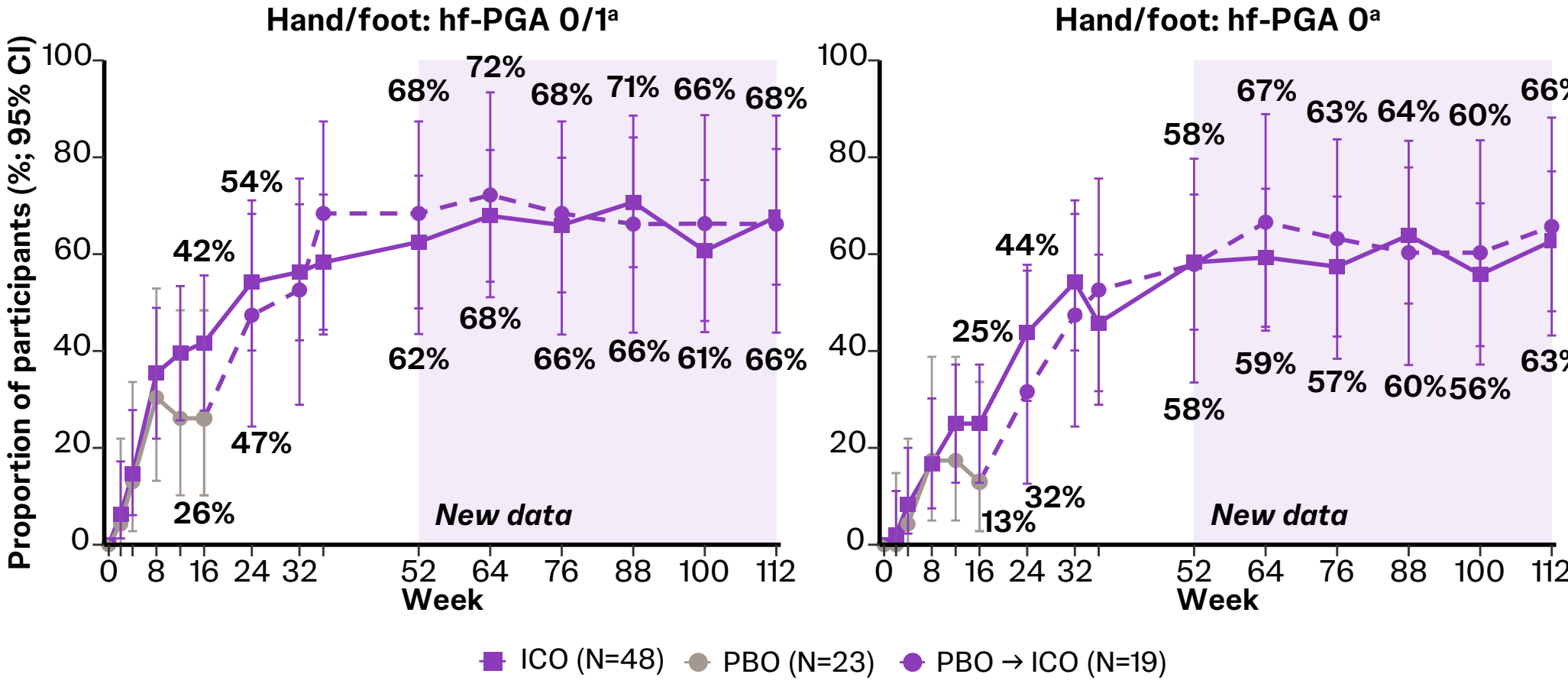


Multiplicity-adjusted ***p<0.001 vs PBO^a

^aAmong pts with a baseline sPGA-G score ≥3. ^bp-values based on Cochran-Mantel-Haenszel chi-square test stratified BSA category. ^cEndpoint was not included in the hierarchical testing strategy.

Hand/foot PsO: hf-PGA 0/1 response rates increased through W24 (54%) and remained stable through W112 (68%) among ICO-randomized pts

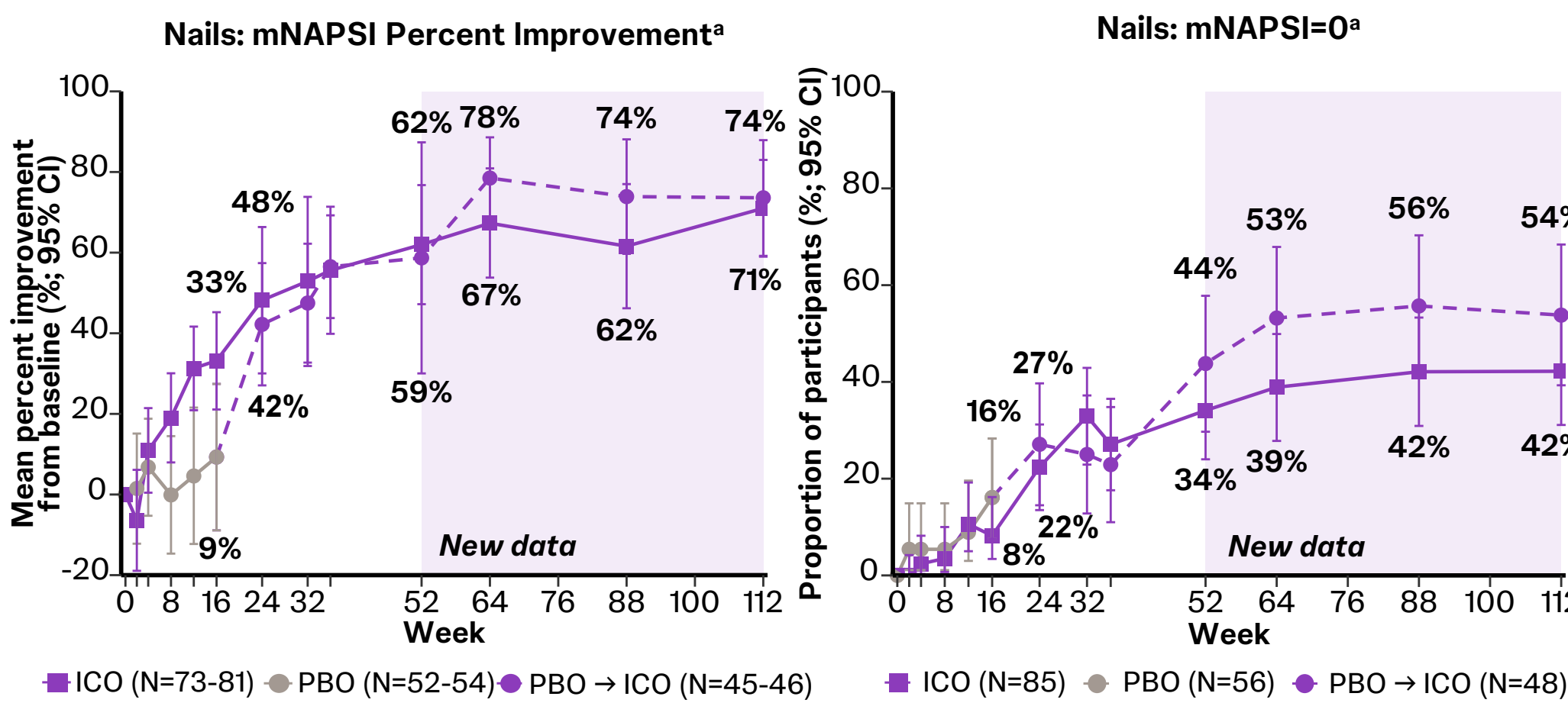
- 63% of ICO-randomized pts achieved completely clear hand/foot PsO (hf-PGA 0) at W112



^aAmong pts with a baseline hf-PGA score ≥3.

Nail PsO: ICO demonstrated increasing improvements through W64 (67%), which were consistent through W112 (71%)

- 42% of ICO-randomized pts achieved completely clear nail PsO (mNAPSI=0) at W112



^aAmong pts with a baseline mNAPSI score >0.

Key Takeaways

Through W112, among adults and adolescents with high-impact site PsO in the phase 3 ICONIC-TOTAL study, ICO demonstrated:

- High and durable rates of overall and high-impact site PsO clearance
- An AE profile similar to PBO through W16 with no new safety signals identified through W112

The robust efficacy and favorable safety profile through 2 years support the use of the once-daily targeted oral peptide ICO for long-term management of high-impact site PsO

Exposure-adjusted AE rates were consistent across treatment groups and study phases through W112

- ICO AE profile was similar to PBO through W16, with no increases in exposure-adjusted rates through 2 years of treatment

AEs Through W112	PBO-controlled (W0-16)		W0-52	W0-W112
	ICO (N=208)	PBO (N=103)	ICO Combined ^a (N=300)	ICO Combined ^a (N=300)
Mean weeks / total PY of follow-up	15.9 / 63.3	15.5 / 30.6	45.0 / 258.9	98.1 / 563.9
Any AE	105 (50%)	46 (45%)	206 (69%)	240 (80%)
Incidence/100PY (95% CI) ^b	232 (188, 277)	219 (156, 282)	160 (138, 182)	122 (106, 137)
SAE	1 (<1%)	2 (2%)	7 (2%)	15 (5%)
Incidence/100PY (95% CI) ^b	2 (0, 9)	7 (1, 24)	3 (1, 6)	3 (1, 4)
AE leading to D/C	6 (3%)	4 (4%)	7 (2%)	10 (3%)
Incidence/100PY (95% CI) ^c	10 (4, 21)	13 (4, 34)	3 (1, 6)	2 (1, 3)
Infection	59 (28%)	23 (22%)	146 (49%)	180 (60%)
Incidence/100PY (95% CI) ^b	110 (82, 138)	89 (53, 126)	82 (69, 95)	58 (50, 67)
Serious infection	0 (0%)	1 (1%)	0 (0%)	2 (1%)
Incidence/100PY (95% CI) ^b	0 (0, 5)	3 (<1, 18)	0 (0, 1)	<1 (0, 1)
GI AE	15 (7%)	8 (8%)	28 (9%)	49 (16%)
Incidence/100PY (95% CI) ^b	25 (12, 38)	27 (12, 54)	12 (7, 16)	10 (7, 12)
Malignancy ^c	1 (<1%)	0 (0%)	2 (1%)	6 (2%)
Incidence/100PY (95% CI) ^b	2 (0, 9)	0 (0, 10)	1 (<1, 3)	1 (<1, 2)

Data shown are n (%) unless otherwise noted. ^aIncludes data for ICO-randomized pts through W52 and for PBO → ICO pts from W16 through W52/W112. ^bCI is based on the normal approximation or an exact method following a Poisson distribution if the number of pts with events is <10. ^cIncludes one of basal cell carcinoma, chronic lymphocytic leukemia, malignant melanoma stage 0, prostate cancer, squamous cell carcinoma and squamous cell carcinoma of the cervix. D/C=discontinuation, GI=gastrointestinal, SAE=serious AE.

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