Durability of Response With Icotrokinra, a Targeted Oral Peptide, in Adults With Moderate-to-Severe Plaque Psoriasis:

One-Year Results From the Phase 3, Placebo- and Active Comparator-Controlled ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2 Trials

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Background

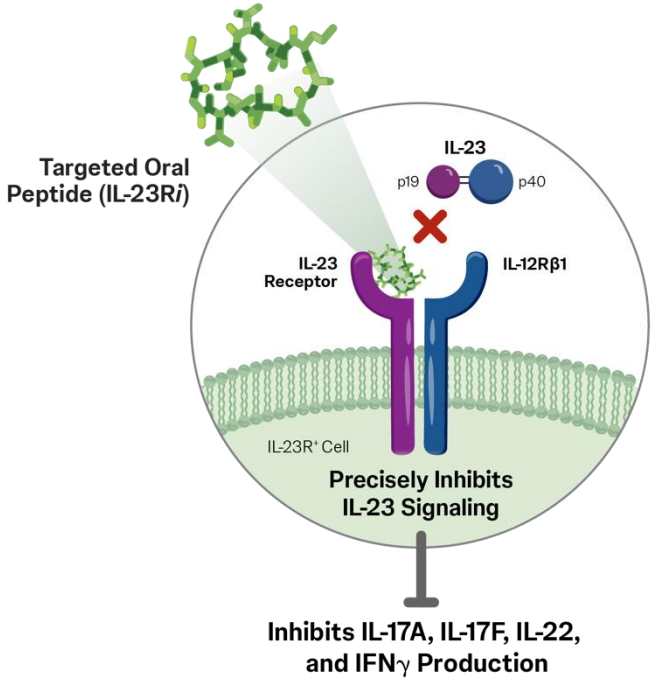
Icotrokinra for Plaque Psoriasis

Patients with moderate-to-severe plaque psoriasis (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 signaling[1]
- In the phase 3 ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2 studies of adults with moderate-to-severe plaque PsO[2]:
  - ICO demonstrated significantly higher rates of skin clearance vs placebo (PBO) at Week (W)16 and vs deucravacitinib (Deucra) at W16 and W24
  - ICO adverse event (AE) profile was similar to PBO through W16, and ICO overall AE and infection rates were lower than Deucra through W24

Icotrokinra Blocks IL-23 From Binding to its Receptor



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

Objective

Assess ICO effects and safety profile through W52 of the ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2 studies

ICONIC-ADVANCE 1 & 2 – Study Design

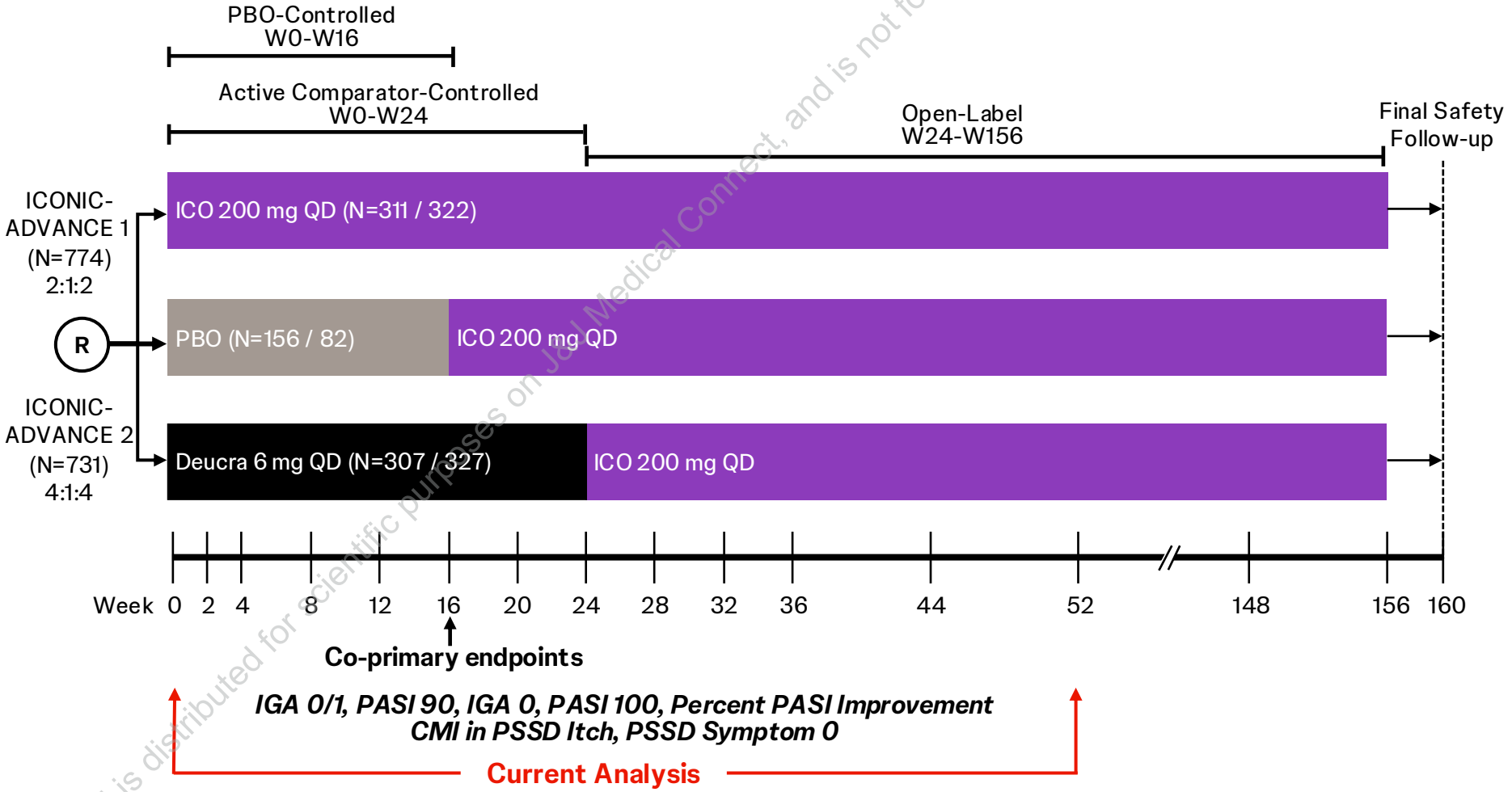
Moderate-to-Severe Plaque PsO

Key inclusion criteria

- ≥18 years
- Plaque PsO for ≥26 weeks
- BSA ≥10%; PASI score ≥12; IGA score ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO
- Suitable candidate for Deucra per approved product labeling

Co-primary endpoints

- IGA score 0/1 & ≥2-grade improvement from baseline (IGA 0/1) and PASI 90 vs PBO at W16



Bolded exploratory endpoints presented in results. **BSA**=body surface area, **CMI**=clinically meaningful improvement (≥4-point improvement from baseline), **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PSSD**=Psoriasis Symptoms and Signs Diary, **QD**=once daily, **R**=randomization.

Outcomes & Analyses

Clinician- and Participant (Pt)-Reported Outcomes Through W52[a,c]

- IGA 0/1, PASI 90
- IGA 0, PASI 100
- Clinically meaningful improvement (CMI; ≥4-point improvement from baseline) in PSSD Itch score, PSSD Symptom score 0

Percent Improvement in PASI Score Through W52[b,d]

- Mean percent improvement from baseline in PASI score for pooled ICONIC-ADVANCE 1 & 2 ICO vs PBO (exploratory endpoint)

AEs Through W52

- Number (%) and exposure-adjusted incidence rates per 100 PY (95% CI) for combined ICONIC-ADVANCE 1 & 2

[a]Nonresponder imputation (NRI) / [b]No 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 drug for other reasons. [c]After accounting for the intercurrent events, pts with missing data were considered nonresponders. [d]The remaining missing data were not imputed.
CI=confidence interval, **PY**=participant-years.

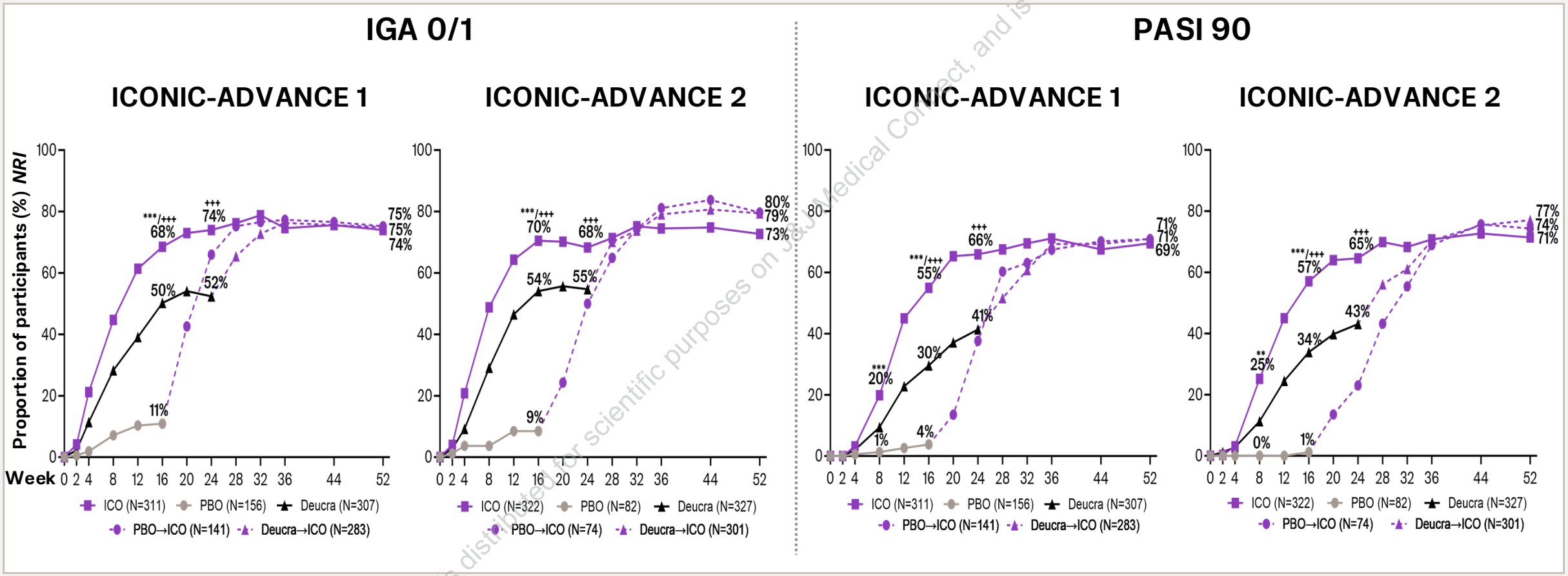
Baseline characteristics were generally comparable among treatment groups and across studies

Baseline Characteristics		ICONIC-ADVANCE 1			ICONIC-ADVANCE 2		
		ICO (N=311)	PBO (N =156)	Deucra (N=307)	ICO (N=322)	PBO (N=82)	Deucra (N=327)
Demographics							
	Age, yrs	47.1 (13.2)	46.9 (12.8)	46.3 (13.9)	45.9 (13.8)	48.4 (13.9)	45.6 (13.2)
	Female	28%	33%	35%	32%	33%	32%
	Race, Asian / Black / White	22% / 1% / 74%	22% / 2% / 76%	25% / 1% / 72%	11% / 3% / 85%	18% / 2% / 79%	12% / 3% / 81%
	BMI, kg/m^2	29.2 (6.3)	29.6 (8.1)	29.9 (7.3)	29.9 (6.4)	29.5 (5.8)	29.9 (6.9)[a]
Disease Characteristics							
	PsO duration, yrs	17.5 (11.1)	17.9 (12.7)	16.8 (12.8)	17.4 (13.4)	21.2 (15.2)	16.8 (12.0)
	% of BSA with PsO	26.7 (15.8)	24.9 (14.8)	26.1 (15.8)	25.7 (13.9)	26.8 (15.1)	25.7 (14.4)
	IGA score						
	Moderate (3) / Severe (4)	81% / 19%	79% / 21%	79% / 21%	78% / 22%	82% / 18%	82% / 18%
	PASI (0-72)	20.3 (6.9)	19.2 (6.6)	20.4 (7.9)	19.9 (7.0)	20.1 (7.5)	19.6 (6.6)
	PSSD symptom score (0-100)[b]	50.4 (25.8)	46.7 (26.4)	50.6 (26.4)	53.3 (26.5)	53.6 (25.7)	54.2 (25.9)
	PSSD itch score (0-10)[b]	6.4 (2.3)	5.9 (2.6)	6.3 (2.5)	6.4 (2.4)	6.3 (2.4)	6.5 (2.5)
Prior PsO Treatments							
	Phototherapy (PUVA and UVB)	36%	34%	32%	30%	38%	33%
	Systemic therapy[c]	76%	71%	73%	70%	71%	70%
	Biologic therapy[d]	28%	27%	26%	24%	32%	24%

Data shown are mean (SD), unless otherwise noted. [a]Deucra: N=325. [b]ICONIC-ADVANCE 1 & 2: ICO N=287/299, PBO N=142/71, Deucra N=277/290. [c]Conventional nonbiologic systemics, novel nonbiologic systemics, 1,25-vitamin D3 and analogues, phototherapy, and biologics. [d]Adalimumab, alefacept, briakinumab, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, infliximab, ixekizumab, natalizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab. **BMI**=body mass index, **PUVA**=psoralen plus ultraviolet A, **SD**=standard deviation, **UVB**=ultraviolet B.

ICO demonstrated high rates of IGA 0/1 & PASI 90 response that were durable or increased from W24 through W52

- Among Deucra-randomized pts who transitioned to ICO, skin clearance rates increased substantially from W24 through W52

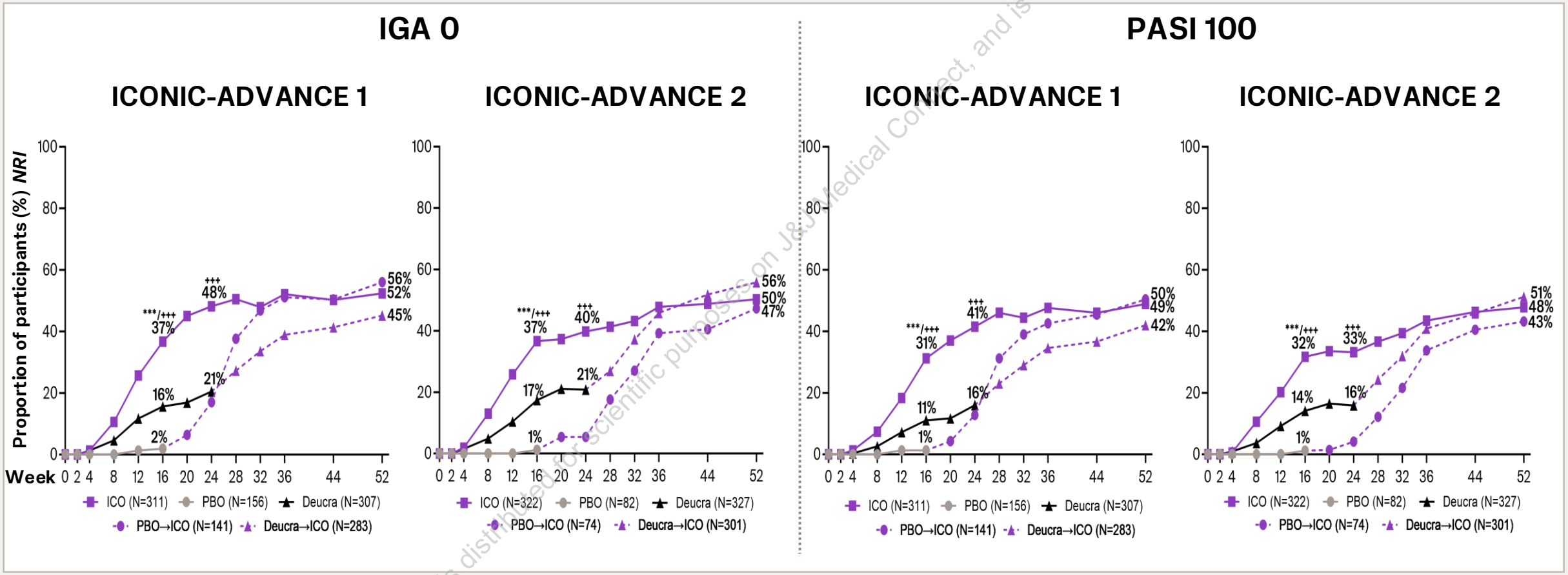


Multiplicity-adjusted **p*<0.05, ***p*<0.01, ****p*<0.001 vs PBO; multiplicity-adjusted ^{+}p<0.05, ^{++}p<0.01, ^{+++}p<0.001 vs Deucra

P-values based on Cochran-Mantel-Haenszel chi-square test stratified by baseline weight category (≤90 kg, >90 kg) and geographic region. **IGA 0/1**=IGA score 0/1 & ≥2-grade improvement from baseline.

~50% of ICO-randomized pts achieved complete skin clearance, with durable or increased response rates observed from W24 through W52

- Among Deucra-randomized pts, rates of complete skin clearance increased by >2-fold after transitioning to ICO at W24



Multiplicity-adjusted **p*<0.05, ***p*<0.01, ****p*<0.001 vs PBO; multiplicity-adjusted ^{+}p<0.05, ^{++}p<0.01, ^{+++}p<0.001 vs Deucra

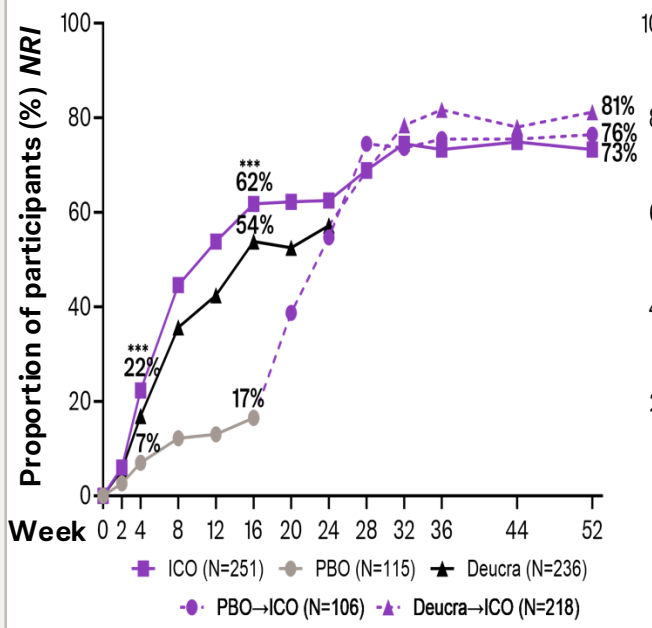
P-values based on Cochran-Mantel-Haenszel chi-square test stratified by baseline weight category (≤90 kg, >90 kg) and geographic region.

ICO demonstrated high rates of meaningful itch improvement & symptom resolution that were durable or increased from W24 through W52

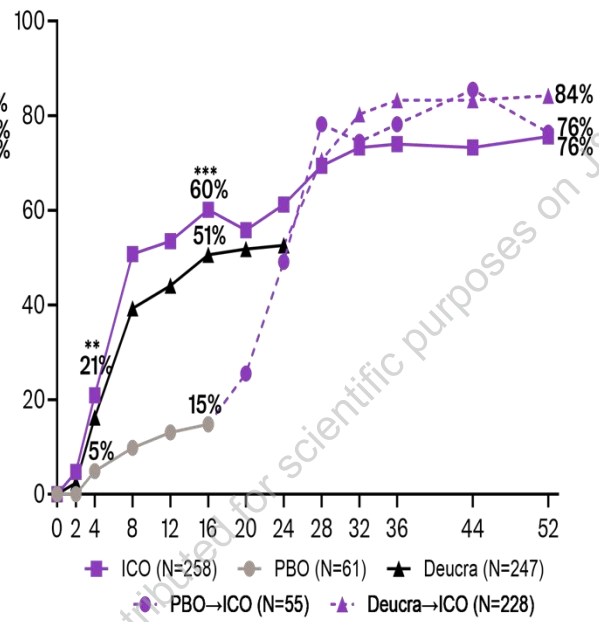
- Among Deucra-randomized pts, rates of meaningful itch improvement and no PsO symptoms increased after transitioning to ICO at W24

Clinically Meaningful Improvement (CMI) in PSSD Itch Score[a]

ICONIC-ADVANCE 1

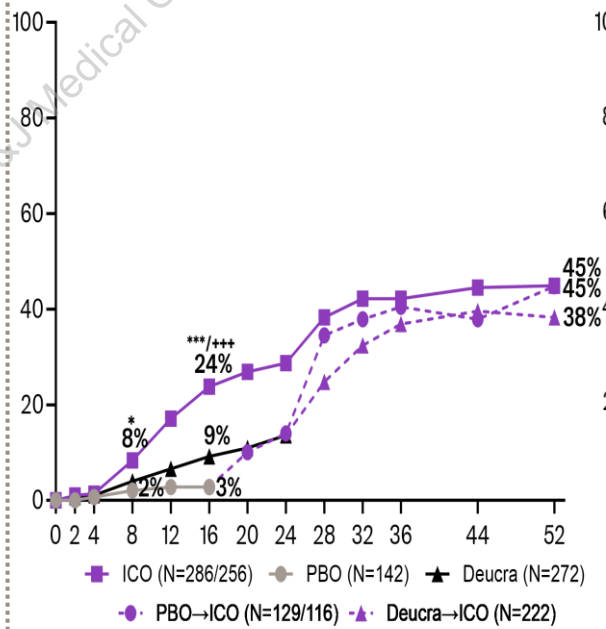


ICONIC-ADVANCE 2

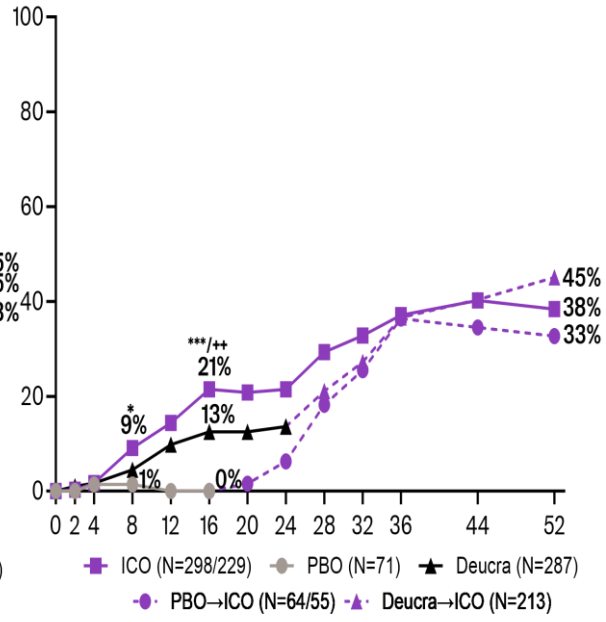


PSSD Symptom Score 0[a,b]

ICONIC-ADVANCE 1



ICONIC-ADVANCE 2

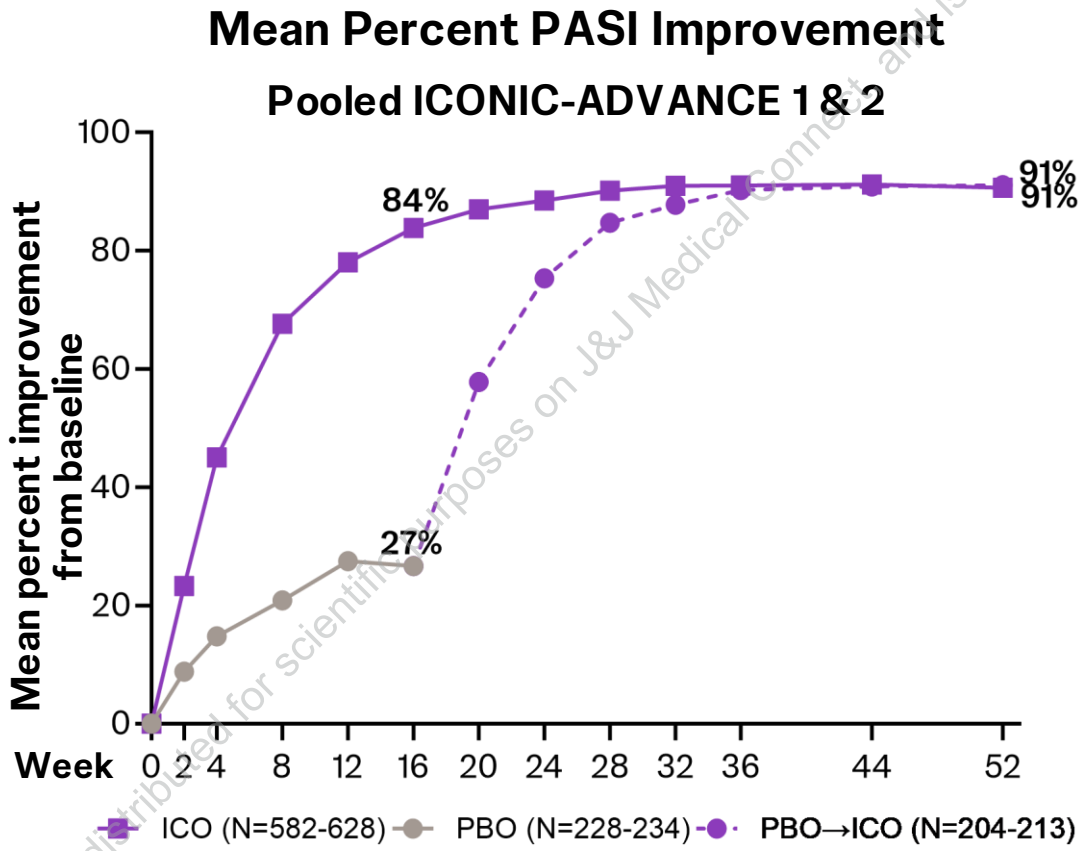


Multiplicity-adjusted **p*<0.05, ***p*<0.01, ****p*<0.001 vs PBO; multiplicity-adjusted ^{+}p<0.05, ^{++}p<0.01, ^{+++}p<0.001 vs Deucra

[a]Among pts with a baseline PSSD Itch score ≥4 or PSSD Symptom score >0. [b]Data impacted by a translation error in the German 7-day recall version of the PSSD after W24 were excluded.
P-values based on Cochran-Mantel-Haenszel chi-square test stratified by baseline weight category (≤90 kg, >90 kg) and geographic region. Fisher's exact test was used to evaluate PSSD Symptom score[10] 0 at W8. **CMI**=clinically meaningful improvement (≥4-point improvement from baseline).

ICO-randomized pts exhibited ~90% mean PASI improvement from W24 through W52

- ICO showed separation from PBO as early as W2
- ICO-randomized pts achieved greater LS mean percent PASI improvement vs PBO at W16 (pooled ICONIC-ADVANCE 1 & 2: 84% vs 27%, respectively); nominal $p<0.001$[a]



[a]LS means and p-value were based on the MMRM model with treatment group, visit, study, treatment group by visit interaction, baseline PASI total score, and baseline PASI total score by visit interaction as covariates. **LS**=least squares, **MMRM**=mixed-effect model for repeated measures.

ICO AE profile through W52 was consistent with that observed through W16 & W24; no safety signal was identified through W52

- ICO AE profile was similar to PBO through W16 and ICO overall AE and infection rates were lower than Deucra through W24

ICONIC-ADVANCE 1 & 2 AEs[a]	PBO-Controlled (Through W16)		Active Comparator-Controlled (Through W24)		Through W52
	PBO (N=237)	ICO (N=632)	ICO (N=632)	Deucra (N=634)	ICO (N=1431)[b]
Mean weeks / total PY of follow-up	15.5 / 70.4	15.9 / 192.6	23.6 / 285.3	23.3 / 283.0	38.5 / 1056.8
Any AE	137 (58%)	308 (49%)	368 (58%)	417 (66%)	931 (65%)
Incidence/100 PY (95% CI)	316 (257, 364)	230 (205, 256)	207 (186, 229)	269 (243, 295)	169 (158, 180)
Serious AE	4 (2%)	14 (2%)	18 (3%)	20 (3%)	56 (4%)
Incidence/100 PY (95% CI)	6 (<1, 9)	7 (3, 11)	6 (3, 9)	7 (4, 10)	5 (4, 7)
AE leading to discontinuation	12 (5%)	14 (2%)	17 (3%)	19 (3%)	32 (2%)
Incidence/100 PY (95% CI)	17 (7, 25)	7 (3, 11)	6 (3, 9)	7 (4, 10)	3 (2, 4)
Infection	74 (31%)	146 (23%)	193 (31%)	254 (40%)	610 (43%)
Incidence/100 PY (95% CI)	130 (96, 154)	87 (72, 100)	82 (70, 93)	119 (104, 134)	80 (73, 86)
Serious infection	1 (<1%)	1 (<1%)	3 (<1%)	5 (1%)	10 (1%)
Incidence/100 PY (95% CI)	1 (0, 9)	1 (0, 3)	1 (<1, 3)	2 (1, 4)	1 (<1, 2)
Gastrointestinal AE	14 (6%)	45 (7%)	55 (9%)	82 (13%)	135 (9%)
Incidence/100 PY (95% CI)	21 (11, 36)	24 (17, 32)	20 (15, 26)	31 (25, 38)	14 (11, 16)
Malignancy	1 (<1%)	3 (<1%)	3 (<1%)	2 (<1%)	6 (<1%)
Incidence/100 PY (95% CI)	1 (0, 9)	2 (<1, 5)	1 (<1, 3)	1 (<1, 3)	1 (<1, 1)

Data shown are n (%), unless otherwise noted. Data for all periods are based on the W52 database lock; data through the controlled periods may be slightly different from the earlier lock. Incidence/100 PY: (number of pts with AEs/total PY at risk) × 100; CI based on study-size adjusted Wald statistics. [a]Safety analysis set included all randomized and treated pts; ICONIC-ADVANCE 1 & 2: PBO N=155/82 (PBO→ICO N=141/74), ICO N=310/322, Deucra N=307/327 (Deucra→ICO N=283/301). [b]Includes pts receiving ICO through W52 and data after W16 for pts receiving PBO and after W24 for pts receiving Deucra who transitioned ICO.

Key Takeaways

Across phase 3 ICONIC-ADVANCE 1 & 2 studies, adults with moderate-to-severe plaque PsO receiving ICO demonstrated:

- **Robust rates of PsO skin clearance & symptom relief that were durable or increased from W24-52**
  - ✓ **~50% of ICO-randomized pts achieved complete skin clearance at W52**
  - ✓ **Deucra-randomized pts exhibited >2-fold increase in rates of complete skin clearance after transitioning to ICO**
  - ✓ **ICO pts exhibited ~90% mean PASI improvement**
  - ✓ **ICO pts reported high rates of meaningful PsO itch improvement & symptom resolution**
- **A favorable safety profile and no safety signal identified through W52, consistent with that observed through W16/24**

References

1. Fourie AM. *Sci Rep*. 2024;14:17515.
2. Stein Gold L. *Lancet*. 2025;406:1363-74.

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