

One-year Efficacy and Safety Results From ICONIC-ADVANCE 1 and 2 in Adults With Moderate-to-Severe Plaque Psoriasis

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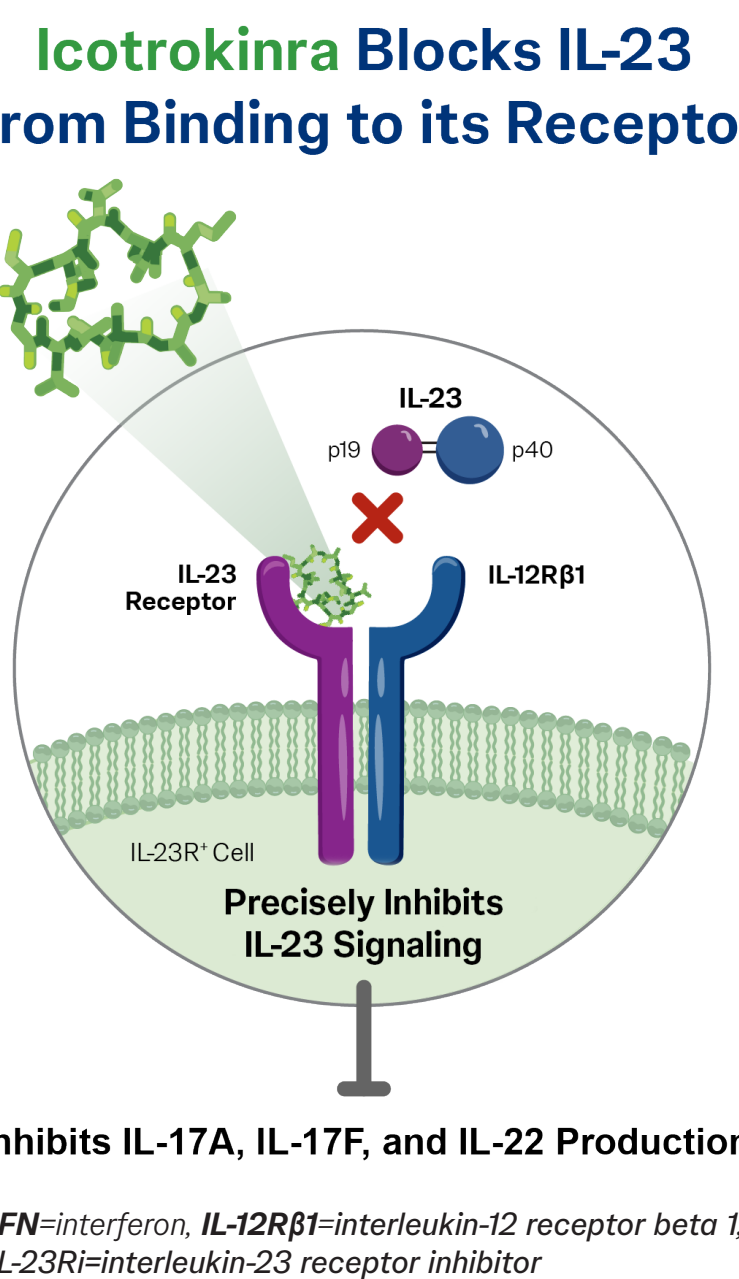
Key Takeaways

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-W52
- ✓ ~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

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 signaling¹
 - In the phase 3 ICONIC-ADVANCE 1 & ICONIC-ADVANCE 2 studies of adults with moderate-to-severe plaque PsO²:
 - 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

Objective

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

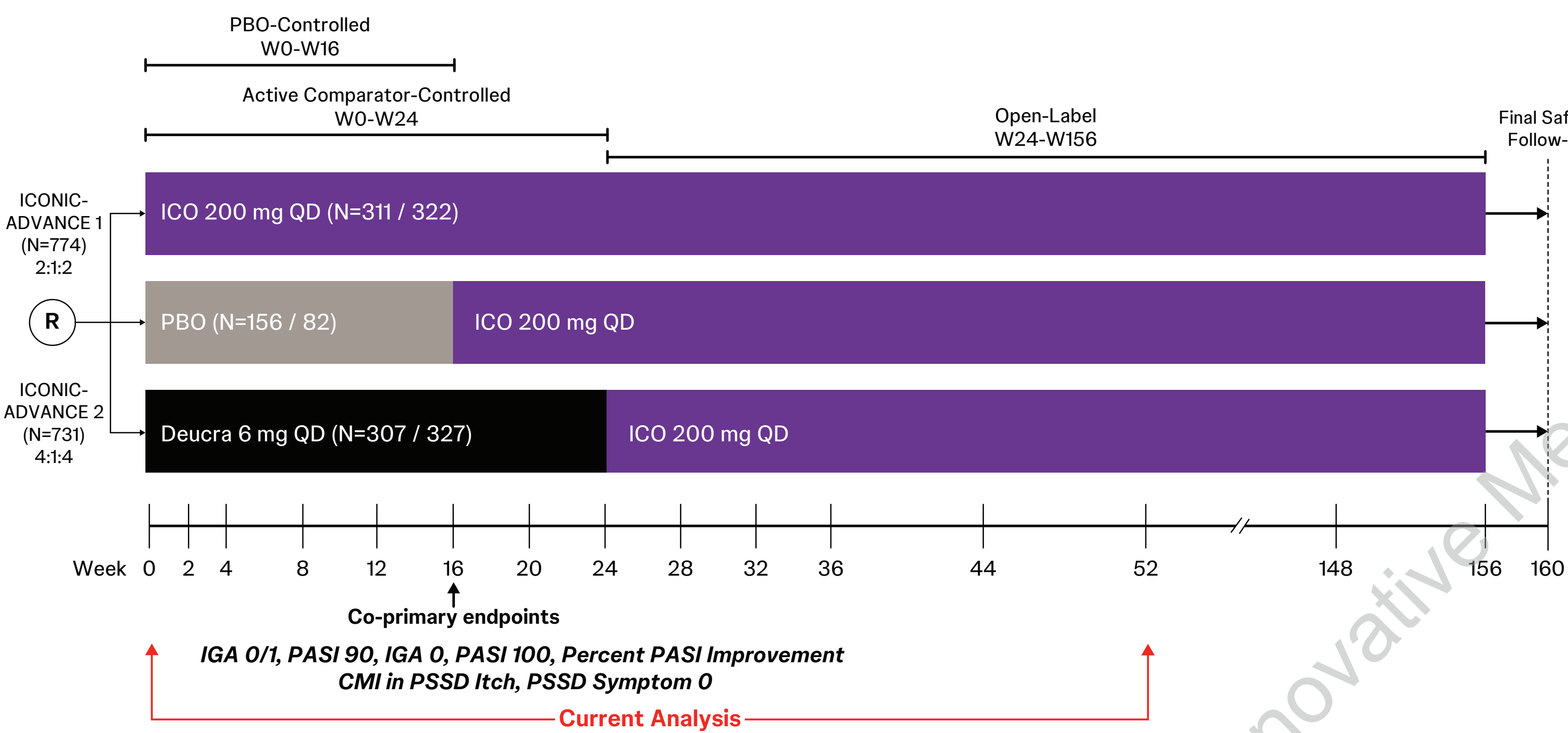
ICONIC-ADVANCE 1 & 2 – Study Design

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



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

^aNonresponder imputation (NRI) / 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. ^bAfter accounting for the intercurrent events, pts with missing data were considered nonresponders. ^cThe remaining missing data were not imputed. ^dAE=adverse event; CI=confidence interval; CMI=clinically meaningful improvement; ICO=icotrokinra; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=placebo; PsO=psoriasis; PSSD=Psoriasis Symptoms and Signs Diary; PY=participant-years; W=week.

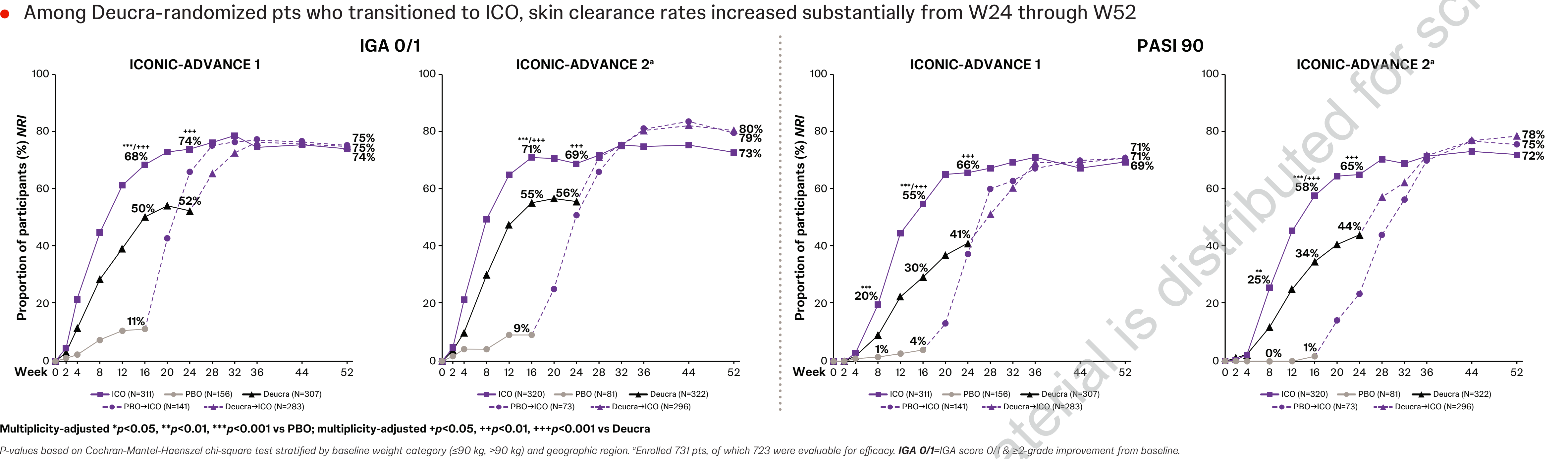
Results

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%	32%	33%	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)	29.5 (8.4)	29.5 (8.8)	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)	53.6 (25.7)	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%

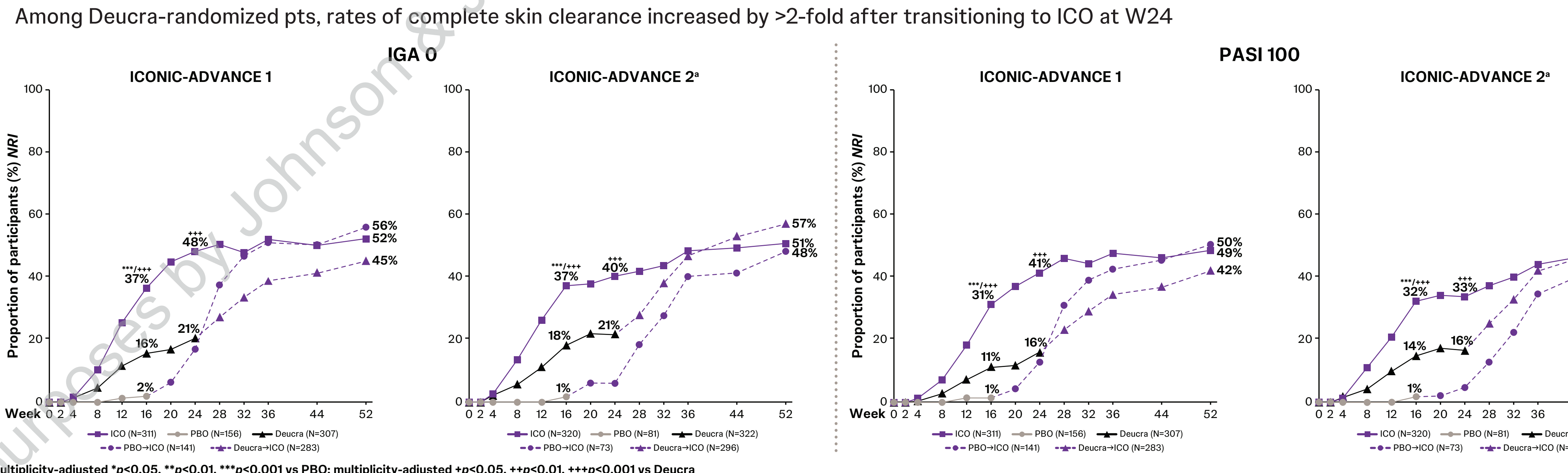
Data shown are mean (SD), unless otherwise noted. ^aDeucra: N=325. ^bICONIC-ADVANCE 1 & 2: ICO N=287/289, PBO N=142/71, Deucra N=277/290. ^cConventional nonbiologic systemic, novel nonbiologic systemic, L25-vitamin D3 and analogues, phototherapy, and biologics. ^dAdalimumab, abatacept, brodalumab, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, infliximab, ixekicimab, natalizumab, risankizumab, secukinumab, tildrakizumab, 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, PSSD=Psoriasis Symptoms and Signs Diary, 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



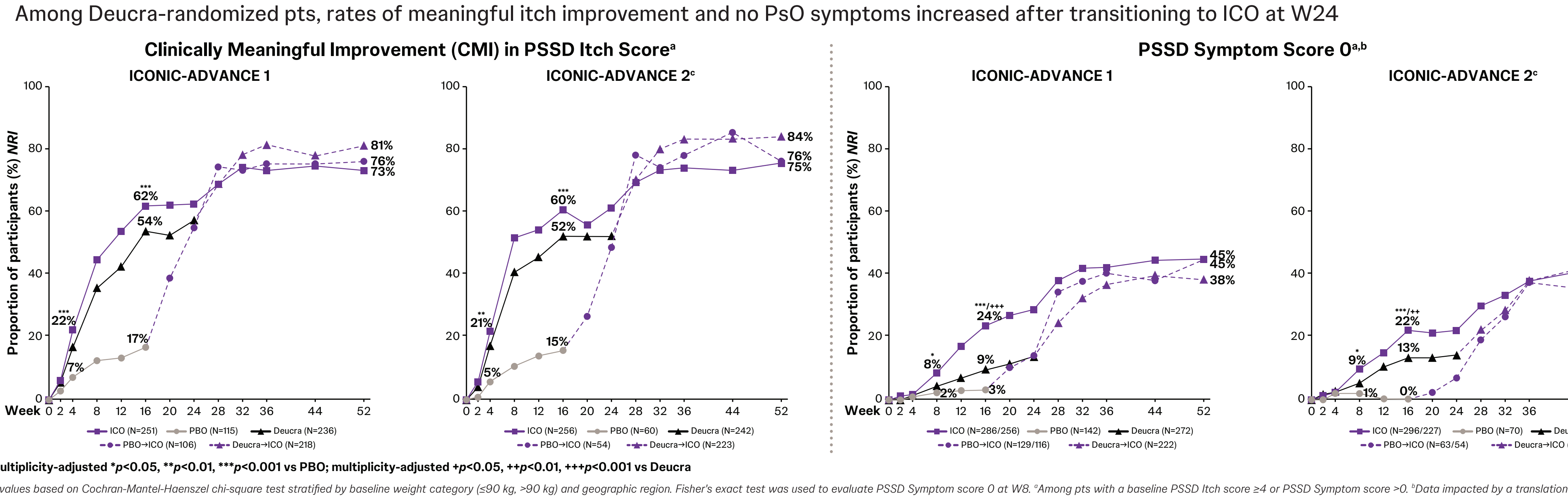
^aP-values based on Cochran-Mantel-Haenszel chi-square test stratified by baseline weight category (<90 kg, ≥90 kg) and geographic region. ^bEnrolled 731 pts, of which 723 were evaluable for efficacy. IGA 0/1: IGA score 0/1 & ≥2-grade improvement from baseline.

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



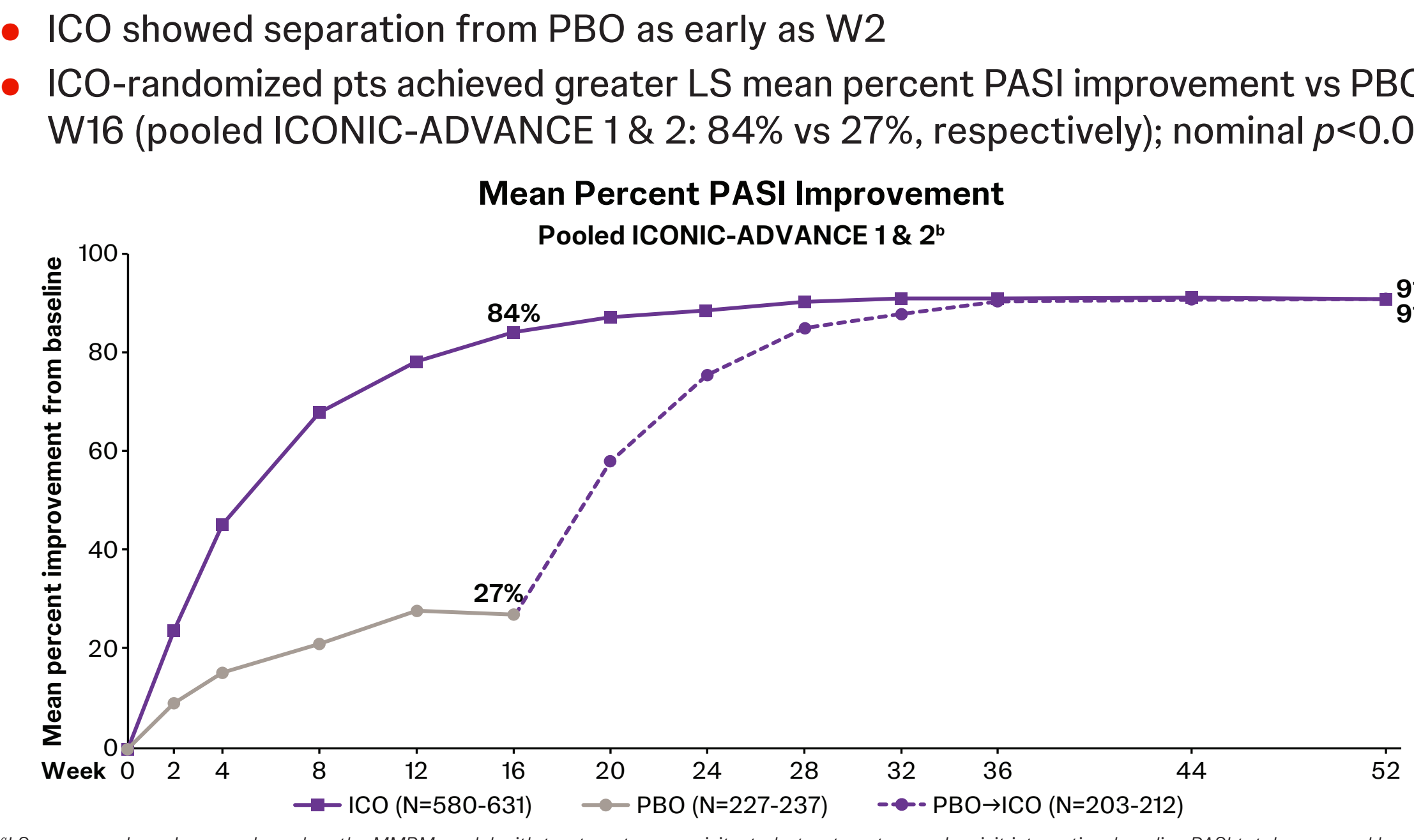
Plots based on Cochran-Mantel-Haenszel chi-square test stratified by baseline weight category (<90 kg, ≥90 kg) and geographic region. ^aEnrolled 731 pts, of which 723 were evaluable for efficacy. ICO=icotrokinra, IGA=Investigator's Global Assessment, NRI=nonresponder imputation, PASI=Psoriasis Area and Severity Index, PBO=placebo.

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



^aP-values based on Cochran-Mantel-Haenszel chi-square test stratified by baseline weight category (<90 kg, ≥90 kg) and geographic region. ^bFisher's exact test was used to evaluate PSSD Symptom score 0 at W16. ^cData impacted by a translation error in the German 7-day recall version of the PSSD after W24 were excluded. ^dEnrolled 731 pts, of which 723 were evaluable for efficacy. CMI=clinically meaningful improvement (≥4-point improvement from baseline), ICO=icotrokinra, NRI=nonresponder imputation, PBO=placebo, PSSD=Psoriasis Symptoms and Signs Diary.

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



^aLS 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. ^bICONIC-ADVANCE 2 enrolled 404 pts in the ICO and PBO groups, of which 401 were evaluable for efficacy. ICO=icotrokinra, LS=least squares, MMRM=mixed-effect model for repeated measures, PASI=Psoriasis Area and Severity Index, PBO=placebo.

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)	
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. ^aICO: CI based on study-size adjusted Wald statistics. ^bSafety analysis set included all randomized and treated pts. ^cICONIC-ADVANCE 1 & 2: PBO N=156/82, PBO=ICO N=142/71, ICO N=287/289, Deucra N=277/290. ^dDeucra=ICO N=283/301. Includes pts receiving ICO through W52 and data after W16 for pts receiving PBO and after W24 for pts receiving Deucra who transitioned to ICO. ^eAE=adverse event, CI=confidence interval, ICO=icotrokinra, PBO=placebo, PY=participant-years, W=week.