

Durability of Response to Icotrokinra in Adults and Adolescents With Moderate-to-Severe Plaque Psoriasis: 2-Year ICONIC-LEAD Findings

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Background

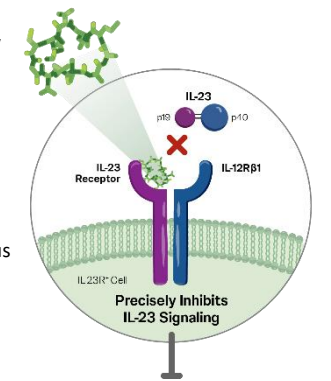
Plaque psoriasis (PsO) is a chronic inflammatory skin disease in which dysregulation of interleukin (IL)-23 activation plays a pivotal role¹

Icotrokinra (ICO) is a first and only targeted oral peptide that precisely blocks the interleukin (IL)-23 receptor (IL-23R) and inhibits IL-23 pathway signaling²

ICONIC-LEAD (NCT06095115)

- Ongoing phase 3 randomized, double-blind, placebo (PBO)-controlled study evaluating the efficacy and safety of once-daily ICO in adults and adolescents with moderate-to-severe plaque PsO^{3,4}
- Demonstrated robust efficacy and a favorable safety profile versus placebo (PBO) through Week (W) 16,³⁻⁵ with consistent results through 1 year⁶⁻⁹

Icotrokinra Blocks IL-23 From Binding to its Receptor



Objective

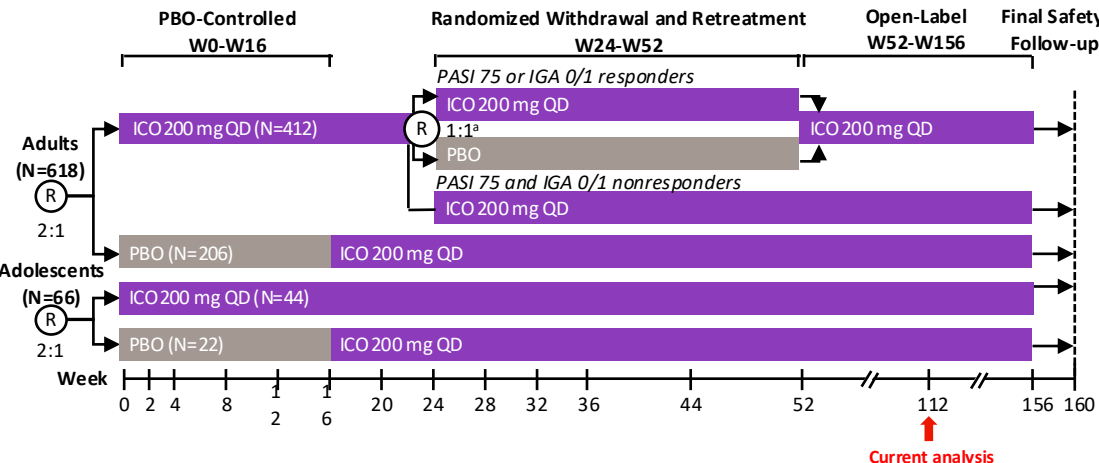
To report clinical efficacy, patient-reported outcomes, and safety of ICO in participants with PsO through 2 years in the ICONIC-LEAD trial

Inhibits IL-17A, IL-17F, and IL-22 Production
IL-12RB1=interleukin-12 receptor beta 1, IL-23R=interleukin-23 receptor.

ICONIC-LEAD – Study Design

Key inclusion criteria

- ≥12 years of age
- Plaque PsO for ≥26 weeks
- BSA ≥10%
- PASI score ≥12
- IGA score ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO



^aAt W24 adults who achieved PASI 75 or IGA score of 0/1 were defined as responders and were rerandomized to continue ICO or PBO. BSA=body surface area, IGA=Investigator's Global Assessment, PASI=Psoriasis Area and Severity Index, QD=once daily, R=ranomized.

Outcomes & Analyses

Clinical outcomes

- Proportion of participants achieving IGA 0/1, IGA 0, PASI 90, PASI 100 from W64 to W112^a
- Response recapture was evaluated 24 weeks after retreatment among adult W24 PASI 75, PASI 90, and IGA 0/1 responders who underwent treatment withdrawal and were PASI 75, PASI 90, and IGA 0/1 nonresponders, respectively, at the time of retreatment^b

PROs

- Proportion of participants achieving PSSD Signs score of 0^c, PSSD Symptoms score of 0^c, CMI in PSSD Itch^d from W64 to W112^a

Safety

- Number (%) of participants and exposure-adjusted incidence rates (/100 PY)^e

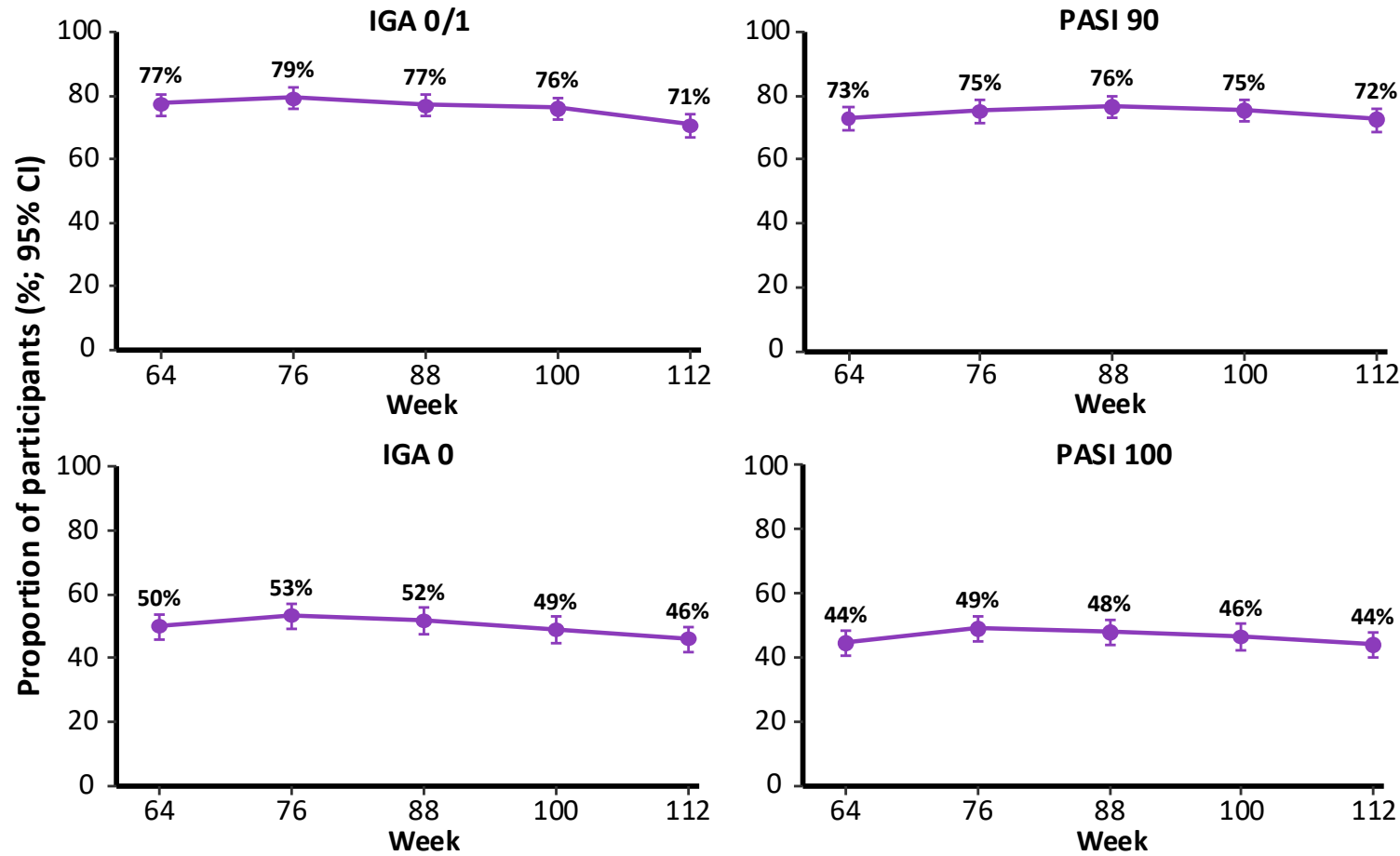
^aAll participants entering the open-label period (W52-W156) received ICO and were included in the analysis; nonresponder imputation was assigned after participant discontinuation of study drug due to lack of efficacy or an AE of worsening PsO. Observed data were used for participants initiating protocol-prohibited medication that could improve PsO or discontinued for other reasons. After accounting for these intercurrent events, subjects with missing data were imputed using multiple imputation method. ^bAfter retreatment, nonresponder imputation was assigned after participant discontinuation of study drug due to lack of efficacy, or an AE of worsening PsO. Additionally, through W52, nonresponder imputation was also assigned after retreatment for initiation of protocol-prohibited medication that could improve PsO. Observed data were used for participants who discontinued due to other reasons. Remaining missing data were not imputed. ^cAmong participants with baseline score ≥0. ^dDefined as ≥4-point improvement from baseline; among participants with baseline PSSD Itch score ≥4. ^eAmong participants who received ≥1 dose of study drug.

AE=adverse event, CMI=clinically meaningful improvement, PRO=patient-reported outcome, PSSD=Psoriasis Symptoms and Signs Diary, PY=patientyears, SAE=severe adverse event.

Results

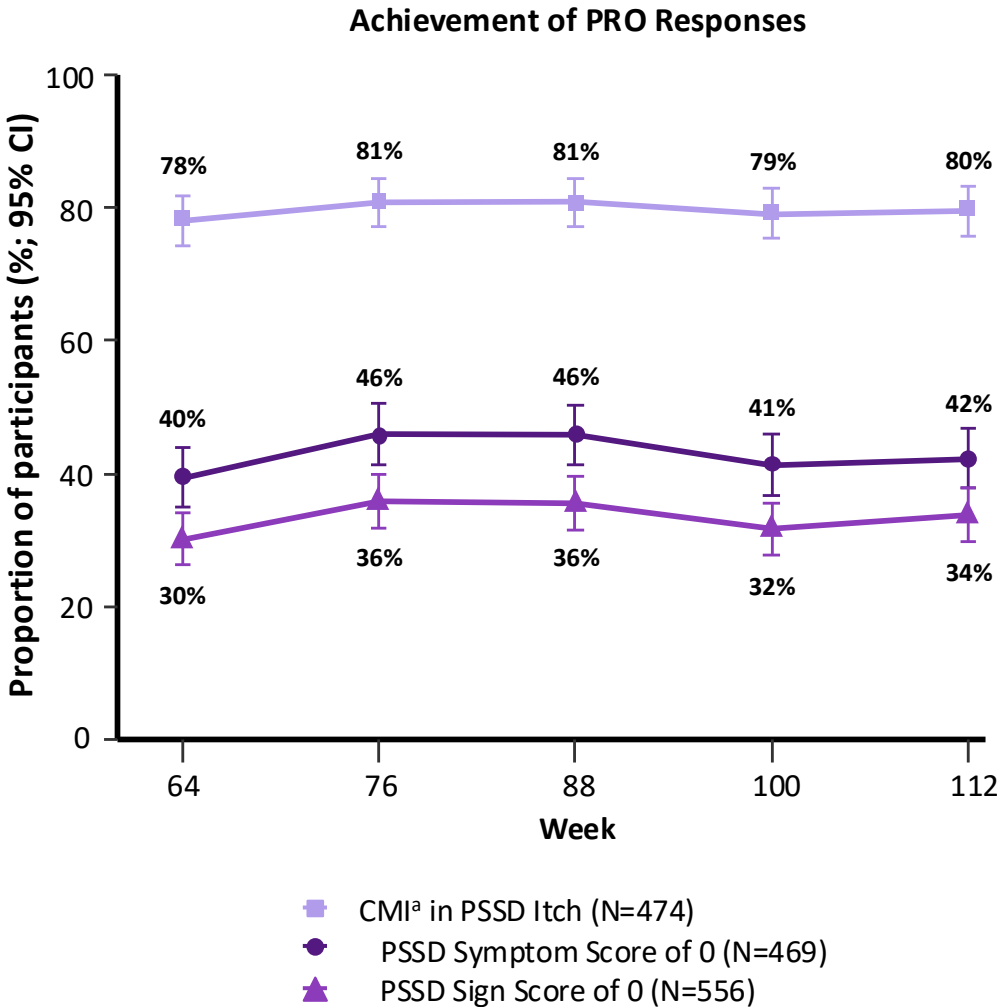
ICO demonstrated high and durable IGA 0/1, IGA 0, PASI 90 and PASI 100 response rates from W64 through W112

- Among participants entering the open label period (N=614), 559 completed treatment through W112
- Among adult PASI 75, PASI 90, and IGA 0/1 responders at W24 who underwent treatment withdrawal and were nonresponders at the time of retreatment, 90%, 85%, and 84%, respectively, regained response 24 weeks after retreatment (data not shown)



^aAll participants entering the open-label period (W52-W156) received ICO and were included in the analysis. CI=confidence interval.

ICO demonstrated durable improvements in PsO itch and PsO symptom and sign resolution from W64 through W112



^aDefined as ≥4-point improvement from baseline; among participants with baseline PSSD Itch score ≥4.

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

AEs Through W112	PBO-controlled (W0-16)		W0-52	W0-W112
	ICO (N=456)	PBO (N=228)	ICO Combined ^a (N=669)	ICO Combined ^a (N=669)
Mean weeks / total PY of follow-up	15.9 / 138.8	15.7 / 68.6	40.8 / 522.6	92.9 / 1190.6
Any AE	230 (50%)	111 (49%)	450 (67%)	522 (78%)
Incidence/100PY (95% CI) ^b	245 (213, 276)	237 (193, 282)	167 (151, 182)	118 (108, 128)
SAE	6 (1%)	6 (3%)	20 (3%)	50 (7%)
Incidence/100PY (95% CI) ^b	4 (2, 10)	9 (3, 19)	4 (2, 6)	4 (3, 6)
AE leading to D/C	6 (1%)	2 (1%)	15 (2%)	21 (3%)
Incidence/100PY (95% CI) ^b	4 (2, 9)	3 (0, 10)	3 (1, 4)	2 (1, 2)
Infection	108 (24%)	51 (22%)	261 (39%)	347 (52%)
Incidence/100PY (95% CI) ^b	91 (74, 108)	86 (62, 109)	66 (58, 74)	47 (42, 52)
Serious infection	1 (<1%)	0 (0%)	2 (<1%)	9 (1%)
Incidence/100PY (95% CI) ^b	1 (0, 4)	0 (0, 4)	<1 (0, 1)	1 (0, 1)
GI AE	27 (6%)	12 (5%)	62 (9%)	93 (14%)
Incidence/100PY (95% CI) ^b	20 (13, 28)	18 (8, 28)	13 (10, 16)	9 (7, 10)
Malignancy ^c	2 (<1%)	0 (0%)	2 (<1%)	6 (1%)
Incidence/100PY (95% CI) ^b	1 (0, 5)	0 (0, 4)	0 (0, 1)	<1 (0, 1)

Data shown are n (%) unless otherwise noted. Data during the withdrawal period (on or after W28 and before retreatment) were excluded for participants who were rerandomized to PBO at W24. ^aIncludes data for ICO-randomized participants and PBO-randomized participants who crossed over after W16 to receive the study treatment. ^bCI is based on the normal approximation or an exact method following a Poisson distribution if the number of participants with events is <10. ^cMalignancies were identified in the eCRF through investigator assessment. D/C=discontinuation, eCRF=electronic Case Report Form, GI=gastrointestinal.

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