Durability of Icotrokinra (Targeted Oral Peptide) Effects in Adolescents With Moderate-to-Severe Plaque Psoriasis: One-Year Results From the ICONIC-LEAD Study

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Background

Pediatric plaque psoriasis

Approximately one-third of patients with plaque psoriasis (PsO) report onset before adulthood; however, few advanced treatment options are available[1]

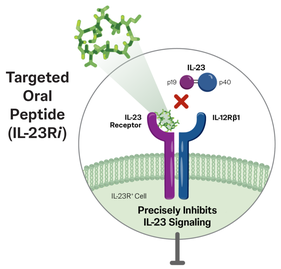
Icotrokinra

Patients with moderate-to-severe plaque 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[2]
- Demonstrated significantly higher rates of skin clearance vs placebo (PBO) at Week (W) 16, with increasing response rates and no safety signal through W24 among all adult and adolescent participants (pts) with moderate-to-severe plaque PsO in the phase 3 ICONIC-LEAD study[3]
  - ICO showed higher skin clearance rates vs PBO at W16 in the adolescent subgroup, with increased response rates and a favorable safety profile through W24[4]

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 longer-term ICO effects and safety in ICONIC-LEAD adolescents through W52

ICONIC-LEAD – Study Design & Adolescent Subgroup

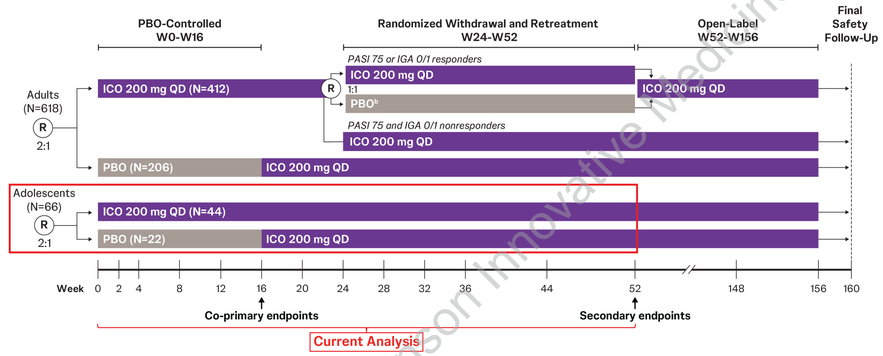
Moderate-to-Severe Plaque PsO (N=684)

Key inclusion criteria

- ≥12 years
  - Adults (≥18 years)
  - Adolescents (12≤18 years)
- Plaque PsO for ≥26 weeks
- BSA ≥10%, PASI score ≥12, IGA score ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO

Adolescent-specific inclusion criteria:

- Body weight ≥40 kg[a]



*[a]Weight limit was set to ensure similar exposures between adults and adolescents. [b]Pts retreated with ICO upon loss of ≥50% PASI improvement observed at W24. **BSA**=body surface area, **ICO**=icotrokinra, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis, **Pts**=participants, **QD**=once daily, **R**=randomized, **W**=week.*

Key Takeaways

- **In ICONIC-LEAD, adolescents with moderate-to-severe plaque PsO receiving ICO:**
  - **Achieved high rates of skin clearance by W24, with >80% demonstrating clear/almost clear skin & ~60% exhibiting complete skin clearance during W24–52**
    - **~90% of ICO adolescents achieving IGA 0/1 or PASI 90 at W24 maintained response at W52**
  - **ICO demonstrated a favorable safety profile in adolescents through W52 that was consistent with the overall study population[5]; no ICO safety signal was identified**
- **Findings further support the use of ICO, a targeted oral peptide, to treat moderate-to-severe plaque PsO in adolescents, addressing an important unmet need with a once-daily pill**

Outcomes/Analyses & Results

Through W52	• IGA 0/1 & ≥2-grade improvement from baseline (IGA 0/1), PASI 90 • IGA 0, PASI 100 • AEs: Number (%) of adolescents and exposure-adjusted incidence rates (per 100 PY)
At W52	• IGA 0/1 among W24 IGA 0/1 responders • PASI 90 among W24 PASI 90 responders
Analyses	• Nonresponder imputation: Pts who 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: Pts who discontinued study drug for other reasons • After accounting for the intercurrent events, pts with missing data were considered nonresponders

***AE**=adverse event, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PsO**=psoriasis, **Pts**=participants, **PY**=participant-years, **W**=week.*

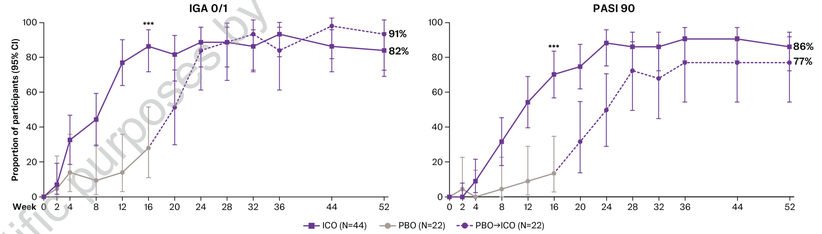
Adolescent characteristics were generally balanced between groups

Baseline Characteristics in Adolescents		ICO (N=44)	PBO (N=22)
Demographics			
	Age, years	15.0 (1.8)	15.0 (1.5)
	Female	52%	64%
	Race, Asian / Black / White	23% / 5% / 70%	23% / 0% / 77%
	BMI, kg/m^2	26.0 (7.1)	24.4 (7.9)
Disease Characteristics			
	PsO disease duration, yrs	4.9 (4.0)	5.8 (3.4)
	% of BSA with PsO	26.1 (15.6)	27.1 (14.0)
	IGA score		
	Moderate (3)	70%	82%
	Severe (4)	30%	18%
	PASI (0–72)	19.8 (8.2)	18.6 (4.0)
Prior PsO Treatments			
	Phototherapy (PUVA or UVB)	23%	14%
	Systemic therapy[a]	52%	50%
	Biologic therapy[b]	14%	41%

*Data shown are mean (SD), unless otherwise noted. [a]Conventional nonbiologic systemics, novel nonbiologic systemics, 1,25-vitamin D3 and analogues, phototherapy, and biologics. [b]Adalimumab, alefacept, briakinumab, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, infliximab, ixekizumab, 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, **PUVA**=psoralen plus ultraviolet A, **SD**=standard deviation, **UVB**=ultraviolet B.*

ICO demonstrated high rates of IGA 0/1 & PASI 90 by W24, with >80% of pts exhibiting clear/almost clear skin during W24–52

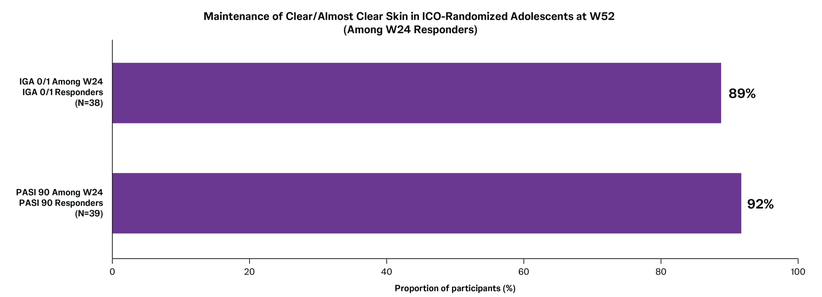
- After transitioning to ICO, PBO-randomized pts achieved IGA 0/1 and PASI 90 response rates at W52 that were consistent with those achieved by ICO-randomized pts



Nominal *p<0.05, **p<0.01, ***p<0.001 vs PBO

*P-values based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region. Known differences between IGA vs PASI score determinations likely account for differences in response rates. **CI**=confidence interval, **ICO**=icotrokinra, **IGA 0/1**=Investigator's Global Assessment score 0/1 & ≥2-grade improvement from baseline, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **Pts**=participants, **W**=week.*

~90% of ICO-randomized adolescents achieving clear/almost clear skin at W24 maintained response at W52



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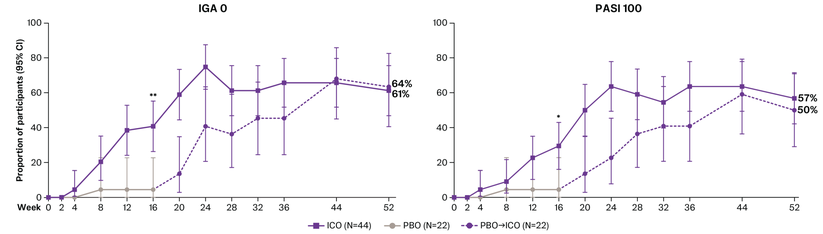
ICO demonstrated high rates of IGA 0 & PASI 100 by W24, with ~60% of pts exhibiting complete skin clearance during W24–52

- After transitioning to ICO, PBO-randomized pts achieved IGA 0 and PASI 100 response rates at W52 that were consistent with those achieved by ICO-randomized pts



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The ICO AE profile in adolescents was similar to PBO through W16, and consistent between W16 & W52

AEs Through W52: Adolescents[a]	PBO-Controlled (Through W16) PBO (N=22)	PBO-Controlled (Through W16) ICO (N=44)	Through W52 ICO Combined (N=66)[a]
Mean weeks / total PY of follow-up	16.2 / 6.8	16.2 / 13.7	46.3 / 58.6
Any AE	16 (73%)	22 (50%)	46 (70%)
Incidence/100 PY (95% CI)[b,c]	521 (266, 776)	238 (139, 338)	164 (117, 212)
Serious AE	0	2 (5%)	4 (6%)
Incidence/100 PY (95% CI)[b,d]	0 (0, 44)	15 (2, 54)	7 (2, 18)
AE leading to discontinuation	0	0	0
Incidence/100 PY (95% CI)[b,d]	0 (0, 44)	0 (0, 22)	0 (0, 5)
Infection	6 (27%)	14 (32%)	31 (47%)
Incidence/100 PY (95% CI)[b,c]	116 (23, 209)	130 (62, 198)	78 (50, 105)
Serious infection	0	0	0
Incidence/100 PY (95% CI)[b,d]	0 (0, 44)	0 (0, 22)	0 (0, 5)
Gastrointestinal AE	1 (5%)	2 (5%)	5 (8%)
Incidence/100 PY (95% CI)[b,d]	15 (<1, 85)	15 (2, 53)	9 (3, 21)
Malignancy	0	0	0
Incidence/100 PY (95% CI)[b,d]	0 (0, 44)	0 (0, 22)	0 (0, 5)

*Data shown are n (%), unless otherwise noted. Safety analysis set included all randomized and treated pts. [a]Includes pts receiving ICO through W52 and data after W16 for pts receiving PBO who transitioned to ICO. [b]Incidence/100 PY, (number of pts with AEs/total PY at risk) × 100. [c]CIs were based on a Wald statistic using the normal assumption. [d]CIs were based on an exact method assuming that the observed number of events follows a Poisson distribution. **AE**=adverse events, **CI**=confidence interval, **ICO**=icotrokinra, **PBO**=placebo, **PY**=participant-years, **W**=week.*

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