

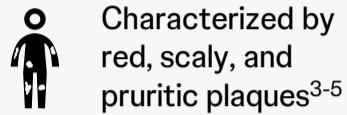
# EVIDENCE SUMMARY: ICOTYDE (icotrokinra)

ICOTYDE is an interleukin-23 (IL-23) receptor antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.<sup>1</sup>

Icotrokinra is a targeted oral peptide that selectively blocks IL-23 pathway activation<sup>2</sup>



Psoriasis (PsO) is a chronic, immune-mediated inflammatory skin disease<sup>3-5</sup>



Characterized by red, scaly, and pruritic plaques<sup>3-5</sup>



Up to **80%** of patients with PsO have scalp involvement<sup>6</sup>



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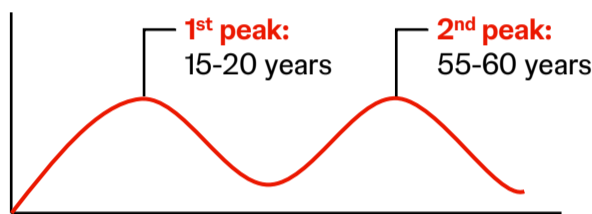
An unmet need exists for advanced oral therapies



Biologics require **injections or infusions**, which can be unsettling and inconvenient for patients<sup>8-10</sup>

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GI intolerability (e.g., PDE4i)<sup>12</sup>



Risks like infections and malignancies (e.g., TYK2i)<sup>12,13</sup>



**modest efficacy** relative to injectable biologics<sup>12,14-16</sup>

## ICONIC-ADVANCE

## ICONIC-LEAD

## ICONIC-TOTAL

## Adverse Events

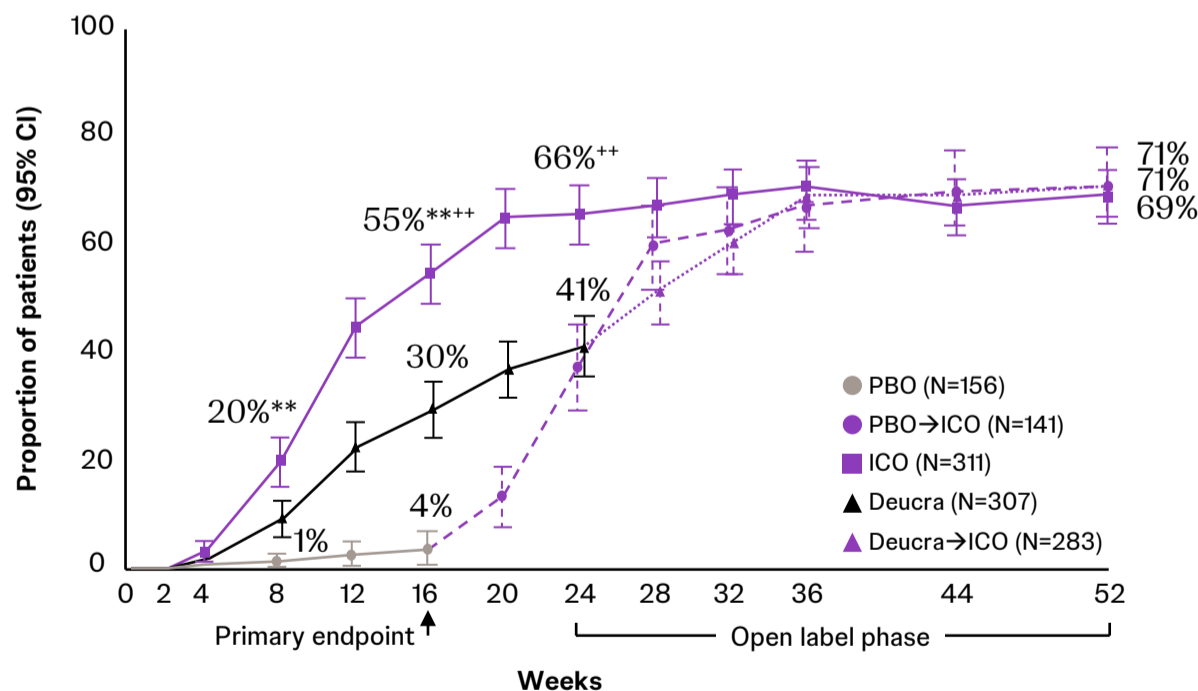
## Safety Information Summary

## ICONIC-ADVANCE<sup>17,18</sup>

Replicate phase 3, double-blind, placebo-controlled and active comparator-controlled, trial of participants  $\geq 18$  years with moderate to severe plaque PsO

## Study design

## ICONIC-ADVANCE 1: PASI 90



## ICONIC-ADVANCE 2:

PASI 90 %(n)<sup>d</sup>

**Week 8 ICO: 25% (81/320)**  
vs PBO: 0% (0/81)\*  
vs Deucra: 12% (37/322)

**Week 16 ICO: 58% (184/320)**  
vs PBO: 1% (1/81)\*\*  
vs Deucra: 35% (111/322)\*\*

**Week 24 ICO: 65% (208/320)**  
vs PBO→ICO: 23% (17/73)  
vs Deucra: 44% (141/322)\*\*

**Week 52 ICO: 72% (230/320)**  
vs PBO→ICO: 75% (55/73)  
vs Deucra→ICO: 78% (232/296)

## PASI 90

## IGA 0/1

Multiplicity adjusted \* $P < 0.01$ , \*\* $P < 0.001$  vs Placebo, \*\* $P < 0.001$  vs DEUCRA. IGA 0/1 and PASI 90 at Week 52 was not multiplicity controlled. Therefore, statistical significance has not been established. Primary endpoint at week 16.

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Deucra; Sotyktu (deucravacitinib); CI, confidence interval; GI, gastrointestinal; HCP, healthcare professional; IBD, inflammatory bowel disease; ICO, icotrokinra; IGA, Investigator's Global Assessment; IL, interleukin; MOA, mechanism of action; NAFLD, nonalcoholic fatty liver disease; PASI, Psoriasis Area and Severity Index; PBO, placebo; PDE4i, phosphodiesterase-4 inhibitors; TYK2i, tyrosine kinase 2 inhibitor.

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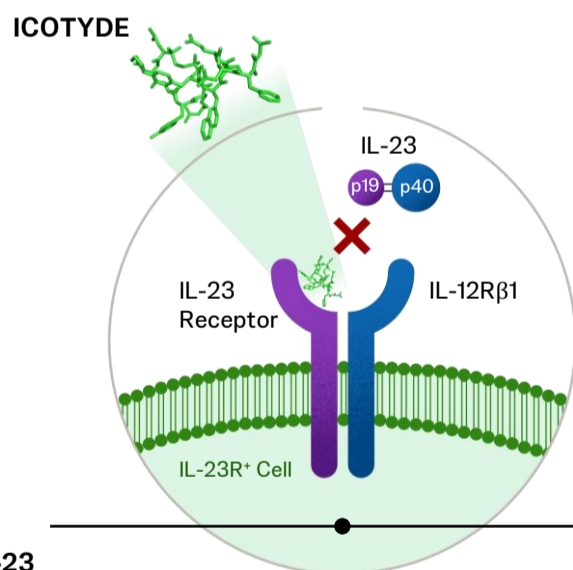


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## ICOTYDE



ICOTYDE is a targeted oral peptide that selectively blocks IL-23 pathway activation<sup>2</sup>



ICOTYDE blocks IL-23 from binding to its receptor (IL-23R)

**Precisely inhibits IL-23 signaling**

**Inhibits IL-17A, IL-17F, and IL-22 production**

- **ICOTYDE is orally administered, GI stable**, and has properties<sup>a</sup> that allow it to be **absorbed systemically** to exert its **potent pharmacodynamic effect**<sup>1</sup>
- **ICOTYDE demonstrates high potency and selectivity** in reducing IL-23-mediated proximal signaling and downstream pro-inflammatory effector cytokine production<sup>1</sup>

**The clinical significance of this mechanistic information has not been established.**

<sup>a</sup>As a cyclic peptide; MW: 1898.19 g/mol.  
GI, gastrointestinal; IFN $\gamma$ , interferon gamma; IL, interleukin; MOA, mechanism of action.

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## ICOTYDE SAFETY INFORMATION SUMMARY



### Warnings and precautions



#### Infections

Avoid treatment with ICOTYDE in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ICOTYDE. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection and/or is not responding to standard therapy, monitor the patient closely and discontinue ICOTYDE until the infection resolves.



#### Tuberculosis (TB)

Consider evaluating for TB prior to initiating treatment with ICOTYDE based on clinical judgement. Consider anti-TB therapy prior to initiating ICOTYDE in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after ICOTYDE treatment. Avoid administering ICOTYDE to patients with active TB.



#### Immunizations

Avoid use of live vaccines in patients during treatment with ICOTYDE. Medications that interact with the immune system may increase the risk of the infection following administration of live vaccines. Prior to initiating therapy with ICOTYDE, complete immunizations according to current immunization guidelines.

### Adverse reactions

Most common adverse reactions ( $\geq 1\%$ ) are headache, nausea, cough, fungal infection, and fatigue. The adverse reactions observed in pediatric patients were consistent with the most common adverse reactions ( $\geq 1\%$ ) observed in the overall population.

### Use in specific populations



#### Moderate or Severe Renal Impairment

Monitor for potential adverse reactions when ICOTYDE is used in patients with an estimated glomerular filtration rate (eGFR)  $< 60$  mL/min.



#### Pregnancy

The available data on the use of ICOTYDE during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

Please read the full [Prescribing Information](#) and [Medication Guide](#) for ICOTYDE.

ICOTYDE™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

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## ICONIC-ADVANCE

## ICONIC-LEAD

## ICONIC-TOTAL

## Adverse Events

## Safety Information Summary

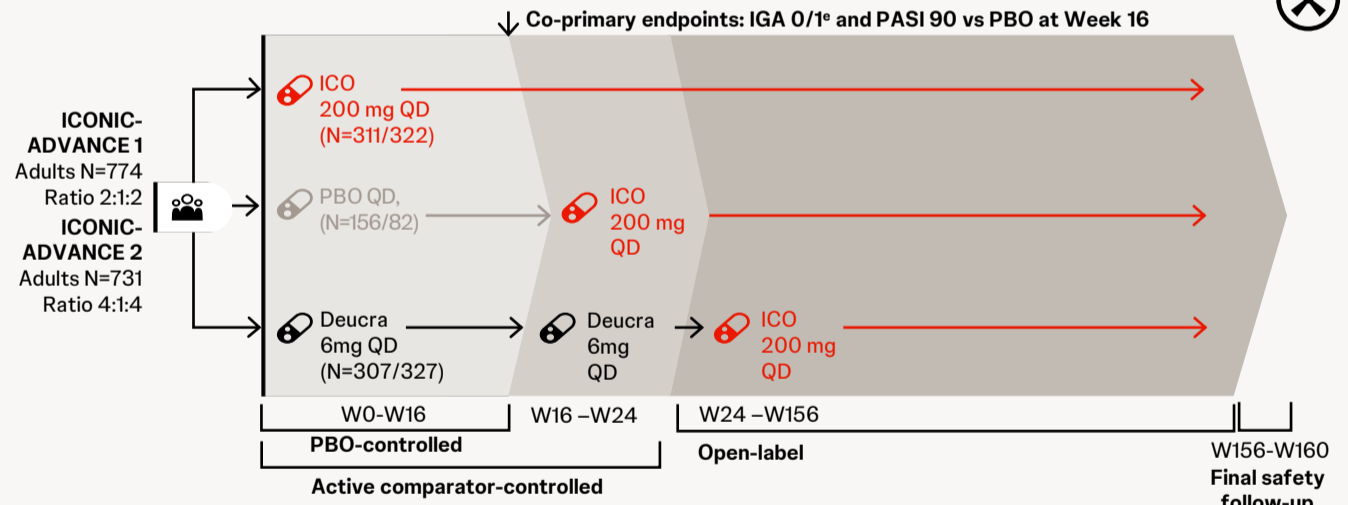
## ICONIC-ADVANCE<sup>17,18</sup>

Replicate phase 3, double-blind, placebo-controlled and active comparator-controlled, trial of participants  $\geq 18$  years with moderate to severe plaque PsO

## Study design

### Key eligibility criteria:

- $\geq 18$  years of age at the screening visit
- Plaque PsO for  $\geq 26$  weeks
- Total BSA  $\geq 10\%$  AND total PASI  $\geq 12$  AND total IGA  $\geq 3$  at screening and baseline.
- Candidate for phototherapy or systemic treatment for plaque PsO



**Key patient characteristics:**  
(Advance-1/Advance-2)

**Disease duration**

ICO: 18 years / 17 years  
PBO: 18 years / 21 years  
Deucra: 17 years / 17 years

**Percent BSA**

ICO: 20% / 21%  
PBO: 20% / 22%  
Deucra: 21% / 20%

**Bio experienced**

ICO: 28% / 24%  
PBO: 27% / 32%  
Deucra: 26% / 24%

ICO, icotrokinra; PBO, placebo; Q12W, every 12 weeks; QD, daily; W, week.

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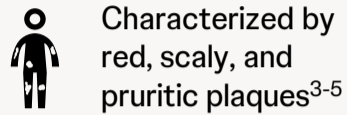
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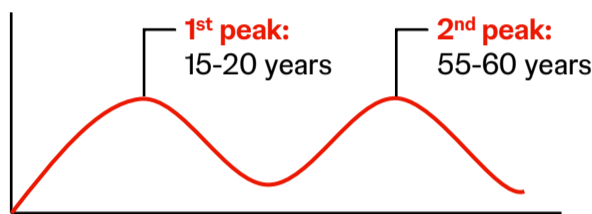
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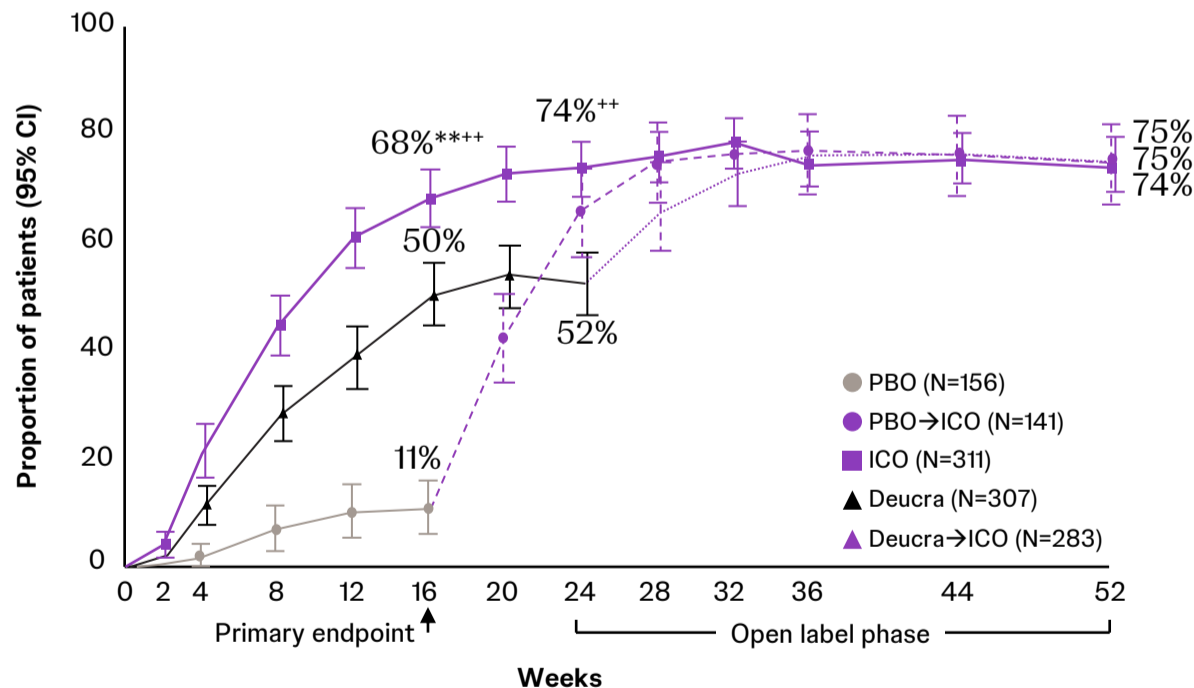
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## Study design

## ICONIC-ADVANCE 1: IGA<sup>e</sup> 0/1



## ICONIC-ADVANCE 2:

IGA 0/1 % (n)<sup>d</sup>

**Week 16** ICO: 71% (227/320)  
vs PBO: 9% (7/81)\*\*  
vs Deucra: 55% (177/322)\*\*

**Week 24** ICO: 69% (220/320)  
vs PBO→ICO: 51% (37/73)  
vs Deucra: 56% (179/322)\*\*

**Week 52** ICO: 73% (233/320)  
vs PBO→ICO: 80% (58/73)  
vs Deucra→ICO: 80% (238/296)

## PASI 90

## IGA 0/1

Multiplicity adjusted \* $P < 0.01$ , \*\* $P < 0.001$  vs Placebo, ++ $P < 0.001$  vs Deucra. IGA 0/1 and PASI 90 at Week 52 was not multiplicity controlled. Therefore, statistical significance has not been established. Primary endpoint at week 16.

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<sup>a</sup>eg, hypertension, dyslipidemia. <sup>b</sup>eg, obesity, metabolic syndrome, insulin resistance, diabetes. <sup>c</sup>Based on an interim analysis of a web-based United States survey between March-April 2025 of 393 adult patients with PsO and 200 HCPs. <sup>d</sup>ICONIC-ADVANCE 2 enrolled 731 patients, of which 723 patients were evaluable for efficacy. <sup>e</sup>IGA 0/1 response with a Grade  $\geq 2$  improvement from baseline.

Deucra; Sotyktu (deucravacitinib); CI, confidence interval; GI, gastrointestinal; HCP, healthcare professional; IBD, inflammatory bowel disease; ICO, icotrokinra; IGA, Investigator's Global Assessment; IL, interleukin; MOA, mechanism of action; NAFLD, nonalcoholic fatty liver disease; PASI, Psoriasis Area and Severity Index; PBO, placebo; PDE4i, phosphodiesterase-4 inhibitors; TYK2i, tyrosine kinase 2 inhibitor.

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Please read the full **Prescribing Information** and **Medication Guide** for ICOTYDE.

# EVIDENCE SUMMARY: ICOTYDE (icotrokinra)

ICOTYDE is an interleukin-23 (IL-23) receptor antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.<sup>1</sup>

Icotrokinra is a targeted oral peptide that selectively blocks IL-23 pathway activation<sup>2</sup>



Psoriasis (PsO) is a chronic, immune-mediated inflammatory skin disease<sup>3-5</sup>



Characterized by red, scaly, and pruritic plaques<sup>3-5</sup>



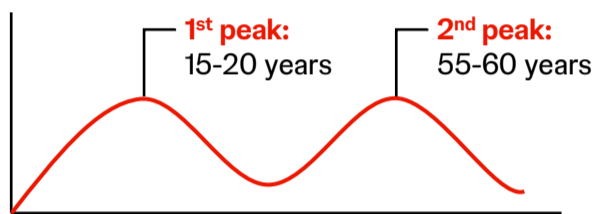
Up to **80%** of patients with PsO have scalp involvement<sup>6</sup>



**Comorbid conditions** commonly observed in patients with PsO include<sup>7</sup>:

- Arthritis, cardiovascular disease<sup>a</sup>, metabolic disease<sup>b</sup>, IBD, depression/anxiety, NAFLD, uveitis

Bimodal onset has been reported<sup>4</sup>:



An unmet need exists for advanced oral therapies



Biologics require **injections or infusions**, which can be unsettling and inconvenient for patients<sup>8-10</sup>

**Oral therapy is the most preferred route of administration** for treating PsO among US adult patients and HCPs<sup>11,c</sup>

Current advanced oral therapies have **several limitations** including:



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Risks like infections and malignancies (e.g., TYK2i)<sup>12,13</sup>



**modest efficacy** relative to injectable biologics<sup>12,14-16</sup>

ICONIC-ADVANCE

**ICONIC-LEAD**

ICONIC-TOTAL

Adverse Events

Safety Information Summary

ICONIC-LEAD<sup>19,20</sup>

A phase 3, double-blind, placebo-controlled, trial of participants  $\geq 12$  years with moderate to severe plaque PsO

Study design

Adolescent population

Co-primary endpoints: IGA 0/1 and PASI 90 at Week 16

Week 16



Week 24

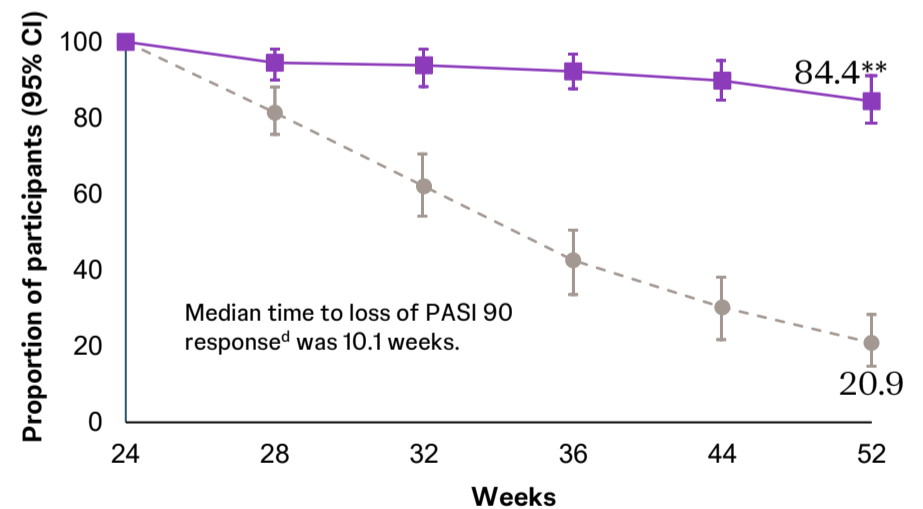


■ ICO (N=456) ■ PBO (N=228)

\*\*adjusted p-value <0.001 vs placebo

Durability of response: IGA 0/1 and PASI 90

PASI 90 maintenance through week 52 among PASI 90 responders at week 24



● PBO (N=129) ■ ICO (N=128)

\*\*Multiplicity-adjusted p<0.001 vs PBO

PASI 90

IGA 0/1

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Please read the full Prescribing Information and Medication Guide for ICOTYDE.

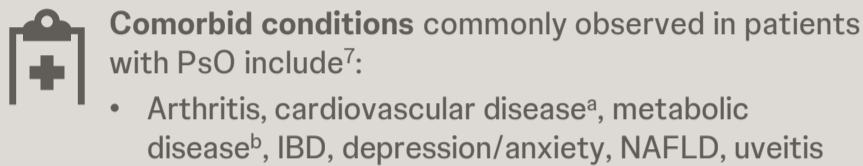
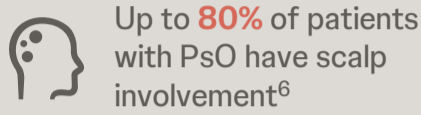
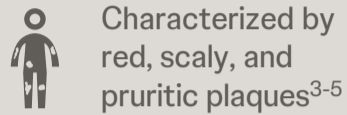
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ICONIC-ADVANCE

**ICONIC-LEAD**

ICONIC-TOTAL

Adverse Events

Safety Information Summary

ICONIC-LEAD<sup>19,20</sup>

A phase 3, double-blind, placebo-controlled, trial of participants ≥12 years with moderate to severe plaque PsO

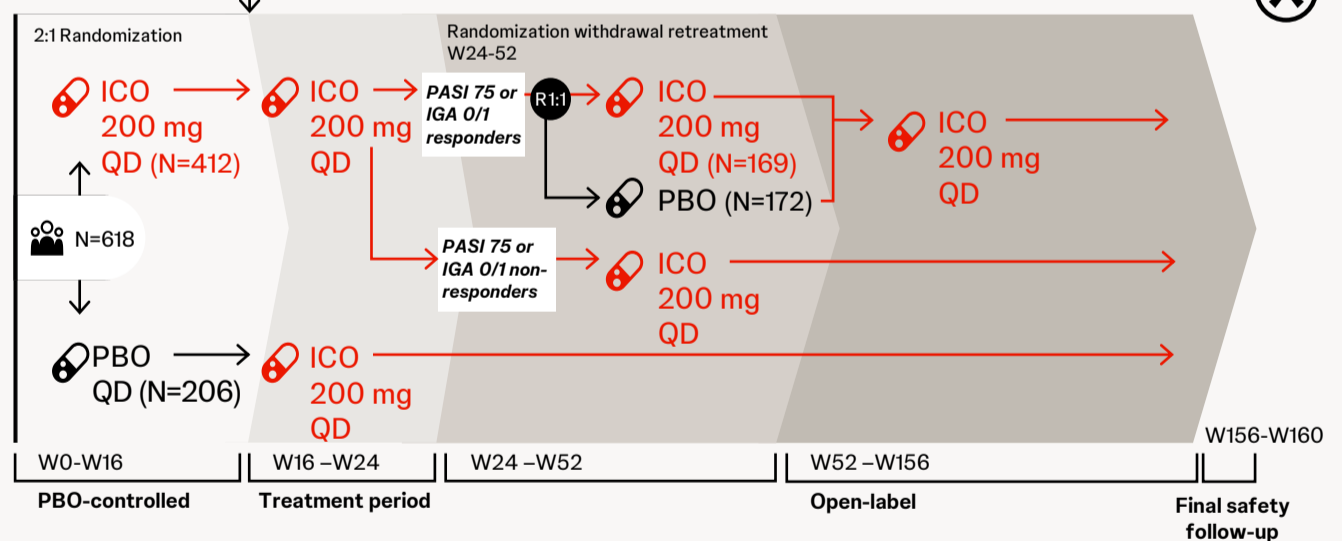
**Study design**

Adolescent population

## Key eligibility criteria:

- ≥12 years of age at the screening visit
- Plaque PsO for ≥26 weeks
- Total BSA ≥10% AND total PASI ≥12 AND total IGA ≥3 at screening and baseline.
- Candidate for phototherapy or systemic treatment for plaque PsO

## Adults



## Key patient characteristics:

**Disease duration**  
ICO: 17 years  
PBO: 17 years

**Percent BSA**  
ICO: 25%  
PBO: 27%

**Bio experienced**  
ICO: 32%  
PBO: 37%

ICO, icotrokinra; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PBO, placebo; QD, daily; R, randomized; W, week.

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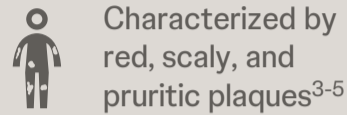
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ICONIC-ADVANCE

**ICONIC-LEAD**

ICONIC-TOTAL

Adverse Events

Safety Information Summary

ICONIC-LEAD<sup>19,20</sup>

A phase 3, double-blind, placebo-controlled, trial of participants  $\geq 12$  years with moderate to severe plaque PsO

Study design

**Adolescent population**

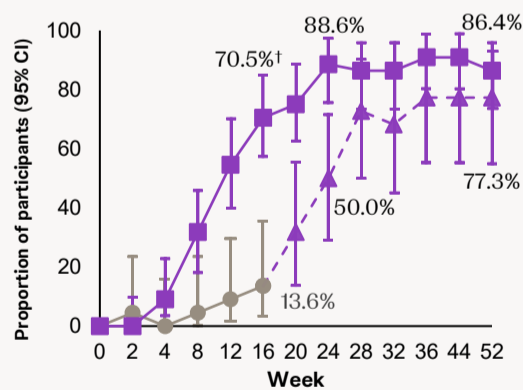
## Adolescent population from ICONIC-LEAD

**ICONIC-LEAD Adolescent population<sup>21</sup>:** Participants 12 to <18 years (body weight  $\geq 40$  kg) (N=66) were randomized 2:1 to receive ICO 200 mg QD or PBO. Patients receiving PBO to Week 16 were transitioned to ICO 200 mg QD. At Week 52, participants will be transitioned to open-label icotrokinra through Week 156.

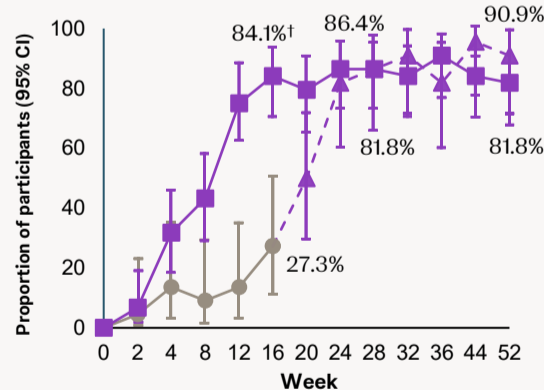


**Results were analyzed as a subgroup and p values are nominal.**

### PASI 90 (NRI)



### IGA 0/1<sup>a</sup> (NRI)



■ ICO (n=44) ● PBO (n=22) ▲ PBO → ICO (n=22) †nominal  $p < 0.001$  vs. PBO

### ICONIC-LEAD (adolescent population) safety<sup>21,22</sup>

Safety analysis set	Through W16 PBO (N=22)	ICO (N=44)	Through W52 ICO combined <sup>b</sup> (N=66)
Mean duration follow-up (weeks)	16.2	16.2	46.3
Any AE, n (%)	16 (73%)	22 (50%)	46 (70%)
SAE, n (%)	0	2 (4%) <sup>c,d</sup>	4 (6%)
Infection, n (%)	6 (27%)	14 (32%)	31 (47%)
Serious infection, n (%)	0	0	0
GI AE, n (%)	1 (5%)	2 (5%)	5 (8%)
Malignancy	0	0	0

<sup>a</sup>IGA 0/1 response with a Grade  $\geq 2$  improvement from baseline. <sup>b</sup>Includes pts receiving ICO through W52 and data after W16 for pts receiving PBO who transitioned to ICO. <sup>c</sup>17-year-old female with a medical history of obesity and a gastric sleeve procedure leading to rapid weight loss before entering the study. CT and ultrasound showed pancreatitis due to cholelithiasis. Cholecystectomy was performed and she was discharged in good condition. Treatment was interrupted but resumed after resolution and she continues in the study. <sup>d</sup>17-year-old female with medical history of joint pain was admitted to the hospital at W4 of the study for further diagnostic evaluation of joint pain. No imaging studies were completed. Treatment was continued without interruption. She was discharged the next day in good condition. No diagnosis was confirmed.

AE, adverse event; CT, computed tomography; ICO, icotrokinra; IGA, Investigator's Global Assessment; NRI, nonresponder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; QD, daily; SAE, serious adverse event; TB, tuberculosis; W, week.

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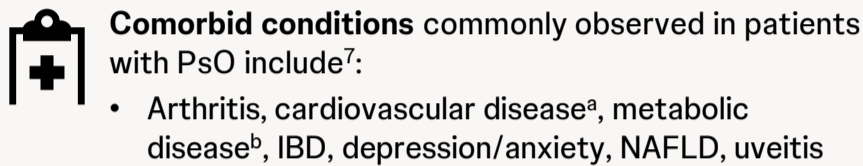
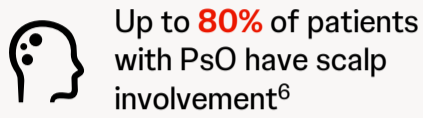
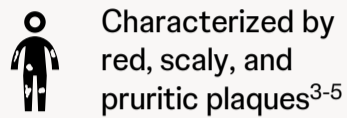
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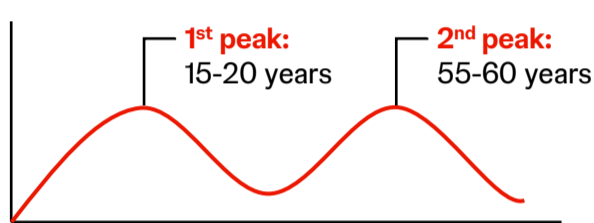
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ICONIC-ADVANCE

**ICONIC-LEAD**

ICONIC-TOTAL

Adverse Events

Safety Information Summary

ICONIC-LEAD<sup>19,20</sup>

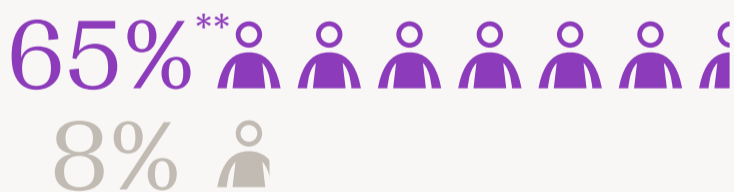
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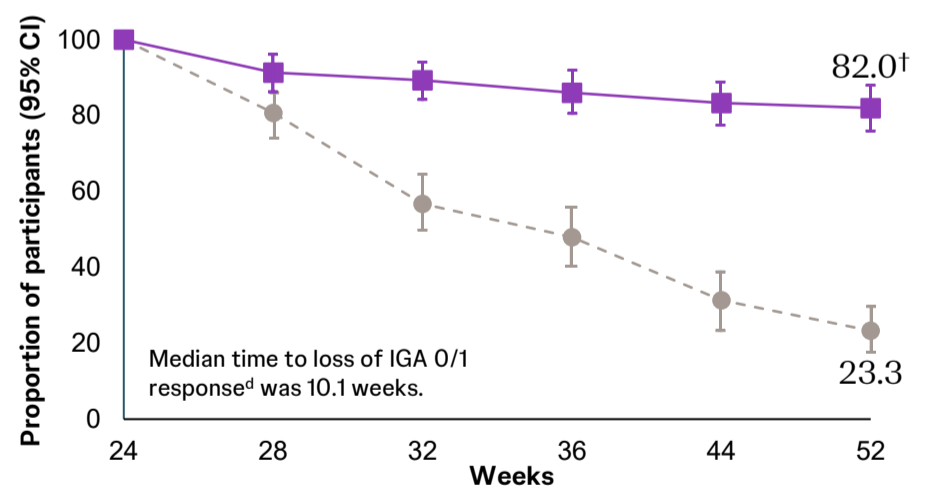


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IGA 0/1 maintenance through week 52 among IGA 0/1 responders at week 24



PBO (N=129) ICO (N=128)

†Nominal p<0.001 vs PBO

PASI 90

**IGA 0/1**

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1. ICOTYDE™ [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. Fourie AM, et al. *Sci Rep*. 2024;14(1):17515. 3. Parisi R, et al. *BMJ*. 2020; 369: m1590. 4. Langley RG, et al. *Ann Rheum Dis*. 2005; 64 Suppl 2(Suppl 2):ii18-23; discussion ii24-5. 5. Weigle N, McBane S. *Ann Fam Physician*. 2013; 87(9):626-33. 6. Chan C, et al. *J Am Acad Dermatol*. 2009;60(6):962-71. 7. Elmets C, et al. *J Am Acad Dermatol*. 2019;80(4):1073-1113. 8. Feldman SR, et al. *J Health Econ Outcomes Res*. 2016;4(2):141-157. 9. Komine M, et al. *J Dermatol*. 2023;50(6):766-777. 10. Duncanson E, et al. *PLoS One*. 2021;16(6):e0253048. 11. Stein Gold L, et al. Presented at 2025 AAD Innovation Academy; July 10-13, 2025; Chicago, IL. 12. Armstrong AW, et al. *JAMA Dermatol*. 2020;156(3):258-269. 13. Armstrong AW, et al. *J Am Acad Dermatol*. 2023;88(1)(suppl):29-39. 14. Armstrong AW, et al. *J Am Acad Dermatol*. 2023;88(1):29-39. 15. Stein Gold LF, et al. *Br J Dermatol*. 2023;189(5):540-552. 16. Armstrong AW, et al. *Dermatol Ther (Heidelb)*. 2023;13(11):2839-2857. 19. Bissonnette R, et al. *N Engl J Med* 2025;393:1784-1795. 20. Soung J, et al. Presented at European Academy of Dermatology and Venereology (EADV); September 17-20, 2025; Paris, France.

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Please read the full **Prescribing Information** and **Medication Guide** for ICOTYDE.

# EVIDENCE SUMMARY: ICOTYDE (icotrokinra)

ICOTYDE is an interleukin-23 (IL-23) receptor antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.<sup>1</sup>

Icotrokinra is a targeted oral peptide that selectively blocks IL-23 pathway activation<sup>2</sup>



Psoriasis (PsO) is a chronic, immune-mediated inflammatory skin disease<sup>3-5</sup>

Characterized by red, scaly, and pruritic plaques<sup>3-5</sup>

Up to **80%** of patients with PsO have scalp involvement<sup>6</sup>

**Comorbid conditions** commonly observed in patients with PsO include<sup>7</sup>:

- Arthritis, cardiovascular disease<sup>a</sup>, metabolic disease<sup>b</sup>, IBD, depression/anxiety, NAFLD, uveitis

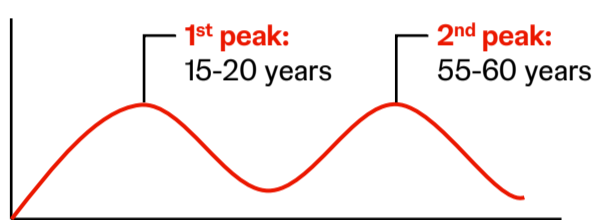
An unmet need exists for advanced oral therapies



Biologics require **injections or infusions**, which can be unsettling and inconvenient for patients<sup>8-10</sup>

**Oral therapy is the most preferred route of administration** for treating PsO among US adult patients and HCPs<sup>11,c</sup>

**Bimodal onset** has been reported<sup>4</sup>:



Current advanced oral therapies have **several limitations** including:



GI intolerability (e.g., PDE4i)<sup>12</sup>



Risks like infections and malignancies (e.g., TYK2i)<sup>12,13</sup>



**modest efficacy** relative to injectable biologics<sup>12,14-16</sup>

ICONIC-ADVANCE

ICONIC-LEAD

**ICONIC-TOTAL**

Adverse Events

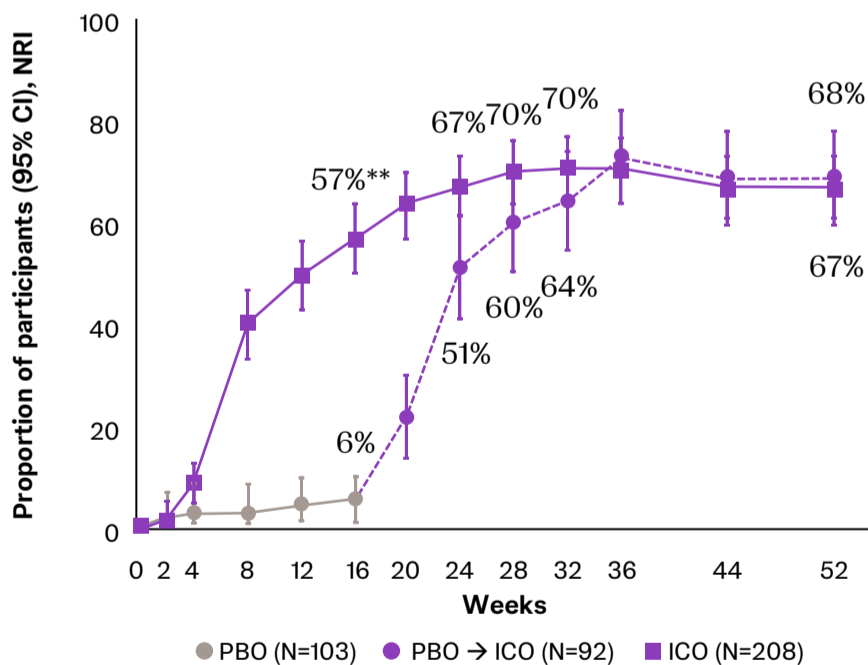
Safety Information Summary

**ICONIC-TOTAL<sup>23</sup>**

A phase 3, double-blind, placebo-controlled, trial of participants  $\geq 12$  years with moderate to severe plaque PsO involving difficult-to-treat, high-impact sites.

Study design

## IGA 0/1 (Primary endpoint)



## Scalp: ss-IGA 0/1<sup>a,c</sup>

**Week 16 ICO: 66%\*\* (N=176) vs PBO: 11% (N=85)**

**Week 24 ICO: 78% vs PBO → ICO: 61% (N=75)**

**Week 52 ICO: 72% vs PBO → ICO: 72%**

## Genital: sPGA-G 0/1<sup>a,d</sup>

**Week 16 ICO: 77%\*\* (N=98) vs PBO: 21% (N=42)**

**Week 24 ICO: 90% vs PBO → ICO: 81% (N=36)**

**Week 52 ICO: 85% vs PBO → ICO: 94%**

## Hand/foot: hf-PGA 0/1<sup>b,e</sup>

**Week 16 ICO: 42% (N=48) vs PBO: 26% (N=23)**

**Week 24 ICO: 54% vs PBO → ICO: 47% (N=19)**

**Week 52 ICO: 62% vs PBO → ICO: 68%**

**Multiplicity-adjusted \*\*p<0.001 vs PBO. Week 52 was not multiplicity controlled. Therefore, statistical significance has not been established.** Scalp, genital and palmoplantar subpopulations are not mutually exclusive.<sup>a</sup>P values were based on Cochran-Mantel-Haenszel chi-square test stratified by geographic region and/or BSA category. <sup>b</sup>Results are not statistically significant. <sup>c</sup>ss-IGA ranges from 0 (absence) to 4 (severe disease). <sup>d</sup>sPGA-G ranges from clear (0) to very severe (5). <sup>e</sup>hf-PGA ranges from clear (0) to severe (4).

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<sup>a</sup>eg, hypertension, dyslipidemia. <sup>b</sup>eg, obesity, metabolic syndrome, insulin resistance, diabetes. <sup>c</sup>Based on an interim analysis of a web-based United States survey between March-April 2025 of 393 adult patients with PsO and 200 HCPs.

GI, gastrointestinal; CI, confidence interval; HCP, healthcare professional; IBD, inflammatory bowel disease; ICO, icotrokinra; IGA, Investigator's Global Assessment; IL, interleukin; MOA, mechanism of action; NAFLD, nonalcoholic fatty liver disease; NRI, nonresponder imputation; PBO, placebo; PDE4i, phosphodiesterase-4 inhibitors; ss-IGA, scalp-specific Investigator's Global Assessment; TYK2i, tyrosine kinase 2 inhibitor.

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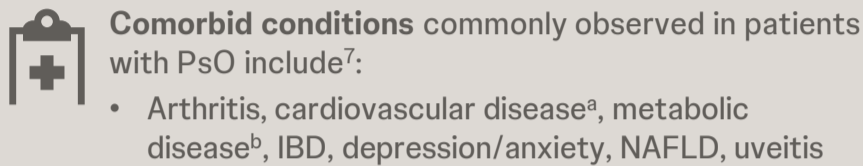
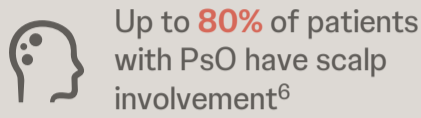
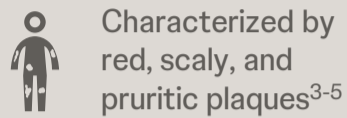
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Psoriasis (PsO) is a chronic, immune-mediated inflammatory skin disease<sup>3-5</sup>



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ICONIC-ADVANCE

ICONIC-LEAD

**ICONIC-TOTAL**

Adverse Events

Safety Information Summary

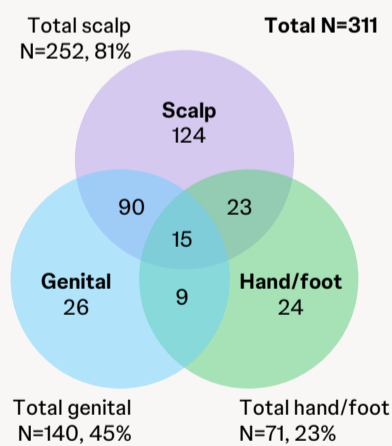
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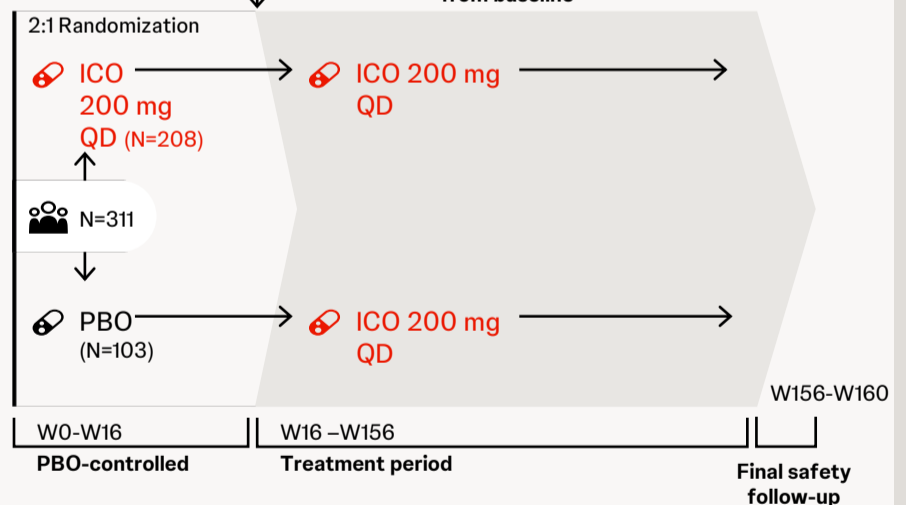
**Study design**

## Key eligibility criteria:

- ≥12 years of age at the screening visit
- Plaque PsO for ≥26 weeks
- Total BSA ≥1% AND total IGA ≥2 at screening and baseline.
- 1+ high impact-area involvement at screening & baseline: ss-IGA ≥3, sPGA-G ≥3, and/or hf-PGA ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO and failed ≥1 topical



Primary endpoint: IGA 0/1 & ≥2-grade improvement from baseline



## Key patient characteristics:

**Disease duration**

ICO: 17 years  
PBO: 15 years

**Percent BSA**

ICO: 17%  
PBO: 15%

**Bio experienced**

ICO: 34%  
PBO: 31%

ICO, icotrokinra; IGA, Investigator's Global Assessment; PBO, placebo; QD, daily; W, week.

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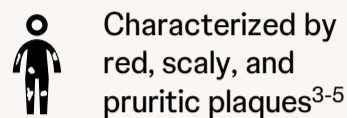
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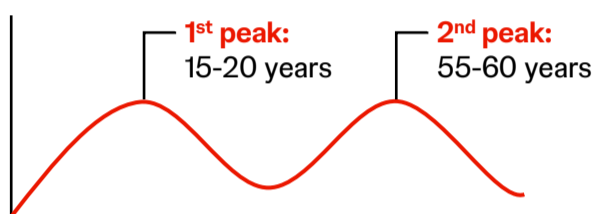
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ICONIC-ADVANCE

ICONIC-LEAD

ICONIC-TOTAL

**Adverse Events**

Safety Information Summary

Treatment-emergent adverse events (TEAE) across multiple trials in PsO<sup>18,a</sup>

Data originated from separate trials for ICOTYDE.

Safety analysis set	16-Week safety ICONIC LEAD+TOTAL+ADV-1+ADV-2		24-Week safety ICONIC ADV-1+ADV-2		Safety data cut-off ICONIC LEAD (W52) + TOTAL (W52) + ADV-1 (W44) + ADV-2 (W24)
	Placebo (N=568)	ICO (N=1296)	ICO (N=632)	Deucra (N=634)	ICO (N=2367) <sup>b</sup>
Duration of follow up (weeks)	15.63	15.92	23.54	23.28	34.58
Participants with ≥1 AE:	295 (51.9%)	636 (49.1%)	364 (57.6%)	414 (65.3%)	1460 (61.7%)
Participants with ≥1 SAE:	12 (2.1%)	21 (1.6%)	18 (2.8%)	20 (3.2%)	76 (3.2%)
Serious Infections	2 (0.4%)	2 (0.2%)	3 (0.5%)	5 (0.8%)	12 (0.5%)
Malignancies (excluding NMSC) <sup>c</sup>	1 (0.2%)	5 (0.4%)	2 (0.3%)	2 (0.3%)	8 (0.3%)
Active TB	0	0	0	0	0
AEs leading to discontinuations	17 (3.0%)	26 (2.0%)	16 (2.5%)	19 (3.0%)	48 (2.0%)
Deaths	0	2 (0.2%)	2 (0.3%)	0	5 (0.2%)

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<sup>a</sup>Data shown are n (%) unless otherwise noted. Participants are counted only once for any given event, regardless of the number of times they actually experienced the event. Adverse events are coded using the MedDRA Version 27.0. <sup>b</sup>Includes data for subjects randomized to ICO, data after Week 16 for placebo subjects who crossed over to receive ICO, and data after Week 24 for deucravacitinib subjects who switched over to receive ICO. <sup>c</sup>Malignancies on ICO: Adenocarcinoma of the colon diagnosis on day 19; Prostate cancer diagnosis on day 48; Pancreatic cancer with liver metastasis presenting with symptoms on day 25; Melanoma in situ diagnosis at Week 16 in a patient with history of melanoma; Breast cancer diagnosis on day 24. Malignancies on Placebo: Infiltrating carcinoma of left breast identified on day 6. Malignancies on Deucra: Squamous cell carcinoma of right buccal mucosa between week 16 and week 20; Malignant melanoma in situ diagnosis at Week 16.

ADV, ICONIC-Advance; AE, adverse event; GI, gastrointestinal; Deucra, Sotyktu (deucravacitinib); HCP, healthcare professional; IBD, inflammatory bowel disease; ICO, icotrokinra; IL, interleukin; MOA, mechanism of action; NAFLD, nonalcoholic fatty liver disease; NMSC, non-melanoma skin cancer; PBO, placebo; PDE4i, phosphodiesterase-4 inhibitors; SAE, serious adverse event; TB, tuberculosis; TYK2i, tyrosine kinase 2 inhibitor; Wk, week.

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