ICOTYDE™
(icotrokinra) tablets

IT'S UNBELIEVABLE

The first and only IL-23R targeted oral peptide in a once-daily pill[1,2]

Pill not actual size.
IL-23R, interleukin-23 receptor.

INDICATION

ICOTYDE™ (icotrokinra) 200 mg is 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.

IMPORTANT SAFETY INFORMATION

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.

Please see Important Safety Information throughout. Please read the full Prescribing Information and Medication Guide for ICOTYDE.

THE ICONIC CLINICAL TRIAL PROGRAM

Trial designs[1,3-5]

ICONIC-ADVANCE 1/ICONIC-ADVANCE 2

ICONIC-ADVANCE 1 (N=774) and ICONIC-ADVANCE 2 (N=731): Two phase 3, multicenter, randomized, double-blind, placebo-controlled and active comparator–controlled trials that evaluated the efficacy and safety of ICOTYDE 200 mg orally once daily in adults with moderate to severe plaque psoriasis defined as IGA ≥3, PASI ≥12, and BSA ≥10%. Patients randomized to placebo crossed over to ICOTYDE at Week 16. Patients randomized to deucravacitinib 6 mg orally once daily crossed over to ICOTYDE at Week 24. Patients received open-label ICOTYDE after Week 24 through Week 156. Safety will be assessed through Week 160.

ICONIC-LEAD

ICONIC-LEAD (N=684): A phase 3, multicenter, randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of ICOTYDE 200 mg orally once daily in adult and adolescent patients 12 years of age and older and weighing at least 40 kg with moderate to severe plaque psoriasis, defined as IGA ≥3, PASI ≥12, and BSA ≥10%. Patients randomized to placebo crossed over to ICOTYDE at Week 16. Adults with a treatment response entered randomized withdrawal and retreatment from Week 24 to Week 52. Patients received open-label ICOTYDE from Week 52 to Week 156. Safety will be assessed through Week 160.

ICONIC-TOTAL

ICONIC-TOTAL (N=311): A phase 3, multicenter, randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of ICOTYDE 200 mg orally once daily in adult and adolescent patients 12 years of age and older and weighing at least 40 kg with moderate to severe plaque psoriasis who had a minimum BSA involvement of ≥1% and IGA ≥2 and had failed to respond to ≥1 topical therapies. Patients had at least 1 of the following baseline conditions: ss-IGA score ≥3, sPGA-G score ≥3, and/or hf-PGA score ≥3. Patients randomized to placebo crossed over to ICOTYDE at Week 16. Efficacy will be evaluated through Week 156. Safety will be evaluated through Week 160.

BSA, body surface area; hf-PGA, Physician's Global Assessment of Hands and Feet; IL-23, interleukin-23; IL-23R, interleukin-23 receptor; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; sPGA-G, Static Physician's Global Assessment of Genitalia; ss-IGA, Scalp-Specific Investigator's Global Assessment.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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PROVEN SAFETY PROFILE

ACROSS 4 PHASE 3 TRIALS WITH 2300+ PATIENTS[1,6*]

RATES OF ADVERSE REACTIONS WERE WITHIN 1% OF PLACEBO[1†]

ADVERSE REACTIONS THROUGH WEEK 16[*†]

	ICOTYDE (n=1296) % (n)	Placebo (n=568) % (n)
Headache	**4.1%** (51)	**3.3%** (19)
Nausea	**1.2%** (15)	**0.5%** (3)
Cough	**1.2%** (15)	**0.2%** (1)
Fungal infection		
Tinea	**0.5%** (6)	**0.0%** (0)
Other[‡]	**0.8%** (10)	**0.0%** (0)
Fatigue	**1.0%** (15)	**0.5%** (3)

RATES OF DISCONTINUATION WERE WITHIN 1% OF PLACEBO[6]

ADVERSE EVENTS THROUGH WEEK 16[*]

	ICOTYDE (n=1296) % (n)	Placebo (n=568) % (n)
Adverse events leading to discontinuation[§]	**2.0%** (26)	**3.0%** (17)
Adverse events	**49.1%** (636)	**51.9%** (295)
Serious adverse events	**1.6%** (21)	**2.1%** (12)
Infections	**24.0%** (311)	**26.1%** (148)
Serious infections	**0.2%** (2)	**0.4%** (2)

Warnings and Precautions include infections, tuberculosis, and immunizations[1]

When treating with ICOTYDE:

NO labeled warnings and precautions for malignancy, IBD, depression, or candidiasis[‖‖]
NO routine lab monitoring[¶¶]
NO reports of new or reactivated latent TB infections to date[1,6#]
NO identified drug–drug interactions[1**]

*Based on safety analysis set. Data were pooled across ADVANCE 1, ADVANCE 2, LEAD, and TOTAL.
†Refers to adverse reactions ≥1% with ICOTYDE and more frequently than placebo.
‡Includes oral candidiasis, onychomycosis, skin candida, urinary tract candidiasis, vulvovaginal candidiasis, fungal skin infection, genital infection fungal, ear infection fungal, laryngitis fungal. Two patients experienced more than 1 event.
§Due to 1 or more adverse events.
‖‖Fungal infection including oral candidiasis (n=2), skin candida (n=1), urinary tract candidiasis (n=1), and vulvovaginal candidiasis (n=1) have been reported with ICOTYDE.
¶¶Consider evaluating patients for TB and instruct patients to report signs and symptoms of infection.
#As of initial US approval: 2026.
**No formal studies have been conducted and no clinically significant drug interactions have been identified.

IBD, inflammatory bowel disease; TB, tuberculosis.

See trial designs on page 2.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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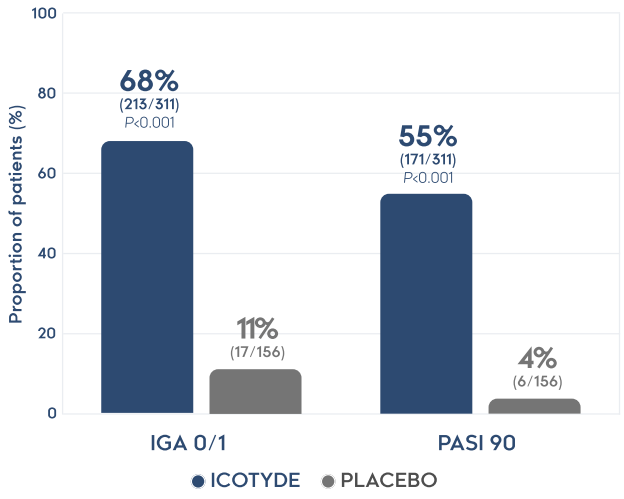
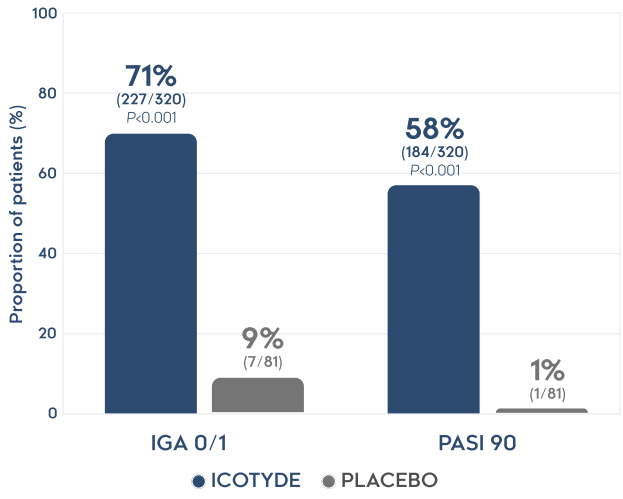
POWERFUL SKIN CLEARANCE WITH ICOTYDE[1]

Based on 2 phase 3, multicenter, randomized, double-blind, placebo-controlled trials with patients with moderate to severe plaque psoriasis[1]:

ICONIC-ADVANCE 1
Co-primary endpoints at Week 16 (NRI)[1,3]



ICONIC-ADVANCE 2
Co-primary endpoints at Week 16 (NRI)[1,3*]



IGA 0: ADVANCE 1

COMPLETELY CLEAR SKIN
~1 IN 2 PATIENTS AT WEEK 24[1]

IGA 0 at Week 24 (NRI)[1,3]
- ADVANCE 1: 48% (150/311) ICOTYDE vs 21% (63/307) active comparator (*P*<0.001)
- ADVANCE 2: 40% (128/320) ICOTYDE vs 21% (68/322) active comparator (*P*<0.001)

PASI 100 at Week 24 (NRI)[1,3]
- ADVANCE 1: 41% (129/311) ICOTYDE vs 16% (49/307) active comparator (*P*<0.001)
- ADVANCE 2: 33% (107/320) ICOTYDE vs 16% (52/322) active comparator (*P*<0.001)

Key secondary endpoints

*ADVANCE 2 enrolled 731 patients, of whom 723 patients were evaluable for efficacy.

IGA, Investigator's Global Assessment; NRI, nonresponder imputation; PASI, Psoriasis Area and Severity Index.

See trial designs on page 2.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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

Please see Important Safety Information throughout. Please read the full Prescribing Information and Medication Guide for ICOTYDE.

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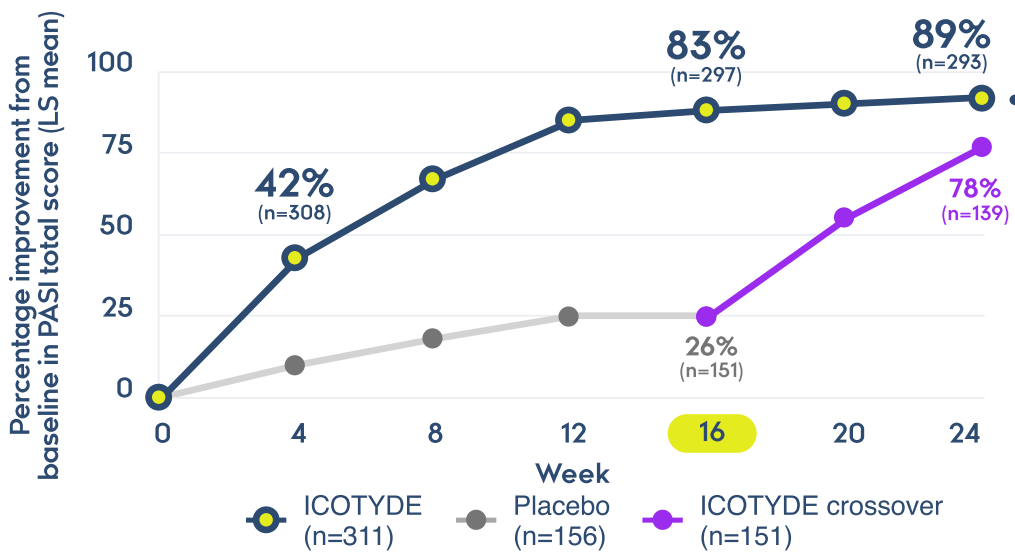
CLEARER SKIN WITH ICOTYDE[6]

Mean PASI improvement from baseline*



ON AVERAGE, PATIENTS SAW:

~90% CLEARER SKIN AT WEEK 24

42% MEAN PASI IMPROVEMENT AT WEEK 4

ADVANCE 1 other secondary endpoint measured at Week 16. Other endpoints were exploratory.

The same patients may not have responded at each time point.

Data were not multiplicity controlled. Therefore, statistical significance has not been established.

ADVANCE 2: mean PASI improvement from baseline (LS mean)*†

- Other secondary endpoint: ICOTYDE 85% (n=309) and placebo 26% (n=77) at Week 16
- Exploratory endpoints: ICOTYDE 47% (n=316) and placebo 17% (n=80) at Week 4; ICOTYDE 87% (n=304) and ICOTYDE crossover 79% (n=306) at Week 24

Mean percent improvement values are shown after Week 16 in patients on placebo who switched to ICOTYDE.

*Patients with missing data were not explicitly imputed; they were accounted for in the analysis model.
†ADVANCE 2 enrolled 731 patients, of whom 723 patients were evaluable for efficacy.

LS, least squares; PASI, Psoriasis Area and Severity Index.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see Important Safety Information throughout. Please read the full Prescribing Information and Medication Guide for ICOTYDE.

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BELIEVE IN ICOTYDE AS YOUR FIRST-CHOICE SYSTEMIC THERAPY[1]

PROVEN SAFETY PROFILE

Rates of adverse reactions were within 1% of placebo[1*]

Rates of adverse events leading to discontinuation were within 1% of placebo[6†]

Co-primary endpoints at Week 16[1]

- IGA 0/1 vs PBO in ADVANCE 1: 68% vs 11% (*P*<0.001) and in ADVANCE 2: 71% vs 9% (*P*<0.001)
- PASI 90 vs PBO in ADVANCE 1: 55% vs 4% (*P*<0.001) and in ADVANCE 2: 58% vs 1% (*P*<0.001)

PASI 100 at Week 24[1,3]

- PASI 100 vs active comparator in ADVANCE 1: 41% vs 16% (*P*<0.001) and in ADVANCE 2: 33% vs 16% (*P*<0.001)

COMPLETELY CLEAR SKIN IN UP TO 1 IN 2 PATIENTS AT WEEK 24[1,3]

IGA 0 vs active comparator in ADVANCE 1: 48% vs 21% (*P*<0.001) and in ADVANCE 2: 40% vs 21% (*P*<0.001)

ON AVERAGE, PATIENTS SAW ~90% CLEARER SKIN AT WEEK 24[6]

Mean PASI improvement from baseline was not multiplicity controlled

ALL IN A ONCE-DAILY PILL[1]

*Refers to adverse reactions ≥1% with ICOTYDE and more frequently than placebo.

†26 patients discontinued ICOTYDE and 17 patients discontinued placebo due to 1 or more adverse events through Week 16.

IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PBO, placebo.

Scan here or click to visit IcotydeHCP.com

Data rates may apply.

See additional safety and trial information inside.

Pill not actual size.

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

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.

Provide the Medication Guide to your patients and encourage discussion.

cp-564098v1

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References: 1. ICOTYDE [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Fourie AM, Cheng X, Chang L, et al. JNJ-77242113, a highly potent, selective peptide targeting the IL-23 receptor, provides robust IL-23 pathway inhibition upon oral dosing in rats and humans. *Sci Rep*. 2024;14(1):17515. doi:10.1038/s41598-024-67371-5 **3.** Gold LS, Armstrong AW, Bissonnette R, et al. Once-daily oral icotrokinra versus placebo and once-daily oral deucravacitinib in participants with moderate-to-severe plaque psoriasis (ICONIC-ADVANCE 1 & 2): two phase 3, randomised, placebo-controlled and active-comparator-controlled trials. *Lancet*. 2025;406(10510):1363-1374. doi:10.1016/S0140-6736(25)01576-4 **4.** Bissonnette R, Soung J, Hebert AA, et al. Oral icotrokinra for plaque psoriasis in adults and adolescents. *N Engl J Med*. 2025;393(18):1784-1795. doi:10.1056/NEJMoa2504187 **5.** Gooderham M, Lain E, Bissonnette R, et al. Targeted oral peptide icotrokinra for psoriasis involving high-impact sites. *NEJM Evid*. 2025;4(12):EVIDoa2500155. doi:10.1056/EVIDoa2500155 **6.** Data on file. Janssen Biotech, Inc.

Please see Important Safety Information throughout. Please read the full Prescribing Information and Medication Guide for ICOTYDE.

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