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

Robert Bissonnette,[1] Jennifer Soung,[2] Andrew E. Pink,[3] Darryl Toth,[4] Andreas Pinter,[5] Angela Moore,[6] Amy Paller,[7] Kilian Eyerich,[8] Jingzhi Jiang,[9] Santiago Munoz,[9] Ya-Wen Yang,[9] Megan Miller-Kassamali,[9] Cynthia DeKlotz,[9] Shu Li,[9] Mark Lebwohl[10]

[1]Innovaderm Research, Montréal, QC, Canada; [2]Southern California Clinical Research, Santa Ana and Harbor University of California Los Angeles, CA, USA; [3]St. John's Institute of Dermatology, Guy's & St. Thomas' NHS Foundation Trust and King's College London, London, UK; [4]Probity Medical Research, Windsor, ON, Canada; [5]University Hospital Frankfurt/Main, Frankfurt/Main, Germany; [6]Baylor University Medical Center, Dallas; University of North Texas Health Sciences Center, Texas Christian University, Fort Worth, TX, USA; University of Texas Medical Branch, Galveston; Arlington Center for Dermatology, Arlington, TX, USA; [7]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [8]University of Freiburg, Freiburg, Germany; [9]Johnson & Johnson, Spring House/Horsham, PA, USA; [10]Icahn School of Medicine at Mount Sinai, New York, NY, USA

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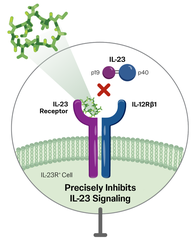
Key Takeaways

- **Through W112, among adults and adolescents with plaque PsO in the phase 3 ICONIC-LEAD study, ICO demonstrated:**
  - **High and durable rates of skin clearance and sustained improvements in patient-reported outcomes**
  - **Robust response recapture 24 weeks following retreatment**
  - **Stable exposure-adjusted AE rates, with no new safety signals identified**
- **These findings support the use of once-daily oral ICO for long-term management of PsO**

Background

- Plaque psoriasis (PsO) is a chronic inflammatory skin disease in which dysregulation of interleukin (IL)-23 activation plays a pivotal role[1]
- 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 signaling[2]
- **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 year[6–9]

Icotrokinra Blocks IL-23 From Binding to its Receptor



Inhibits IL-17A, IL-17F, and IL-22 Production

*IL=interleukin, **IL-12Rβ1**=interleukin-12 receptor beta 1, **IL-23R**=interleukin-23 receptor.*

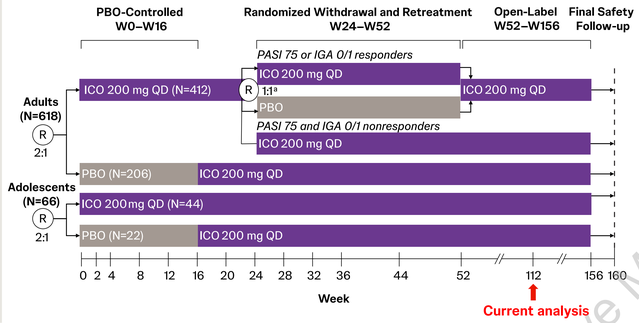
Objective

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

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



*[a]At 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, **ICO**=icotrokinra, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PBO**=placebo, **PsO**=psoriasis, **QD**=once daily, **R**=randomized, **W**=week.*

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 pts and exposure-adjusted incidence rates (/100 PY)[e]

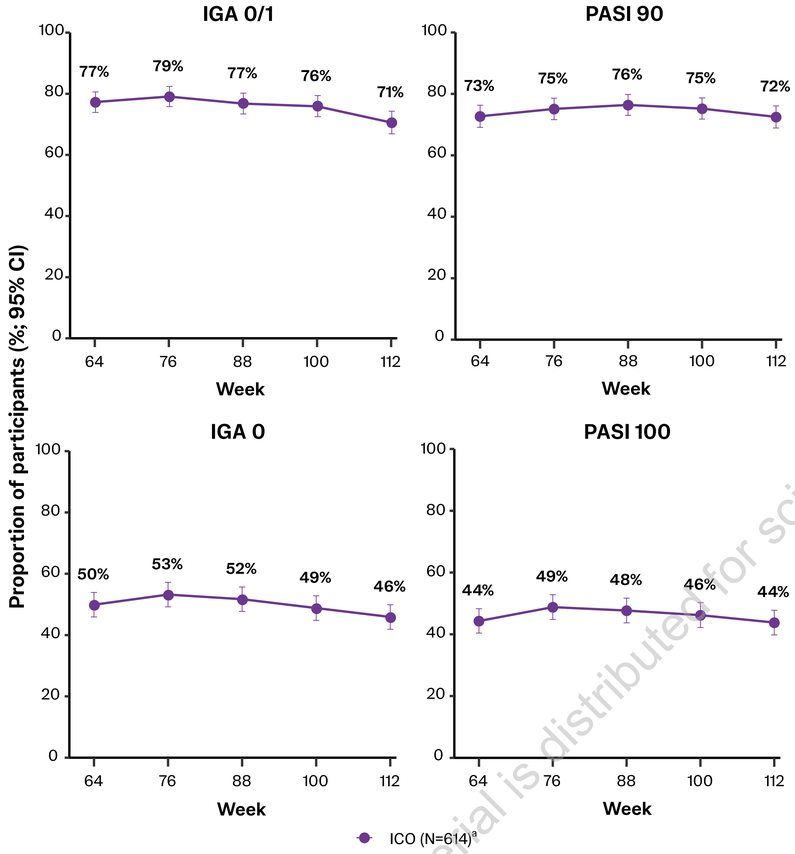
[a]All pts entering the open-label period (W52–W156) received ICO and were included in the analysis; nonresponder imputation was assigned after participant discontinuation of study drug due to lack of efficacy or an AE of worsening PsO. Observed data were used for participants initiating protocol-prohibited 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. [b]After retreatment, nonresponder status was assigned after participant discontinuation of study drug due to lack of efficacy, or an AE of worsening PsO. Additionally, through W52, nonresponder imputation method 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. [c]Among participants with baseline score >0. [d]Defined as ≥4-point improvement from baseline; among participants with baseline PSSD Itch score ≥4. [e]Among pts who received ≥1 dose of study drug.

***AE**=adverse event, **CMI**=clinically meaningful improvement, **ICO**=icotrokinra, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity Index, **PsO**=psoriasis, **PRO**=patient-reported outcome, **PSSD**=Psoriasis Symptoms and Signs Diary, **PY**=patient years, **W**=week.*

Results

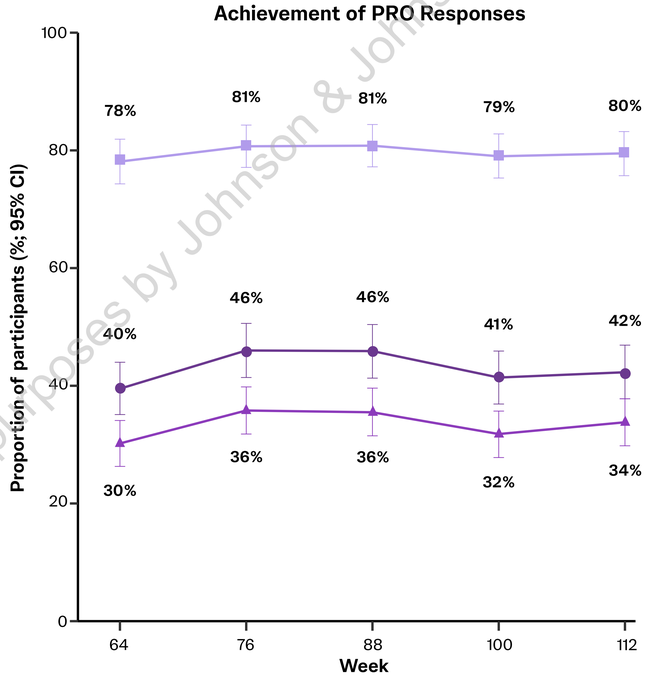
ICO demonstrated high and durable IGA 0/1, IGA 0, PASI 90, and PASI 100 response rates from W64 through W112

- 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)



*[a]All participants entering the open-label period (W52-W156) received ICO and were included in the analysis. **CI**=confidence interval, **ICO**=icotrokinra, **IGA**=Investigator's Global Assessment, **PASI**=Psoriasis Area and Severity, **W**=week.*

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



*[a]Defined as ≥4-point improvement from baseline; among participants with baseline PSSD Itch score ≥4. **CI**=confidence interval, **CMI**=clinically meaningful improvement, **PRO**=patient-reported outcome, **PSSD**=Psoriasis Symptoms and Signs Diary.*

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)	<1 (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. [a]Includes data for ICO-randomized participants and PBO-randomized participants who crossed over after W16 to receive the study treatment. [b]CI is based on the normal approximation or an exact method following a Poisson distribution if the number of pts with events is <10. [c]Malignancies were identified in the eCRF through investigator assessment. **AE**=adverse event, **CI**=confidence interval, **D/C**=discontinuation, **eCRF**=electronic Case Report Form, **GI**=gastrointestinal, **ICO**=icotrokinra, **PBO**=placebo, **PY**=patient years, **SAE**=serious adverse event, **W**=week.*

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PRESENTED BY: Santiago Munoz at the Society of Dermatology Physician Associates (SDPA) Annual Fall Dermatology Conference, November 11–15, 2026; Hollywood, FL, USA. **REFERENCES: 1.** Merola JF. *Dermatol Ther.* 2018;31:e12589. **2.** Fourie AM. *Sci Rep.* 2024;14:17515. **3.** Bissonnette R. *N Engl J Med.* 2025;393:1784–95. **4.** Soung J, EADV; September 17–20, 2025; Paris, France. **5.** Gooderham, M. NEJM Evid. 2025. EVIDoa2500155. **6.** Warren, RB. J Eur Acad Dermatol Venereol. 2026. 40:502–1514. **7.** Soung, J. J Am Acad Dermatol. 2026. doi:101016/j.jaad.2026.05.048. **8.** Soung, J. J Am Acad Dermatol. 2026. doi: 101016/j.jaad.2026.05.035. **9.** Stein Gold, L. *Br J Dermatol.* 2026. doi:10.1093/bjd/ljag264. Medical writing support was provided by JSS Medical Research under the direction of the authors in accordance with Good Publication Practice guidelines (Ann Intern Med. 2022;175:1298–1304). Layout design and formatting for this encore poster were provided by Sandeep Chavan (Siro Medical Writing Pvt. Ltd. India). This presentation was sponsored by Johnson & Johnson. **DISCLOSURES: RB:** Advisory board member, consultant, speaker and/or investigator for and received honoraria and/or grants from AbbVie, Alumis, Amgen, AnaptysBio, Arcutis, Bristol Myers Squibb, Celgene, Dermavant, Eli Lilly, Johnson & Johnson, LEO Pharma, Nimbus, Takeda, UCB, VentyxBio, Vyne, Xencor, Zai Lab, and Zurabio and employee and shareholder of Innovaderm Research. **JS:** Served as a speaker, consultant and/or investigator for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Coval Biopharma, Dermavant, Eli Lilly, Johnson & Johnson, KoBio Labs, LEO Pharma, National Psoriasis Foundation, Novartis, Pfizer, Regeneron, Sanofi, and UCB. **AEP:** Served as an investigator, advisor and/or speaker and/or received educational support from AbbVie, Almirall, Amgen, BI, Bristol Myers Squibb, Galderma, Johnson & Johnson, LEO Pharma, Eli Lilly, Novartis, Pfizer, Sanofi, UCB. **DT:** Served as an investigator for AbbVie, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, DS Biopharma, Eli Lilly, Galderma, Incyte Corporation, Johnson & Johnson, Kymab, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Reistone Biopharma, Sanofi, Sun Pharma, Takeda, UCB, and Zai Lab. **API:** Served as an advisor and/or received speaker's honoraria and/or received grants and/or participated in clinical trials for AbbVie, Almirall Hermal, Amgen, Biogen Idec, BioNTech, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Galderma, GSK, Hexal, Johnson & Johnson-Cilag GmbH, Klinge Pharma, LEO Pharma, MC2, Medac, Merch Serono, Mitsubishi, MSD, Novartis, Pascoe, Pfizer, Regeneron, Roche, Sandoz Biopharmaceuticals, Sanofi Genzyme, Schering-Plough, Tigercat Pharma, UCB Pharma and Zuellig Pharma. **AM:** Honoraria or research grants: AbbVie, Acelyrin, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Galderma, Incyte, Johnson & Johnson, Novartis, Pfizer, Sanofi, Takeda, and UCB. **AP:** Investigator: AbbVie, Applied Pharma Research, Biomendics, Dermavant, Eli Lilly, Incyte, Johnson & Johnson, Krystal, Regeneron, Timber, and UCB; Consultant: AbbVie, Abeona, Apogee Therapeutics, Arcutis, Aslan, BioCryst, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Incyte, Johnson & Johnson, Krystal, LEO Pharma, Mitsubishi Tanabe, Nektar, Primus, Procter and Gamble, Regeneron, Sanofi, Seanergy, TWI Biotech, and UCB; DSMB: AbbVie, Abeona, and Galderma. **KE:** Speaker/advisory board: AbbVie, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Hexal, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Sanofi, Sityx, and UCB; Co-founder/shareholder: Dermagnostix and Dermagnostix R&D. **JJ, SM, YWY, MMK, CDK,** and **SL:** Employees of Johnson & Johnson; may own stocks/stock options in Johnson & Johnson. **ML:** Employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for Almirall, AltruBio Inc., Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, Dermsquared, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica. **PREVIOUSLY PRESENTED AT:** FCD Annual Meeting: October 8–11, 2026; Wynn Las Vegas, NV, USA.