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NEWS RELEASE

Icotrokinra shows superiority to deucravacitinib in first reported head-to-head trials reinforcing promise of novel targeted oral peptide for treatment of plaque psoriasis

2025-09-17

Icotrokinra demonstrated superior skin clearance at Weeks 16 and 24 compared to deucravacitinib and similar adverse event rates to placebo in Phase 3 ICONIC-ADVANCE studies

Icotrokinra also showed sustained skin clearance and favorable safety profile in both adults and adolescents at Week 52 in Phase 3 ICONIC-LEAD study

Robust findings continue to demonstrate the potential of icotrokinra to disrupt the treatment paradigm to set a new standard for treating patients with moderate-to-severe plaque psoriasis

SPRING HOUSE, Pa., Sept. 17, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data from the Phase 3 ICONIC-ADVANCE 1 and 2 studies which assessed the superiority of icotrokinra, a first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor, compared to deucravacitinib in patients with moderate-to-severe plaque psoriasis. These data are being presented at the 2025 European Academy of Dermatology and Venereology (EADV) Congress.[1] Additionally, new long-term 52-week data from the Phase 3 ICONIC-LEAD study investigating icotrokinra in adults and pediatric patients 12 years of age and older (adolescents) with moderate-to-severe plaque psoriasis will be presented as a late-breaking abstract at EADV.[2]

Icotrokinra met both co-primary endpoints compared to placebo at Week 16 with similar adverse event rates and showed superiority to deucravacitinib at multiple timepoints in adult patients in the ICONIC-ADVANCE 1 and 2 studies[a]

- Icotrokinra showed superior skin clearance vs placebo (Week 16) and deucravacitinib (Weeks 16 and 24).[1]
- Icotrokinra demonstrated similar adverse event rates (AEs) to placebo, with no new safety signals identified. Icotrokinra AE rates were numerically lower vs deucravacitinib through Week 24.[1]

"These head-to-head data clearly demonstrate superior complete skin clearance rates for icotrokinra compared to deucravacitinib," said Linda Stein Gold, M.D., Director of Dermatology Clinical Research at Henry Ford Health and ICONIC-ADVANCE study investigator.[b] "With significantly higher response rates seen as early as Week 16 and increasing at Week 24, this novel targeted oral peptide treatment has the potential to be an appealing new option for patients with moderate-to-severe plaque psoriasis."

Johnson & Johnson has also initiated the Phase 3 ICONIC-ASCEND study,[c] the first-ever head-to-head study seeking to demonstrate the superiority of an oral pill, icotrokinra, compared to an injectable biologic, ustekinumab, in psoriasis, representing an important step forward in psoriasis research.

Icotrokinra demonstrated sustained skin clearance and a favorable safety profile through Week 52 with no new safety signals identified in the ICONIC-LEAD[d] drug withdrawal/re-retreatment study

- At Week 52, adult icotrokinra PASI 90 responders re-randomized to icotrokinra at Week 24 had superior maintenance of PASI 90 response versus those re-randomized to placebo (84% vs 21%; $p<0.001$).[2, e]
- At Week 52, 86% of adolescents who received icotrokinra for the full 52 weeks and 77% of those switched from placebo to icotrokinra at Week 16 achieved PASI 90 response.[2]
- ICONIC-LEAD Week 16 primary endpoint data was previously **presented** at the American Academy of Dermatology 2025 Congress.[3]

"The long-term data from ICONIC-LEAD continue to demonstrate the potential of icotrokinra to address the need for a novel targeted oral psoriasis treatment," said Jennifer Soung, M.D., Director of Clinical Research at Southern California Dermatology and ICONIC-LEAD study investigator.[b] "With a substantial proportion of adults and adolescents achieving clear or almost clear skin while maintaining a favorable safety profile through 52 weeks, icotrokinra could be a compelling new therapeutic option that aligns with both patient and provider goals for an oral treatment once approved."

"We're excited to see the icotrokinra Phase 3 ICONIC program continue to deliver robust and clinically meaningful head-to-head and long-term results," said Liza O'Dowd, MD, Vice President, Immunodermatology and Respiratory Disease Areas Lead, Johnson & Johnson Innovative Medicine. "A novel oral therapy that can provide complete skin clearance, a favorable safety profile and the simplicity of a once daily pill may offer an important new option that could increase the use of systemic treatments among patients with moderate-to-severe plaque psoriasis."

For further details and the full list of data presented at the 2025 EADV Congress, visit **https://www.jnj.com/innovativemedicine/immunology/immunodermatology**

Editor's notes:

a. ICONIC- ADVANCE 1 and 2 are Phase 3 RCTs evaluating the efficacy and safety of icotrokinra compared with placebo and deucravacitinib in participants with moderate-to-severe plaque PsO with PASI 90 and IGA score of 0/1 with at least a 2-grade improvement as co-primary endpoints.
b. Drs. Soung and Stein Gold are paid consultants for Johnson & Johnson. They have not been compensated for any media work.
c. ICONIC-ASCEND is a Phase 3 RCT and the first-ever head-to-head study seeking to demonstrate the superiority of an oral pill, icotrokinra, compared to an injectable biologic, ustekinumab in moderate-to-severe plaque PsO.[4]
d. ICONIC-LEAD is a Phase 3 randomized controlled trial (RCT) evaluating the efficacy and safety of icotrokinra compared with placebo in 684 participants (icotrokinra=456; placebo=228) 12 years of age or older with moderate-to-severe plaque PsO, with the higher efficacy bar of PASI 90 and IGA score of 0/1 with at least a 2-grade improvement as co-primary endpoints. ICONIC-LEAD enrolled 66 adolescent patients 12 years of age and older.
e. The PASI score grades the amount of surface area on each body region that is covered by psoriasis plaques and the severity of plaques for their redness, thickness and scaliness. PASI 90 means a 90% reduction in baseline PASI score.

About the ICONIC Clinical Development Program

The pivotal Phase 3 ICONIC clinical development program of icotrokinra (JNJ-2113) in adult and pediatric patients 12 years of age and older with moderate-to-severe plaque PsO was initiated with two studies in Q4 2023 – ICONIC-LEAD and ICONIC-TOTAL – pursuant to the license and collaboration agreement between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc., a Johnson & Johnson company.[5]

ICONIC-LEAD (**NCT06095115**) is a RCT to evaluate the efficacy and safety of icotrokinra compared with placebo in participants with moderate-to-severe plaque PsO, with PASI 90 and IGA score of 0 or 1 with at least a 2-grade improvement as co-primary endpoints.[6]

ICONIC-TOTAL (**NCT06095102**) is a RCT to evaluate the efficacy and safety of icotrokinra compared with placebo for the treatment of PsO in participants with at least moderate severity affecting special areas (e.g., scalp, genital, and/or hands and feet) with overall IGA score of 0 or 1 with at least a 2-grade improvement as the primary endpoint.[7]

Other Phase 3 studies in the development program include ICONIC-ADVANCE 1 (**NCT06143878**) and ICONIC-

ADVANCE 2 (**NCT06220604**), which are evaluating the efficacy and safety of icotrokinra compared with both placebo and deucravacitinib in adults with moderate-to-severe plaque PsO.[8,9] ICONIC-ASCEND will evaluate the efficacy and safety of icotrokinra compared with placebo and ustekinumab in participants with moderate-to-severe plaque psoriasis. ICONIC-PsA 1 (**NCT06878404**) and ICONIC-PsA 2 (**NCT06807424**) will evaluate the efficacy and safety of icotrokinra compared to placebo in participants with active psoriatic arthritis.[10,11]

About Plaque Psoriasis

Plaque psoriasis (PsO) is a chronic immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[12] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[13] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate-to-severe.[14] Plaques typically appear as raised patches with a silvery white buildup of dead skin cells or scales. Plaques may appear red in lighter skin or more of a purple, gray or dark brown color in patients with darker skin tones. Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso.[14] Living with plaque PsO can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[15] Psoriasis on highly visible areas of the body or sensitive skin, such as the scalp, hands, feet, and genitals, can have an increased negative impact on quality of life.[15,16]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[17] which underpins the inflammatory response in moderate-to-severe plaque PsO, ulcerative colitis and offers potential in other IL-23-mediated diseases.[18,19] Icotrokinra binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, selective inhibition of IL-23 signaling in human T cells.[20] The license and collaboration agreement established between Protagonist Therapeutics, Inc. and Janssen Biotech, Inc., a Johnson & Johnson company, in 2017 enabled the companies to work together to discover and develop next-generation compounds that ultimately led to icotrokinra.[21]

Icotrokinra was jointly discovered and is being developed pursuant to the license and collaboration agreement between Protagonist and Johnson & Johnson. Johnson & Johnson retains exclusive worldwide rights to develop icotrokinra in Phase 2 clinical trials and beyond, and to commercialize compounds derived from the research conducted pursuant to the agreement against a broad range of indications.[22,23,24]

Icotrokinra is being studied in the pivotal Phase 3 ICONIC clinical development program in moderate-to-severe plaque psoriasis, including ICONIC-ASCEND; the ICONIC-PSA 1 and ICONIC-PSA 2 studies in active psoriatic arthritis; and the Phase 2b ANTHEM-UC study in moderately to severely active ulcerative colitis.

WHAT IS STELARA® (ustekinumab)?

STELARA® is a prescription medicine used to treat:

- adults and children 6 years of age and older with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years of age and older with active psoriatic arthritis.
- adults with moderately to severely active Crohn's disease.
- adults with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

STELARA® is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects, including:

Serious Infections

STELARA® may lower your ability to fight infections and may increase your risk of infections. Some people have serious infections during treatment with STELARA®, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your healthcare provider should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.
- If your healthcare provider feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start STELARA® if you have any kind of infection unless your healthcare provider says it is okay.

Before starting STELARA®, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:

- fever, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal
- feel very tired

- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB or have been in close contact with someone with TB.

After starting STELARA®, call your healthcare provider right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. STELARA® can make you more likely to get infections or make an infection that you have worse.

People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take STELARA® may also be more likely to get these infections.

Cancers

STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your healthcare provider if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA®. Tell your healthcare provider if you have any new skin growths.

Serious Allergic Reactions

Serious allergic reactions can occur. Stop using STELARA® and get medical help right away if you get any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. Tell your healthcare provider right away if you get any symptoms of PRES during treatment with STELARA®, including: headache, seizures, confusion, and vision problems.

Lung Inflammation

Cases of lung inflammation have happened in some people who receive STELARA® and may be serious. These lung problems may need to be treated in a hospital. Tell your healthcare provider right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before you use or receive STELARA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections or cancers.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your healthcare provider if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who are being treated with STELARA® should avoid receiving live vaccines. Tell your healthcare provider if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system and can cause serious problems. You should avoid receiving the BCG vaccine during the one year before receiving STELARA® or one year after you stop receiving STELARA®.
- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your healthcare provider should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. STELARA® can pass into your breast milk.
- talk to your healthcare provider about the best way to feed your baby if you receive STELARA®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

When prescribed STELARA®:

- Use STELARA® exactly as your healthcare provider tells you to. The healthcare provider will determine the right dose of STELARA®, the amount for each injection, and how often it should be given. Be sure to keep all scheduled follow-up appointments.
- STELARA® is intended for use under the guidance and supervision of your healthcare provider. In children, it is recommended that STELARA® be administered by a healthcare provider. If your healthcare provider decides that you or a caregiver may give your injections of STELARA® at home, you or a caregiver should receive training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® until you have been shown how to inject STELARA® by a healthcare provider.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, influenza, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain, and joint

pain. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

Please read the full **Prescribing Information** and **Medication Guide** for STELARA® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **https://www.fda.gov/medwatch** or call **1-800-FDA-1088**.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding icotrokinra (JNJ-2113). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at **www.sec.gov**, **www.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to

update any forward-looking statement as a result of new information or future events or developments.

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