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NEWS RELEASE

ICOTYDE™ (icotrokinra) one-year results confirm lasting skin clearance and favorable safety profile in once-daily pill for plaque psoriasis

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Johnson & Johnson presents new data showing high rates of complete skin clearance achieved at Week 24 and Week 52 in ICONIC-ADVANCE 1 and 2 studies

Nearly 60% of adolescents treated with ICOTYDE achieved completely clear skin at Week 52 in the ICONIC-LEAD study

SPRING HOUSE, Pa., March 28, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new long-term 52-week data from the Phase 3 ICONIC-ADVANCE 1 and 2 and ICONIC-LEAD studies, which assessed the efficacy and safety of ICOTYDE™ (icotrokinra) in the treatment of patients with moderate-to-severe plaque psoriasis (PsO). ICOTYDE is the first and only targeted oral peptide that precisely blocks the IL-23 receptor.[1] These data are being presented at the 2026 American Academy of Dermatology (AAD) Annual Meeting.

ICOTYDE achieved high levels of complete skin clearance up to Week 52 with no new safety signals[2,a]

- In the ICOTYDE treatment arms, rates of completely clear skin (PASI 100) increased from 41% to 49% and 33% to 48% from Week 24 to Week 52 in ADVANCE 1 and 2, respectively.[a,b]
- Patients who switched from placebo to ICOTYDE at Week 16 achieved similar rates of complete skin clearance by Week 52 (50% and 43% in ADVANCE 1 and 2, respectively) as those who were treated with ICOTYDE for the full 52 weeks.
- The ICOTYDE adverse event profile through Week 52 was consistent with that observed through Weeks 16

and 24, and no new safety signal was identified through Week 52. ICOTYDE overall adverse event and infection rates were lower than deucravacitinib through Week 24.

"Introducing a once-daily targeted oral peptide for treating moderate-to-severe plaque psoriasis offers patients an option with a unique combination of benefits and a favorable safety profile," said Linda Stein Gold, M.D., Director of Dermatology Clinical Research at Henry Ford Health and ICONIC-ADVANCE study investigator.[c] "The results from one-year studies show encouraging outcomes for patients as they navigate this chronic condition."

ICOTYDE demonstrated sustained skin clearance and a favorable safety profile in adolescents through Week 52 with no new safety signals identified in the ICONIC-LEAD study[3,d]

- Nearly 60% of adolescents treated with ICOTYDE achieved completely clear skin (57% PASI 100, 61% IGA 0) at Week 52.
- In adolescents enrolled in ICONIC-LEAD, 86% achieved PASI 90 response at one year, with 92% maintaining that response from Week 24 to Week 52.
- No increase in AE incidence was observed over one year of treatment.
- Additional Week 52 data from ICONIC-LEAD was previously **presented** at the 2025 European Academy of Dermatology and Venereology (EADV) Congress.

"For the first time, patients 12 and older have access to a novel therapy capable of delivering sustained skin clearance and a favorable safety profile in a once-daily pill," said Jennifer Soung, M.D., Director of Clinical Research at Southern California Dermatology and ICONIC-LEAD study investigator.[c] "ICOTYDE is a transformative advance in plaque psoriasis treatment and expands what's possible for this age group."

"The ICOTYDE one year data showcase what's possible when targeted science meets real-world patient needs," said Liza O'Dowd, M.D., Vice President, Immunodermatology and Respiratory Disease Areas Lead, Johnson & Johnson. "Across age groups, high-impact disease sites, and in head-to-head trials, the results point to a new first-line systemic therapy that can move the needle on treatment gaps in plaque psoriasis."

Editor's notes:

a. ICONIC-ADVANCE 1 & 2 are Phase 3 randomized controlled trials (RCTs) evaluating the efficacy and safety of ICOTYDE 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. 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 100 corresponds to an improvement of >=100% in PASI score from baseline.[4]

c. Drs. Soung and Stein Gold are paid consultants for Johnson & Johnson. They have not been compensated

for any media work.

d. ICONIC-LEAD is a Phase 3 RCT evaluating the efficacy and safety of ICOTYDE compared with placebo in 684 participants (ICOTYDE=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.

About the ICONIC Clinical Development Program

The pivotal Phase 3 ICONIC clinical development program includes five Phase 3 studies of ICOTYDE in patients 12 and older with moderate-to-severe plaque PsO.

- ICONIC-LEAD (**NCT06095115**) is a RCT to evaluate the efficacy and safety of ICOTYDE 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.[5]
- ICONIC-TOTAL (**NCT06095102**) is a RCT to evaluate the efficacy and safety of ICOTYDE 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.[6]
- ICONIC-ADVANCE 1 (**NCT06143878**) and ICONIC-ADVANCE 2 (**NCT06220604**) are RCTs to evaluate the efficacy and safety of ICOTYDE compared with both placebo and deucravacitinib in adults with moderate-to-severe plaque PsO.[7,8]
- ICONIC-ASCEND (**NCT06934226**) is a RCT to evaluate the efficacy and safety of ICOTYDE compared with placebo and ustekinumab in participants with moderate-to-severe plaque.[9]

Additional studies underway in other disease areas include: ICONIC-PsA 1 (**NCT06878404**) and ICONIC-PsA 2 (**NCT06807424**) in active psoriatic arthritis; ICONIC-UC (**NCT071196748**) in moderately to severely active ulcerative colitis; and ICONIC-CD (**NCT7196722**) in moderately to severely active Crohn's disease.[10,11,12,13]

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.[14] It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.[15] 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.[16] 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.[17] 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.[14,18]

About ICOTYDE™ (icotrokinra)

ICOTYDE™ (icotrokinra) is the first and only targeted oral peptide designed to precisely block the IL-23 receptor, which underpins the inflammatory response in moderate-to-severe plaque PsO.[1,19,20] ICOTYDE binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, precise inhibition of IL-23 signaling in human T cells.[21] Clinical significance of these findings is unknown.

ICOTYDE is currently approved in the U.S. for the treatment of adults, and pediatric patients 12 years of age and older who weigh at least 40 kg, with moderate-to-severe plaque PsO who are candidates for systemic therapy or phototherapy. Patients on ICOTYDE take one pill, once a day with water upon waking, 30 minutes prior to eating food.[22]

ICOTYDE 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 ICOTYDE 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.[23,24,25]

ICOTYDE is also being studied in active psoriatic arthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.[10,11,12,13]

ICOTYDE™ INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS ICOTYDE™ (icotrokinra)?

ICOTYDE™ 200 mg is a prescription medicine used to treat moderate to severe plaque psoriasis in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg), who may benefit from taking injections or medicines by mouth (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ICOTYDE?

- Infections. Medicines that interact with the immune system, such as ICOTYDE, may lower your ability to fight infections and may increase your risk of infections. Your healthcare provider may check you for infections and tuberculosis (TB) before starting treatment and may treat you for TB before you begin treatment with ICOTYDE if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with ICOTYDE.

Tell your healthcare provider right away if you have any infection or have symptoms of an infection, including:

- fever, sweat, or chills
- cough
- shortness of breath
- blood in your mucus (phlegm)
- muscle aches
- warm, red, or painful skin or sores on your body different from your psoriasis
- weight loss
- diarrhea or stomach pain
- burning when you urinate or urinating more often than normal

Before taking ICOTYDE, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection that does not go away or that keeps coming back.
- have tuberculosis (TB) or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). Avoid receiving live vaccines during treatment with ICOTYDE.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if ICOTYDE can harm your unborn baby. Pregnancy Safety Study. There is a pregnancy safety study for women who take ICOTYDE during pregnancy. The purpose of this study is to collect information about the health of you and your baby. If you are pregnant or become pregnant during treatment with ICOTYDE, you can report your pregnancy by calling 1-800-526-7736 or visiting **www.ICOTYDE.com.**
- are breastfeeding or plan to breastfeed. It is not known if ICOTYDE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ICOTYDE.

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

What are the possible side effects of ICOTYDE?

ICOTYDE may cause serious side effects. See "What is the most important information I should know about ICOTYDE?"

The most common side effects of ICOTYDE include:

- headache
- nausea
- cough
- fungal infection
- tiredness

These are not all the possible side effects of ICOTYDE. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088.

How should I take ICOTYDE?

- Take ICOTYDE exactly as your healthcare provider tells you to take it.
- Take ICOTYDE 1 time a day when you wake up on an empty stomach with water. Wait at least 30 minutes after taking ICOTYDE before eating food.
- If you have difficulty swallowing tablets, ICOTYDE can be dispersed in water. For more information, please read the Medication Guide.
- If you miss a dose of ICOTYDE, take the dose as soon as you remember and go back to your regular schedule the next day.

Please read the full **Prescribing Information**, including **Medication Guide**, for ICOTYDE and discuss any questions that you have with your doctor.

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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 ICOTYDE™ (icotrokinra). 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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