Johnson&Johnson

NEWS RELEASE

Icotrokinra maintains standout combination of therapeutic benefit and a favorable safety profile in once-daily pill through 28 weeks in ulcerative colitis

2025-10-27

Building on 12-week findings, icotrokinra demonstrated clinically meaningful outcomes at Week 28 with 31.7% of patients achieving clinical remission and 38.1% showing endoscopic improvement versus placebo in the Phase 2b ANTHEM-UC study

Results support Phase 3 clinical development of icotrokinra, a first-in-class targeted oral peptide that precisely blocks the IL-23 receptor, in both moderately to severely active ulcerative colitis and Crohn's disease

PHOENIX, Oct. 27, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced Week 28 results from the Phase 2b ANTHEM-UC study of icotrokinra, a first-in-class investigational targeted oral peptide that precisely blocks the IL-23 receptor, in adults with moderately to severely active ulcerative colitis (UC). These results underscore the potential of icotrokinra to deliver a combination of therapeutic benefit and a favorable safety profile with once-daily oral dosing and will be featured among Johnson & Johnson's 23 accepted abstracts at the 2025 American College of Gastroenterology Annual Scientific Meeting (ACG).

At Week 28, icotrokinra demonstrated sustained and clinically meaningful results, with all doses (100 mg, 200 mg and 400 mg) showing higher rates of clinical response[a], clinical remission[b], endoscopic improvement[c] and histologic-endoscopic mucosal improvement (HEMI)[d] at Week 28 compared to placebo.[1] These outcomes build on Week 12 data recently **presented at United European Gastroenterology (UEG) Week 2025** where all doses of icotrokinra demonstrated superiority to placebo for the primary endpoint of clinical response.[2]

Icotrokinra 400 mg once daily	Week 12	Week 28	Placebo (at Week 28)
Clinical response[1]	63.5 %	66.7 %	25.4 %
Clinical remission[1]	30.2 %	31.7 %	9.5 %
Endoscopic improvement[1]	36.5 %	38.1 %	11.1 %
HEMI rates[1]	28.6 %	33.1 %	11.1 %

"The ANTHEM-UC results show that targeting the IL-23 pathway with a once-daily oral therapy can provide meaningful, sustained benefit and a favorable safety profile, giving healthcare providers a potential new approach to managing this challenging disease," said Vipul Jairath, MBChB, DPhil, Professor of Medicine at Western University in Ontario, and study investigator.[e] "For those living with ulcerative colitis, icotrokinra could represent an important step forward in how their disease is managed."

Similar proportions of participants reported adverse events and serious adverse events through Week 28 across all icotrokinra dose groups and the placebo group.[1]

"These exciting results show how we are harnessing our deep understanding of the IL-23 pathway to advance innovative treatments for inflammatory bowel disease that address the daily needs of patients," said Esi Lamousé-Smith, M.D., Ph.D., Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson. "With Phase 3 development now underway in both adult and adolescent patients, our aim is to establish icotrokinra as a promising therapy that could transform the treatment paradigm in ulcerative colitis and bring patients a potential new option."

Based on results from the Phase 2b ANTHEM-UC study, Johnson & Johnson has initiated the ICONIC-UC Phase 3 protocol in adults and adolescents with moderately to severely active UC as well as the ICONIC-CD Phase 2b/3 protocol in adults with moderate to severely active Crohn's disease. Icotrokinra is also being studied in the pivotal Phase 3 ICONIC program in moderate-to-severe plaque psoriasis and the ICONIC-PSA 1 and ICONIC-PSA 2 studies in active psoriatic arthritis. A New Drug Application (NDA) **was submitted** to the U.S. Food and Drug Administration (FDA) in July 2025 seeking the first approval of icotrokinra for the treatment of adults and pediatric patients 12 years of age and older with moderate to severe plaque psoriasis.

Editor's notes:

a. Clinical response was defined as a decrease from baseline in the modified Mayo score by greater than or equal to (>=) 30 percent (%) and >=2 points, with either a >=1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.
b. Clinical remission was defined as a stool frequency subscore of 0 or 1, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1.

c. Endoscopic improvement was defined as an endoscopy subscore of 0 or 1.

d. Histologic-endoscopic mucosal improvement (HEMI) was defined as histologic remission (absence of neutrophils from the mucosa in both lamina propria and epithelium, no crypt destruction, and no erosions, ulcerations, or granulation tissue according to the Geboes grading system) and endoscopic improvement (MES of 0 or 1).

e. Dr. Jairath is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

About ANTHEM-UC

ANTHEM-UC (**NCT06049017**) is a Phase 2b multicenter, randomized, placebo-controlled, dose-ranging study to evaluate the efficacy and safety of icotrokinra (JNJ-77242113, JNJ-2113) in patients with moderately to severely active ulcerative colitis who had an inadequate response or intolerance to conventional therapy (e.g., thiopurines or corticosteroids), prior biologics (TNF antagonists or vedolizumab) and/or ozanimod or approved JAK inhibitors. The study is evaluating three once-daily dosages of icotrokinra taken orally. Participants who complete the Week 28 assessments and have achieved clinical response at Week 28 and who, in the opinion of the investigator, will continue to benefit from treatment with study intervention will continue in the 48-week long term extension (LTE) period and receive the same treatment up to Week 76.[3]

About Ulcerative Colitis

Ulcerative colitis (UC) is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus. It is the result of the immune system's overactive response. Symptoms vary but may typically include loose and more urgent bowel movements, rectal bleeding or bloody stool, persistent diarrhea, abdominal pain, loss of appetite, weight loss, and fatigue.[4]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to precisely block the IL-23 receptor,[5] which underpins the inflammatory response in moderate-to-severe plaque psoriasis, ulcerative colitis and offers potential in other IL-23-mediated diseases.[6,7] Icotrokinra binds to the IL-23 receptor with single-digit picomolar affinity and demonstrated potent, precise inhibition of IL-23 signalling in human T cells.[8] 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.[9] 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.[10,11,12]

Icotrokinra is being studied in the Phase 3 ICONIC clinical development program in moderate-to-severe plaque psoriasis, active psoriatic arthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease.

About Johnson & Johnson

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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.

References:

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