Johnson&Johnson

NEWS RELEASE

Icotrokinra data in ulcerative colitis show potential for a standout combination of therapeutic benefit and a favorable safety profile in once-daily pill

2025-10-07

Icotrokinra met the primary endpoint of clinical response at all three doses, with 36.5% of patients treated with the highest dose achieving endoscopic improvement at Week 12 in the Phase 2b ANTHEM-UC study

These data support the promise of a first-in-class targeted oral peptide that selectively blocks the IL-23 receptor as a potential new option for people with moderately to severely active ulcerative colitis

SPRING HOUSE, Pa., Oct. 7, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced additional Week 12 results from the Phase 2b ANTHEM-UC study of icotrokinra, a first-in-class investigational targeted oral peptide that selectively blocks the IL-23 receptor, in adults with moderately to severely active ulcerative colitis (UC). The study met its primary endpoint, with all once-daily icotrokinra dose groups achieving clinical response[a] at Week 12 and showing clinically meaningful improvements versus placebo across key secondary endpoints.[1] 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 are featured among Johnson & Johnson's 20 accepted abstracts at United European Gastroenterology (UEG) Week 2025.

At Week 12, patients treated with 400 mg of icotrokinra once-daily achieved a clinical response rate of 63.5% versus 27% for placebo ($p<0.001$), while patients treated with 200 mg and 100 mg of icotrokinra once-daily achieved 58.1% and 54.7% response rates, respectively.[1]

Across multiple secondary endpoints, in the 400 mg icotrokinra group, significantly greater proportions of patients achieved clinical remission, symptomatic remission and endoscopic improvement at Week 12 compared to

placebo. Both the 200 mg and 100 mg once-daily dosing groups also showed meaningful improvements in these secondary endpoints relative to placebo. All icotrokinra doses demonstrated higher rates of symptomatic remission compared to placebo as early as Week 4.[1]

At Week 12:	Icotrokinra 400 mg	Icotrokinra 200 mg	Icotrokinra 100 mg	Placebo
Clinical remission[b]	30.2% p=0.006	24.2% p=0.054	21.9% p=0.092	11.1 %
Symptomatic remission[c]	46.0% p<0.001	41.9% p=0.005	53.1% p<0.001	19 %
Endoscopic improvement[d]	36.5% p=0.002	33.9% p=0.007	26.6% p=0.072	14.3 %

Similar proportions of participants reported adverse events and serious adverse events through Week 12 across all icotrokinra dose groups and the placebo group.[1]

"Ulcerative colitis can bring unpredictable and often debilitating symptoms that make even simple daily activities a challenge for many patients," said Maria T. Abreu, M.D., Executive Director of the F. Widjaja Inflammatory Bowel Disease Institute at Cedars-Sinai in Los Angeles and study investigator.[e] "The ANTHEM-UC study results highlight how icotrokinra can selectively target the IL-23 pathway and address the underlying inflammation using a once-daily, oral therapy that is easy for patients, while offering therapeutic benefit and a favorable safety profile. This approach reflects the continued progress in translating scientific advances into innovations for people living with ulcerative colitis."

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 moderately to severely active Crohn's disease.[2,3] 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.

"Icotrokinra marks the next chapter in our history of innovation in inflammatory bowel disease, building on our deep scientific expertise in the IL-23 pathway to develop targeted solutions that address the complexity of disease biology and meet the real-world needs of patients," said Esi Lamousé-Smith, M.D., Ph.D., Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson. "We look forward to initiating our Phase 3 investigation of icotrokinra in UC, with the aim of delivering meaningful improvements to patients living with this debilitating disease."

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 Mayo stool frequency subscore of 0 or 1, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopic subscore of 0 or 1.
c. Symptomatic remission per Mayo score was defined as a stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0.
d. Endoscopic improvement was defined as an endoscopy subscore of 0 or 1.
e. Dr. Abreu is a paid consultant for Johnson & Johnson. She 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.[4]

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.[5]

About Icotrokinra (JNJ-77242113, JNJ-2113)

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

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.11,12,13

Icotrokinra is being studied in the pivotal Phase 3 ICONIC clinical development program in moderate-to-severe plaque psoriasis and active psoriatic arthritis; 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.

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.

Learn more at **https://www.jnj.com/** or at **www.innovativemedicine.jnj.com**.

Follow us at **@JNJInnovMed.**

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:

[1] Abreu M., et al. Icotrokinra, a targeted oral peptide that selectively blocks IL-23 receptor activation, in moderately to severely active ulcerative colitis: week 12 results from the phase 2b, randomized, double-blind, placebo-controlled, treat-through, dose-ranging ANTHEMUC trial. Oral presentation OP206 at United European Gastroenterology Week (UEGW) 2025. October 2025.

[2] Clinicaltrials.gov. A Protocol of Icotrokinra Therapy in Adult and Adolescent Participants With Moderately to Severely Active Ulcerative Colitis (ICONIC-UC). Identifier NCT07196748. **https://clinicaltrials.gov/study/NCT07196748**. Accessed October 2025.

[3] Clinicaltrials.gov. A Study of Icotrokinra in Participants With Moderately to Severely Active Crohn's Disease. Identifier NCT07196722. **https://clinicaltrials.gov/study/NCT07196722**. Accessed October 2025.

[4] Clinicaltrials.gov. A Study of JNJ-77242113 in Participants With Moderately to Severely Active Ulcerative Colitis (ANTHEM-UC). Identifier NCT06049017. **https://clinicaltrials.gov/study/NCT06049017?term=ANTHEM-UC&rank=1**. Accessed February 2025.

[5] Crohn's & Colitis Foundation. What is ulcerative colitis? Available at: **https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis**. Accessed April 2024.

[6] Bissonnette R, et al. Data presentation. A phase 2, randomized, placebo-controlled, dose-ranging study of oral JNJ-77242113 for the treatment of moderate-to-severe plaque psoriasis: FRONTIER 1. Presented at WCD 2023, July 3-8.

[7] Razawy W, et al. The role of IL-23 receptor signaling in inflammation-mediated erosive autoimmune arthritis and bone remodeling. Eur J Immunol. 2018 Feb; 48(2): 220–229.

[8] Tang C, et al. Interleukin-23: as a drug target for autoimmune inflammatory diseases. Immunology. 2012 Feb; 135(2): 112–124.

[9] Pinter A, et al. Data Presentation. JNJ-77242113 Treatment Induces a Strong Systemic Pharmacodynamic Response Versus Placebo in Serum Samples of Patients with Plaque Psoriasis: Results from the Phase 2, FRONTIER 1 Study. Presented at EADV 2023, October 11-14.

[10] Johnson & Johnson. Press release. Janssen enters into worldwide exclusive license and collaboration agreement with Protagonist Therapeutics, Inc. for the oral Interlukin-23 receptor antagonist drug candidate for the treatment of Inflammatory Bowel Disease. Available at: **https://www.jnj.com/media-center/press-releases/janssen-enters-into-worldwide-exclusive-license-and-collaboration-agreement-with-protagonist-therapeutics-inc-for-the-oral-interlukin-23-receptor-antagonist-drug-candidate-for-the-treatment-of-inflammatory-bowel-disease**. Accessed November 2024.

[11] Protagonist Therapeutics. Press release. Protagonist Therapeutics announces amendment of agreement with Janssen Biotech for the continued development and commercialization of IL-23 antagonists. Available at: **https://www.prnewswire.com/news-releases/protagonist-therapeutics-announces-amendment-of-agreement-**

with-janssen-biotech-for-the-continued-development-and-commercialization-of-il-23-antagonists-301343621.html. Accessed November 2024.

[12] Protagonist Therapeutics. Press release. Protagonist Reports positive results from Phase 1 and pre-clinical studies of oral Interleukin-23 receptor antagonist JNJ-2113. Available at: https://www.prnewswire.com/news-releases/protagonist-reports-positive-results-from-phase-1-and-pre-clinical-studies-of-oral-interleukin-23-receptor-antagonist-jnj-2113-301823039.html. Accessed November 2024.

[13] Protagonist Therapeutics. Press release. Protagonist Therapeutics announces positive topline results for Phase 2b FRONTIER 1 clinical trial of oral IL-23 receptor antagonist JNJ-2113 (PN-235) in psoriasis. Available at: https://www.prnewswire.com/news-releases/protagonist-therapeutics-announces-positive-topline-results-for-phase-2b-frontier-1-clinical-trial-of-oral-il-23-receptor-antagonist-jnj-2113-pn-235-in-psoriasis-301764181.html. Accessed November 2024.

Media contact:
Craig Stoltz
cstoltz@its.jnj.com

Investor contact:
Lauren Johnson
investor-relations@its.jnj.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/icotrokinra-data-in-ulcerative-colitis-show-potential-for-a-standout-combination-of-therapeutic-benefit-and-a-favorable-safety-profile-in-once-daily-pill-302576329.html

SOURCE Johnson & Johnson