Johnson&Johnson

NEWS RELEASE

Icotrokinra meets primary endpoint of clinical response in ulcerative colitis study and shows potential to transform the treatment paradigm for patients

2025-03-10

Topline results also show investigational targeted oral peptide icotrokinra achieved clinical remission rates up to 30.2% at Week 12 and a favorable safety profile in Phase 2b ANTHEM-UC study

Clinical response and remission rates continued to improve through Week 28, building on strong data recently reported for the plaque psoriasis Phase 3 program

Icotrokinra demonstrates potential to offer therapeutic benefit and tolerability with a once daily oral treatment

SPRING HOUSE, Pa., March 10, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced positive topline results from ANTHEM-UC, a Phase 2b study of icotrokinra (JNJ-2113), the first 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 of clinical response[a] in all icotrokinra dose groups evaluated and demonstrated clinically meaningful differences versus placebo in key secondary endpoints of clinical remission[b], symptomatic remission and endoscopic improvement at Week 12.

In the ANTHEM-UC study (n=252), three doses of once daily icotrokinra were tested with all meeting the primary endpoint of clinical response at Week 12. A response rate of 63.5% for patients treated with the highest dose of icotrokinra was achieved at Week 12 versus 27% for placebo ($p<0.001$). Further, 30.2% of patients treated with the highest dose of icotrokinra demonstrated clinical remission at Week 12 versus 11.1% of patients who received placebo ($p<0.001$). Remission and response rates continued to improve through Week 28.[1]

Icotrokinra was well tolerated with proportions of participants reporting one or more adverse events (AEs) being similar between the icotrokinra dose groups and the placebo group.[1]

"These impressive findings show the potential of icotrokinra to transform the treatment paradigm for people living with ulcerative colitis by offering a distinctive combination of therapeutic benefit, tolerability, and convenience with a once-daily oral treatment," said Esi Lamousé-Smith, M.D., Ph.D., Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson. "With over a quarter century of innovation in inflammatory bowel disease, coupled with our deep expertise in the IL-23 pathway, we are excited about these results and the groundbreaking potential of icotrokinra in the treatment of immune-mediated diseases."

Comprehensive results from the ANTHEM-UC study are being prepared for presentation at upcoming medical congresses.

Editor's notes:

a. Clinical response is defined as 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 is defined as a Mayo stool frequency subscore of 0 or 1 and not increased from induction baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability present on the endoscopy.

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.[2]

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.[3]

About Icotrokinra (JNJ-77242113, JNJ-2113)

Investigational icotrokinra is the first targeted oral peptide designed to selectively block the IL-23 receptor,[4] which underpins the inflammatory response in moderate-to-severe plaque psoriasis, ulcerative colitis and offers potential in other IL-23-mediated diseases.[5,6] 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.[7] 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.[8] 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.[9,10,11]

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

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Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

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 Janssen Research & Development, LLC, Janssen Biotech, Inc. and/or 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. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1]Data on file.

[2]**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.

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

[4]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.

[5]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.

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

[7]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.

[8]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.

[9]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.

[10]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.

[11]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.

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