



PRESS RELEASE

AbbVie's RINVOQ® (upadacitinib) Receives Health Canada Approval as the First and Only Oral Therapy for the Treatment of Adults with Moderately to Severely Active Crohn's Disease

- *Approval is based on results from three Phase 3 clinical trials demonstrating RINVOQ achieved the co-primary endpoints of clinical remission and endoscopic response as induction and maintenance treatment* ^{1,2,3,4,5}
- *Safety results were generally consistent with the known safety profile of RINVOQ, with no new safety risks observed* ^{1-5, 6,7,8,9}
- *RINVOQ is the first JAK inhibitor indicated in both Crohn's disease and ulcerative colitis, and this approval underscores AbbVie's longstanding commitment to deliver innovative medicines for people living with immune-mediated gastrointestinal diseases*
- *Milestone marks the seventh Health Canada-approved indication for RINVOQ across gastroenterology, dermatology and rheumatology* ⁴

MONTREAL, QC, October 17, 2023 – AbbVie (NYSE: ABBV), today announced that Health Canada has approved RINVOQ® (upadacitinib, 45 mg [induction dose] and 15 mg and 30 mg [maintenance dose]), an oral, once-daily selective and reversible JAK inhibitor, for the treatment of adults with moderately to severely active Crohn's disease.

Crohn's disease is a chronic, systemic disease that manifests as inflammation within the gastrointestinal (digestive) tract, causing persistent diarrhea and abdominal pain.^{10,11} It is a progressive disease, meaning it gets worse over time in a substantial proportion of patients or may develop complications that require urgent medical care, including surgery.¹² Because the signs and symptoms of Crohn's disease are unpredictable, it causes a significant burden on people living with the disease, not only physically, but also emotionally and economically.¹¹ Canada has one of the highest rates of inflammatory bowel disease (IBD) in the world, the two main forms of which are Crohn's disease and ulcerative colitis.¹³ More than 320,000 Canadians live with IBD, and the rate of diagnosis is increasing amongst certain demographics including seniors.¹²

"This approval is a significant milestone for the IBD community as RINVOQ is the first JAK inhibitor indicated in both Crohn's disease and ulcerative colitis. RINVOQ offers people living with Crohn's disease a once-daily oral treatment capable of achieving important endpoints like clinical remission and endoscopic response, which can result in rapid and sustained symptom relief that makes a meaningful difference in a person's daily life," explains Dr. Remo Panaccione, MD, Professor of Medicine and Director of the IBD unit, University of Calgary. "In addition, this is the first time we have seen steroid-free remission rates so early in a clinical trial, which greatly raises the bar on our expectation of patient outcomes in Crohn's disease."

"Crohn's disease robbed me of my quality of life. It became so difficult to do the things I love to do, like travel, go out with family and friends, or even just go to work. Everything I did was influenced by my disease and I had no control. I wasn't able to live my life the way I wanted to," explains Lyanne B., Edmonton, Alberta. "Finding a treatment that works for me has made such a



difference. Not only do I feel like myself again, but I am able to find enjoyment in the little things like taking my dogs for a walk or spending time with family. I am so grateful for the chance to get my life back.”

This approval is supported by data from three Phase 3 clinical trials, including two induction studies (U-EXCEED & U-EXCEL) and one maintenance study (U-ENDURE).¹⁻⁵ Across all three studies, significantly more patients treated with upadacitinib achieved the co-primary endpoints of clinical remission and endoscopic response, with clinical remission measured by the Crohn's Disease Activity Index (CDAI) or by the patient-reported symptoms of stool frequency/abdominal pain score (SF/APS).¹⁻⁵ The safety results of upadacitinib in U-EXCEED, U-EXCEL and U-ENDURE were generally consistent with the known safety profile of upadacitinib, with no new safety risks observed.

Lori Radke, President and CEO, Crohn's and Colitis Canada said, "Crohn's and Colitis Canada always welcomes new treatments for people with Crohn's disease in Canada. Crohn's and colitis are chronic diseases that are debilitating, lead to hospitalizations and surgeries, and have a tremendous impact on the quality of life for the 322,000 Canadians living with them in Canada today. These diseases are complex and often require a personalized approach and multiple treatment options to achieve remission.”

“For more than 20 years, AbbVie has worked hand-in-hand with the IBD research community to advance patient-centered clinical practice and elevate the standard of care, which ultimately makes a significant difference in people's lives,” said Tracey Ramsay, Vice President and General Manager, AbbVie Canada. “We are proud of our incredible legacy in gastroenterology, starting with HUMIRA¹⁴, and now with SKYRIZI¹⁵ and RINVOQ. This new indication for RINVOQ in Crohn's disease represents the third indication approved across our IBD portfolio in the past year—a remarkable achievement that demonstrates our longstanding commitment to delivering innovative new therapies for Canadians living with IBD.”

About the U-EXCEED and U-EXCEL Induction and U-ENDURE Maintenance Studies ^{1,2,3,5}

The three Phase 3 studies are multicenter, randomized, double-blind, placebo-controlled studies to evaluate the efficacy and safety of upadacitinib 45 mg once daily as induction therapy, and upadacitinib 15 mg and 30 mg once daily as maintenance therapy in adults with moderately to severely active Crohn's disease. More information on these trials can be found on www.clinicaltrials.gov (NCT03345836, NCT03345849, NCT03345823).

About RINVOQ® (upadacitinib) ⁴

Discovered and developed by AbbVie scientists, RINVOQ is a once-daily oral medication in an extended-release tablet. It is a selective Janus kinase (JAK) inhibitor that interferes with the JAK-STAT signaling pathway, which is thought to play a role in inflammatory response.

RINVOQ is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate; for adults with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other DMARDs; for adults and adolescents 12 years of age and older with refractory moderate to severe atopic dermatitis who are not adequately controlled with a systemic treatment or when use



of those therapies is inadvisable; for adults with active ankylosing spondylitis who have had an inadequate response to a biologic DMARD or when use of those therapies is inadvisable; for adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response to a biologic DMARD or when use of those therapies is inadvisable; and for adults with moderately to severely active ulcerative colitis who have demonstrated prior treatment failure, i.e., an inadequate response to, loss of response to, or intolerance to at least one of conventional, and/or biologic therapy.

For important safety information, please consult the RINVOQ Product Monograph at www.abbvie.ca.

About AbbVie in Gastroenterology

AbbVie has focused on improving care in gastroenterology for more than 10 years. With a robust clinical trial program in inflammatory bowel disease (IBD), we are committed to cutting-edge research to drive new discoveries and developments in Crohn's disease and ulcerative colitis. By innovating, learning and adapting, AbbVie aspires to eliminate the burden of IBD and make a positive long-term impact in the lives of people with IBD.

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas – immunology, oncology, neuroscience, and eye care – and products and services in our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on X ([Twitter](#)), on [Instagram](#), or find us on [LinkedIn](#).

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