



PRESS RELEASE

Health Canada Approves AbbVie's RINVOQ® (upadacitinib) for the Treatment of Adults with Moderately to Severely Active Ulcerative Colitis

- Approval is based on results from three Phase 3 studies: two for induction and one for maintenance^{1,2,3}
- In clinical trials, patients taking RINVOQ achieved the primary endpoint of clinical remission (per modified Mayo Score [mMS]) at weeks 8 and 52^{1,2,3}
- Safety results in ulcerative colitis were generally consistent with the known safety profile of RINVOQ, with no new important safety risks observed^{4,5,6,7,8,9}
- Approval underscores AbbVie's longstanding commitment to deliver innovative medicines for people living with immune-mediated gastrointestinal diseases
- Milestone marks the sixth Health Canada-approved indication for RINVOQ across gastroenterology, dermatology and rheumatology¹⁰

MONTREAL, QC, July 25, 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 ulcerative colitis (UC) 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.

Ulcerative colitis is a chronic, immune-mediated inflammatory bowel disease (IBD) of the large intestine that can lead to substantial burden and often disability among patients.^{11,12} Canada has one of the highest rates of inflammatory bowel disease in the world, the two main forms of which are Crohn's disease and ulcerative colitis.¹³ More than 300,000 Canadians are living with IBD, and the rate of diagnosis is increasing amongst certain demographics including seniors.¹³

"Patients with ulcerative colitis live with unpredictable symptoms, including bowel urgency, uncontrollable diarrhea, abdominal pain and rectal bleeding, which can significantly affect their quality of life often paralyzing them during a flare. The impacts of UC are far-reaching, affecting patients beyond physical symptoms with significant impacts on mental health." explains Dr. Remo Panaccione, MD, Professor of Medicine and Director of the IBD unit, University of Calgary. "The approval of RINVOQ is exciting and welcome news, as it represents a new selective class of treatment and is a once-daily oral therapy approved in UC. RINVOQ has demonstrated it can rapidly improve symptoms within days to get patients back on track with their lives while also healing the damaged bowel, paving the road to a brighter future without flares."

"At the height of my symptoms, UC dictated my life. For about five years I struggled with pain and worry. Going out to work or anything else was near impossible. Always worrying about needing a nearby restroom or what to be careful of eating had been recurring thoughts that tormented me daily. When you do everything you can to feel better but see no real results, you feel ready to give up," explained Ryan L., of Brampton, Ontario. "Once I found a treatment that worked for me, I felt normal again, which seemed like a



miracle. Being able to go out again without the added worry makes one appreciate what it means to be healthy. I'm glad this new medication will be available for Canadians living with UC."

This approval is supported by data from two induction studies, U-ACHIEVE induction and U-ACCOMPLISH, and one maintenance study, U-ACHIEVE maintenance.^{1,2,3} Across all three Phase 3 studies, significantly more patients treated with RINVOQ achieved the primary endpoint of clinical remission (per modified Mayo Score [mMS] at weeks 8 and 52.^{1,2,3} In addition, each study met all prespecified secondary endpoints, including symptoms, endoscopy and histology.⁴ Additionally, safety results of RINVOQ in UC were consistent with the known safety profile of RINVOQ in rheumatoid arthritis, with no new important safety risks observed.⁴⁻⁹

"In a recent patient survey, we asked people if the currently available medications were adequate to control their disease. Sadly, only 24% of those living with IBD thought that the available medications were adequate," says Gail Attara, President and Chief Executive Officer of the Gastrointestinal Society. "People living with ulcerative colitis need access to new treatment options to help manage the unrelenting bowel symptoms and to hope for mucosal healing. I am pleased to learn that Health Canada has now approved RINVOQ for the treatment of adults with moderately to severely active ulcerative colitis."

"With more than 30 ongoing or planned trials in IBD, we are relentless in our commitment to elevate the standard of care for patients. Our many years of research experience have given us invaluable insights into the challenges faced by people living with UC, and a deep understanding of the continued need for new treatment options," said Tracey Ramsay, Vice President and General Manager, AbbVie Canada. "We celebrate this approval as it will make a meaningful difference in the lives of Canadians with UC."

About the U-ACHIEVE and U-ACCOMPLISH Induction Studies, and the U-ACHIEVE Maintenance Study^{1,2,3}

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 subjects with moderately to severely active ulcerative colitis. Topline results of the U-ACHIEVE induction study were announced in December 2020, topline results of the second induction study, U-ACCOMPLISH, were announced in February 2021, and topline results of the U-ACHIEVE maintenance study were announced in June 2021. More information can be found on <http://www.clinicaltrials.gov> (NCT03006068, NCT03653026, NCT02819635).

About RINVOQ® (upadacitinib) ¹⁰

Discovered and developed by AbbVie scientists, RINVOQ is a once-daily oral medication in an extended-release tablet. It is a 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 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, eye care, virology, women's health and gastroenterology, in addition to products and services across our Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on [Twitter](#), on [Instagram](#), or find us on [LinkedIn](#).

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