

PRESS RELEASE

AbbVie's SKYRIZI® (risankizumab) Receives Health Canada Approval as the First and Only Specific Interleukin-23 (IL-23) to Treat Moderately to Severely Active Crohn's Disease in Adults

- *Third approved indication for SKYRIZI (risankizumab) is supported by safety and efficacy data from two induction and one maintenance Phase 3 clinical trials: ADVANCE, MOTIVATE and FORTIFY^{1,2,3}*
- *As early as Week 4 in the induction studies, clinical response and clinical remission were achieved by significantly more people treated with SKYRIZI versus placebo^{1,2,3}*
- *Approval represents AbbVie's longstanding dedication to delivering innovative medicines for people living with immune-mediated gastroenterological diseases*

MONTREAL, QC, October 20, 2022 – AbbVie (NYSE: ABBV) today announced Health Canada approval for SKYRIZI® (risankizumab 600 mg intravenous [IV] induction at Week 0, Week 4 and Week 8, followed by 360 mg subcutaneous [SC] injection maintenance at Week 12 and every eight weeks thereafter) for the treatment of adults with moderately to severely active Crohn's disease who have had an inadequate response, intolerance, or demonstrated dependence to corticosteroids; or an inadequate response, intolerance, or loss of response to immunomodulators or biologic therapies.

Crohn's disease is a chronic, systemic disease that manifests as inflammation within the gastrointestinal (or digestive) tract, causing persistent diarrhea and abdominal pain.⁴ It is a progressive disease, meaning it gets worse over time, and in many cases leads to surgery.⁴ 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.⁵ More than 300,000 Canadians live with IBD, and the rate of diagnosis is increasing amongst certain demographics including seniors.^{5,6}

"The clinical trials for SKYRIZI in Crohn's disease have helped raise the bar in IBD research through more stringent endpoints and innovative clinical trial design. Beyond the traditional endpoint of clinical remission, this is the first time we have seen a co-primary endpoint of endoscopic response in a Phase 3 trial, which is very exciting," says Dr. Remo Panaccione, MD, Professor of Medicine and Director of the IBD unit, University of Calgary. "In addition to helping patients get better quickly, there was evidence of significant healing of the bowel within three months. It has been shown that when people achieve endoscopic healing, they have lower rates of hospitalizations and surgeries, and an overall improved quality of life. SKYRIZI has also been used successfully in other therapeutic areas and comes with a well-established safety profile that will be also welcomed by patients.

"Living with Crohn's disease means having a hidden disease that wreaks havoc on your mental health. I cannot be a mom or a wife when I am having a flare up. Because Crohn's disease is unpredictable, I was often on edge, waiting for that feeling of urgency to strike and hoping a bathroom would be available," explains Lindsey Rion of Spruce Grove, Alberta. "Finding a treatment that works for me has been life-altering. I am physically healing and my mental health has also improved. I'm so pleased that Canadians living with Crohn's disease will now have a



new medication available to them, as having multiple approved treatment options is critical.”

This approval is supported by data from three Phase 3 clinical trials – ADVANCE, MOTIVATE (induction studies) and FORTIFY (maintenance study).^{1,2,3} Across all three studies, significantly more patients treated with risankizumab achieved the co-primary endpoints of endoscopic response and clinical remission.^{1,2,3,7,8} This includes statistically significant improvements with 600 mg intravenous infusions for the ADVANCE and MOTIVATE induction studies on these primary endpoints at Week 12 compared to placebo.^{1,2,7} Additionally, a significantly greater proportion of patients treated with risankizumab 360 mg subcutaneous injections achieved endoscopic response and clinical remission at 52 weeks compared to placebo withdrawal (patients treated with placebo after risankizumab induction) in the FORTIFY maintenance study.^{3,8} Safety results of risankizumab in Crohn’s disease were consistent with the known safety profile of risankizumab, with no new safety risks observed.^{1,2,3,7,8,9,10}

“We are excited that a new treatment has been approved for use in people with Crohn’s disease in Canada. Crohn’s disease and ulcerative colitis are debilitating diseases, often leading to multiple hospitalizations and surgeries, and they have a tremendous impact on quality of life. These diseases are complex and often require a personalized approach and multiple treatment options to bring about remission. It’s important that Canadians have access to new treatment options because not all therapies will work for everyone, and many people have run out of options. Crohn’s and Colitis Canada continues to advocate for improved coverage and timely access to new treatments on public and private drug plans,” says Lori Radke, President and CEO of Crohn’s and Colitis Canada.

“For more than 15 years, we have worked side-by-side with the Canadian IBD research community to advance the standards of care in Crohn’s disease. We are proud of our commitment to investigating treatment approaches that go beyond managing symptoms to focus on changing the course of disease management,” adds Tracey Ramsay, Vice President and General Manager, AbbVie Canada. “This approval represents the first new treatment option in six years for people with moderately to severely active Crohn’s disease, and we are pleased that Canadians will now be able to benefit from this therapy.”

SKYRIZI (risankizumab) is part of a collaboration between Boehringer Ingelheim and AbbVie, with AbbVie leading development and commercialization globally.

About the ADVANCE and MOTIVATE Inductions Studies, and the FORTIFY Maintenance Study^{1,2,3}

The three Phase 3 studies are multicenter, randomized, double-blind, placebo-controlled studies to demonstrate the efficacy and safety of risankizumab 600 mg as induction therapy, and risankizumab 360 mg as maintenance therapy in subjects with moderately to severely active Crohn’s disease. More information can be found on www.clinicaltrials.gov (ADVANCE: NCT03105128; MOTIVATE: NCT03104413, FORTIFY: NCT03105102).

About SKYRIZI® (risankizumab)¹¹

SKYRIZI is an interleukin-23 (IL-23) inhibitor that selectively blocks IL-23 by binding to its p19 subunit. IL-23, a cytokine involved in inflammatory processes, is thought to be linked to a number of chronic immune-mediated diseases, including Crohn’s disease. SKYRIZI is also approved in Canada for the treatment of moderate to severe plaque psoriasis in adult patients who are



candidates for systemic therapy or phototherapy, and for the treatment of adult patients with active psoriatic arthritis.

For important safety information, please consult the SKYRIZI 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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¹¹ SKYRIZI (risankizumab) product monograph. AbbVie Corporation. Available at: https://www.abbvie.ca/content/dam/abbviedotcom/ca/en/documents/products/SKYRIZI_PM_EN.pdf. Accessed October 20, 2022.