



## PRESS RELEASE

### Health Canada Approves AbbVie's RINVOQ® (upadacitinib) for the Treatment of Adults with Active Ankylosing Spondylitis

- Approval is supported by efficacy and safety data of two pivotal studies in which RINVOQ demonstrated improvements in disease activity and function<sup>1</sup>
- Milestone marks the fourth Health Canada-approved indication for RINVOQ<sup>2</sup>

**MONTREAL, QC, July 20, 2022** – AbbVie (NYSE: ABBV), today announced that Health Canada has approved RINVOQ® (upadacitinib, 15 mg), the first oral, once-daily selective and reversible JAK inhibitor for the treatment of adults with active ankylosing spondylitis (AS) who have had an inadequate response to a biologic disease modifying anti-rheumatic drug (DMARD) or when use of those therapies is inadvisable. RINVOQ may be used as monotherapy or in combination with nonsteroidal anti-inflammatory drugs (NSAIDs).<sup>2</sup>

“Ankylosing spondylitis is a lifelong, progressive inflammatory disease that affects young people. AS is difficult to diagnose, and causes patients constant symptoms including pain and stiffness, particularly in the spine, which results in significant impairment of a person’s quality of life,” said Walter Maksymowych, Professor of Medicine, University of Alberta, and Chief Medical Officer, CARE Arthritis. “To date, there have been limited treatments options for people living with AS, so it is very encouraging to now have a new, oral therapeutic choice available for patients.”

“Living with AS for most of my adult life, I have gotten used to living with pain. I had muscle spasms, and I couldn’t walk. It was hard to move. The pain in my back and my glutes made everyday movement, particularly anything that involved hip movement, really difficult. Finding a treatment that works for me has been life changing and has allowed me to get back to normal and simply focus on living. This is why I am happy to know that Canadians with AS now have a new therapeutic option,” explained Marianne Skippings, of Edmonton, Alberta.

This approval is supported by data from two pivotal studies with more than 600 patients: SELECT-AXIS 1, a Phase 2/3 study in adult patients with active AS who were naïve to biologic DMARDs and had an inadequate response or intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs)<sup>1</sup> and SELECT-AXIS 2, a Phase 3 study in adult patients with active AS who were biologic-inadequate responders<sup>3</sup>. In both studies, a significantly greater proportion of patients treated with RINVOQ 15 mg achieved an Assessment of Spondyloarthritis International Society (ASAS) 40 response compared to placebo at Week 14. Onset of efficacy was seen as early as Week 2 in SELECT-AXIS 1 and Week 4 in SELECT-AXIS 2.

“We are pleased to learn that RINVOQ has received Health Canada approval for the treatment of adults with ankylosing spondylitis. Our hope is that this approval is followed by timely and equitable access for all patients. Diverse and affordable treatment options are essential for those living with this painful and debilitating condition affecting both physical and mental health. It is a promising and hopeful time to know there are new treatment options available to people living with AS,” said Dr. Elie Karam, Chair, Canadian Spondylitis Association.



“At AbbVie, we are deeply committed to improving the standard of care for people living with inflammatory arthritis. For more than two decades, we have been dedicated to discovering and delivering innovative therapies for people with rheumatic diseases,” said Tracey Ramsey, Vice President and General Manager, AbbVie Canada. “We are proud to expand our portfolio of treatment options for Canadians impacted by ankylosing spondylitis, in particular, offering patients the first once-daily oral advanced therapy in AS.”

### **About SELECT-AXIS 1<sup>1</sup>**

SELECT-AXIS 1 is a Phase 2/3, multicenter, randomized, double-blind, parallel-group, placebo-controlled study designed to evaluate the safety and efficacy of RINVOQ in adult patients with active ankylosing spondylitis who are bDMARD-naïve and had inadequate response to at least two NSAIDs or intolerance to/contraindication for NSAIDs. More information on this trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03178487).

### **About SELECT-AXIS 2<sup>3</sup>**

SELECT-AXIS 2 (Study 1) is a Phase 3 randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of RINVOQ in adult patients with active ankylosing spondylitis who had an inadequate response to one or two biologic DMARDs. More information on this trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04169373).

### **About RINVOQ<sup>®</sup> (upadacitinib)<sup>2</sup>**

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 (RA) who have had an inadequate response or intolerance to methotrexate, for adults with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other DMARDs, for adults and adolescents 12 years of age and older with moderate to severe atopic dermatitis (AD) who are not adequately controlled with a systemic treatment or when use of those therapies is inadvisable, and for adults with active ankylosing spondylitis (AS) who have had an inadequate response to a biologic DMARD or when use of those therapies is inadvisable.

For important safety information, please consult the RINVOQ Product Monograph at [www.abbvie.ca](http://www.abbvie.ca).

### **About AbbVie in Rheumatology**

For more than 20 years, AbbVie has been dedicated to improving care for people living with rheumatic diseases. Anchored by a longstanding commitment to discovering and delivering transformative therapies, we pursue cutting-edge science that improves our understanding of promising new pathways and targets, ultimately helping more people living with rheumatic diseases reach their treatment goals.



## 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 its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at [www.abbvie.ca](http://www.abbvie.ca). Follow @abbviecanada on [Twitter](https://twitter.com/abbviecanada) and [Instagram](https://www.instagram.com/abbviecanada), or find us on [LinkedIn](https://www.linkedin.com/company/abbvie).

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## References

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