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PRESS RELEASE

Health Canada Approves AbbVie's RINVOQ® (upadacitinib) for the Treatment of Adults with Active Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

- *Approval is based on results from the Phase 3 SELECT-AXIS 2 pivotal clinical trial in which RINVOQ delivered rapid and meaningful disease control, meeting the primary endpoint of ASAS40 response at week 14 versus placebo* [1]
- *RINVOQ is the first and only Janus Kinase (JAK) inhibitor approved to treat patients across the spectrum of axial spondyloarthritis (nr-axSpA and ankylosing spondylitis) in Canada* [1, 2, 3]

MONTREAL, QC, May 9, 2023 – 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 non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response to a biologic disease modifying anti-rheumatic drug (DMARD) or when use of those therapies is inadvisable.

This indication follows the July 2022 Health Canada approval of RINVOQ 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, making RINVOQ the first and only JAK inhibitor approved for the full spectrum of axial spondyloarthritis.[2]

Nr-axSpA is a chronic, progressive inflammatory rheumatic disease that causes joint inflammation leading to back pain and stiffness.[4] It cannot be detected by x-ray, which makes it extremely difficult to diagnose.[5] Nr-axSpA and AS are considered as two sub-types of a broader condition called axial spondyloarthritis (axSpA). A recent multi-country study reported that approximately 16 percent of patients with nr-axSpA will progress to AS after five years.[6]

"Non-radiographic axial SpA is a very complex disease that is difficult to diagnose. And yet early detection and treatment are critical to improving health outcomes," explained Dr. Denis Choquette, Rheumatologist at the Institut de Rhumatologie de Montréal and Scientific Director, Rhumadata. "This new indication for RINVOQ is a significant milestone for rheumatologists and patients. AxSpA is typically diagnosed in young people under 45 years old, so it is very encouraging to now have a new, oral therapeutic choice for patients."

"Today, as a patient, but also as Chair of the Canadian Spondyloarthritis Association, I can say that we are thrilled to learn that RINVOQ is now approved for the treatment of adults with non-radiographic axial spondyloarthritis. When I first started experiencing symptoms of nr-axSpA, I thought I had a back sprain from playing sports. That first flare went on for three months. Over time, I also experienced inflammatory flares in my ankles, neck, and shoulders. By age 33, I felt like an old man. Getting my diagnosis was difficult as I didn't have the typical AS inflammatory markers; my x-rays came back negative. Two years after the onset of pain, I was prescribed an MRI centered on the sacroiliac joints, which confirmed that I had nr-axSpA. My story is truly ironic because I was a doctor specializing in the musculoskeletal field, working with other

experts, and we all missed my diagnosis for years. And yet comparatively, I was lucky; it takes, on average, seven to ten years for people to be diagnosed with this disease. As AS warriors, we can become resistant to medications with time and so access to new innovative medicines is crucial. My hope is that RINVOQ's approval is followed by timely and equitable access for all patients. This access is essential for people living with this painful and debilitating condition," said Dr. Élie Karam, Chair, Canadian Spondylitis Association.

This approval is supported by data from the Phase 3 SELECT-AXIS 2 clinical trial (Study 2), which evaluated the efficacy, safety, and tolerability of upadacitinib in patients with nr-axSpA.[ii] Study results show RINVOQ delivered rapid and meaningful disease control with nearly half of patients achieving the primary endpoint of ASAS40* versus placebo, as well as significant improvement in signs and symptoms of nr-axSpA at week 14.[1]

**ASAS40 is a composite index that measures disease activity.[1] To achieve an ASAS40 response, a patient's disease activity must have improved by at least 40%, as well as improved by two units (on a 0 to 10 scale) in at least three of four disease areas assessed, and the remaining area must not have gotten worse, including back pain, patient global assessment of disease activity, physical function, and morning stiffness.[1]*

"For nearly a quarter century, AbbVie has been dedicated to discovering and delivering innovative therapies for people living with rheumatic diseases," added Tracey Ramsay, Vice President and General Manager, AbbVie Canada. "The needs and experiences of patients drive our relentless pursuit to improve the standards of care, which is why we are proud to now offer Canadians the first once-daily oral advanced therapy that works across the spectrum of axial spondyloarthritis."

About the SELECT-AXIS 2 trial program [7]

SELECT-AXIS 2 was conducted as a master study protocol that contains two standalone studies with randomization, data collection, analysis and reporting conducted independently. The Phase 3, randomized, placebo-controlled, double-blind studies are evaluating the efficacy and safety of RINVOQ compared with placebo on reduction of signs and symptoms in adult participants with active axial spondyloarthritis (axSpA), including bDMARD-IR AS (Study 1) and non-radiographic axial spondyloarthritis (nr-axSpA) (Study 2). More information on this trial can be found at www.clinicaltrials.gov (NCT04169373).

About RINVOQ® (upadacitinib) [2]

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 (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 refractory moderate to severe atopic dermatitis (AD) who are not adequately controlled with a systemic treatment or when use of those therapies is inadvisable, 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, and 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.

For important safety information, please consult the RINVOQ Product Monograph at 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, gynecology 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 @abbviecanada on Twitter and Instagram, or find us on LinkedIn.

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[1] Deodhar A, Van den Bosch F, Poddubnyy D, et al. U Upadacitinib for the treatment of active non-radiographic axial spondyloarthritis (SELECT-AXIS 2): a randomized, double-blind, placebo-controlled, phase 3 trial. Lancet. 2022;400:369–79. doi:10.1016/S0140-6736(22)01212-0.

[2] RINVOQ (upadacitinib) product monograph. AbbVie Corporation. Available at: https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/RINVOQ_PM_EN.pdf Accessed May 8, 2023.

[3] van der Heijde D, Baraliakos X, Sieper J, et al. Efficacy and safety of upadacitinib for active ankylosing spondylitis refractory to biological therapy: a double-blind, randomized, placebo-controlled phase 3 trial. Ann Rheum Dis. 2022;0:1–9. doi:10.1136/annrheumdis-2022-222608.

[4] Sieper J, Poddubnyy D. Axial spondyloarthritis. Lancet 2017; 390: 73–84.

[5] Deodhar AA, Understanding Axial Spondyloarthritis: A Primer for Managed Care. Am J Manag Care. 2019;25:S319-S330.

[6] Poddubnyy D, et al. Radiographic Progression From Non-radiographic to Radiographic Axial Spondyloarthritis: Results From a 5-year Multicountry Prospective Observational Study. Ann Rheum Dis 2022;81:96-97

[7] A Study to Evaluate Efficacy and Safety of Upadacitinib in Adult Participants With Axial Spondyloarthritis (SELECT AXIS 2). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT04169373 Accessed March 30, 2023