PRESS RELEASE

Health Canada Approves AbbVie's RINVOQ® (upadacitinib) for the Treatment of Adults with Active Psoriatic Arthritis

- *Approval supported by efficacy and safety data of two pivotal Phase 3 studies in which RINVOQ demonstrated improved joint outcomes, physical function and skin symptoms, with a greater proportion of patients achieving minimal disease activity versus placebo* [1,2]*
- *Significantly more patients taking RINVOQ achieved an ACR20 response than patients receiving placebo [1,2]*

MONTREAL, QC, June 7, 2021 – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that Health Canada has approved RINVOQ® (upadacitinib, 15 mg), an oral, once-daily selective and reversible JAK inhibitor for the treatment of adults with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other Disease-Modifying Anti-Rheumatic Drugs (DMARDs).[3]

"Psoriatic arthritis is a debilitating disease that can cause severe pain, restricted mobility, and lasting structural damage.[4, 5] The immune system creates inflammation that can lead to skin lesions associated with psoriasis, as well as pain, fatigue and stiffness in the joints," [6,7] said Dr. Proton Rahman, FRCPC, Clinical Rheumatologist at Eastern Health and University Research Professor at Memorial University. "Despite treatment advances, some people living with PsA do not achieve their treatment goals, which is why access to new therapies is so critical. The approval of RINVOQ offers Canadian physicians and their patients an important new therapeutic option."

"I have had psoriatic arthritis and psoriasis for more than 30 years. At one point, most of my body was covered in psoriasis, and I was using arm and leg braces to help me walk. These diseases have had a huge impact on my life, which is why I am so pleased that Canadians with psoriatic arthritis now have a new treatment option available to them," said Marilyn Porth, of Winnipeg, Manitoba.

This approval is supported by data from two Phase 3 studies across a broad range of more than 2,000 patients with active psoriatic arthritis.[1,2] In both studies, RINVOQ met the primary endpoint of ACR20 response at week 12 versus placebo.[1,2] RINVOQ 15 mg also achieved non-inferiority versus adalimumab in terms of ACR20 response at week 12.[1] Patients receiving RINVOQ also experienced greater improvements in physical function (HAQ-DI*) and skin symptoms (PASI 75*), and a greater proportion achieved minimal disease activity.[1,2] Overall, the safety profile of RINVOQ in psoriatic arthritis was consistent with previously reported results across the Phase 3 rheumatoid arthritis clinical trial program, with no new significant safety risks detected.[1,2,8]

“The approval of RINVOQ is wonderful news for Canadians living with psoriatic arthritis, and an important step forward for the psoriatic arthritis community,” says Wendy Gerhart, Executive Director, Canadian Spondylitis Association. “From our recent member surveys, we know this devastating disease has a profound impact on people’s quality of life including their physical and mental health. This approval provides a new treatment option to Canadian patients. It is a hopeful time for people living with psoriatic arthritis.”

“For more than 20 years, 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. “We are proud of our deep heritage in rheumatology and pleased to expand our portfolio of treatment options for Canadians living with psoriatic arthritis, particularly by offering people the convenience of a once-daily oral medication.”

**Physical function was measured by the Health Assessment Questionnaire Disability Index (HAQ-DI). Skin symptoms were measured by a 75 percent improvement in the Psoriasis Area and Severity Index (PASI 75). Minimal disease activity is defined as the fulfillment of five of seven outcome measures: Tender joint count ≤1; swollen joint count ≤1; PASI ≤1 or body surface area-psoriasis ≤3 percent; Patient's Assessment of Pain Numerical Rating Scale (NRS) ≤1.5; Patient Global Assessment-Disease Activity NRS ≤2.0; HAQ-DI score ≤0.5; and Leeds Enthesitis Index ≤1.*

About SELECT-PsA 1 [1,3]

SELECT-PsA 1 is a Phase 3, multicenter, randomized, double-blind, parallel-group, active and placebo-controlled study designed to evaluate the safety and efficacy of upadacitinib compared to placebo and adalimumab in adult patients with active psoriatic arthritis who have a history of inadequate response to at least one non-biologic DMARD.

Top-line results from SELECT-PsA 1 were previously announced in February 2020. More information on this trial can be found at www.clinicaltrials.gov (NCT03104400).

About SELECT-PsA 2 [2,3]

SELECT-PsA 2 is a Phase 3, multicenter, randomized, double-blind, parallel-group, placebo-controlled study designed to evaluate the safety and efficacy of RINVOQ in adult patients with active psoriatic arthritis who have a history of inadequate response to at least one biologic DMARD.

Top-line results from SELECT-PsA 2 were previously announced in October 2019. More information on this trial can be found at www.clinicaltrials.gov (NCT03104374).

About RINVOQ® (upadacitinib)

RINVOQ is a 15 mg, 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, as well as for adults with active psoriatic arthritis who have had an inadequate response or intolerance to

methotrexate or other DMARDs. In RA, RINVOQ may be used as a monotherapy or in combination with methotrexate or other nonbiologic DMARDs. In PsA, RINVOQ may be used as a monotherapy or in combination with methotrexate.

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. Our longstanding commitment to discovering and delivering innovative therapies is underscored by our pursuit of cutting-edge science that improves our understanding of promising new pathways and targets in order to help 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. Follow @abbviecanada on Twitter or find us on Facebook, Instagram, YouTube and LinkedIn.

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