PRESS RELEASE

AbbVie Receives Health Canada Approval of RINVOQ® (upadacitinib), an Oral Medication for the Treatment of Adults with Moderate to Severe Active Rheumatoid Arthritis

- *Approval supported by efficacy and safety data from the pivotal Phase 3 SELECT rheumatoid arthritis (RA) program, one of the largest registrational Phase 3 programs in RA with approximately 4,400 patients evaluated across five studies*[1-5]
- *About one in every 100 adult Canadians, or approximately 300,000 people, are living with rheumatoid arthritis, the majority of whom don't achieve remission*[6,7]

MONTREAL, QC, January 7, 2020 – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that Health Canada has approved RINVOQ® (upadacitinib) for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate (MTX). RINVOQ is a 15 mg, once-daily oral Janus kinase (JAK) inhibitor and may be used as monotherapy or in combination with MTX or other nonbiologic disease-modifying anti-rheumatic drugs (DMARDs).

"While there has been tremendous progress in the treatment of rheumatoid arthritis over the past two decades, too many patients still don't reach remission and continue to suffer from pain, fatigue and morning joint stiffness," said Dr. Edward Keystone, MD, FRCPC, Professor of Medicine, University of Toronto. "RINVOQ had one of the largest Phase 3 clinical trial programs in rheumatoid arthritis, and this medicine has the potential to significantly improve signs and symptoms of the disease."

Gaétane Lepire, who lives with rheumatoid arthritis, explained the impact the disease has had on her life: "It affected me because I had pain in my feet, my knees, my back and my hands 24 hours a day, seven days a week. I tried to function as if everything were okay, but it affected me, and sometimes I couldn't do the things I was used to doing. I had trouble getting out of bed, going up and down three steps, getting in and out of the car, etc."

"Rheumatoid arthritis affects 1 in 100 Canadians and causes disability in many. RINVOQ has been approved for the treatment of moderate to severe active rheumatoid arthritis and offers hope for patients with this destructive autoimmune disease," explained Dr. Janet Pope, MD, MPH, FRCPC, Professor of Medicine, Division of Rheumatology, the Schulich School of Medicine & Dentistry at Western University, and Medical Director of the Rheumatology Centre at St. Joseph's Health Care London.

Designed to help accommodate the physical limitations of people living with RA, the packaging for RINVOQ includes a bottle cap with a wide, easy-to-grip texture and an embedded tool that punctures the foil liner to simplify medication access.

"For many people living with arthritis, the act of opening a medicine bottle or picking up a tablet can be extremely difficult, and AbbVie designed the RINVOQ tablet, bottle and cap with this in mind," said Ken Gagnon, Vice President, Corporate Partnerships, The Arthritis Society. "We are pleased to give this medication our Ease of Use designation, which recognizes products that are designed to make life easier for people with arthritis."

“AbbVie has been dedicated to discovering and delivering innovative therapies for people living with rheumatic diseases for nearly two decades,” added Stéphane Lassignardie, Vice President and General Manager, AbbVie Canada. “We are proud to expand our portfolio of treatment options for Canadians living with RA, particularly by offering people the convenience of a medication taken orally, in a once-daily extended-release tablet.”

About the Phase 3 SELECT Rheumatoid Arthritis Program

The Health Canada approval of RINVOQ was supported by data from the global Phase 3 SELECT rheumatoid arthritis program, which evaluated nearly 4,400 patients with moderate to severe active rheumatoid arthritis in five pivotal studies.[1-5]

The studies include assessments of efficacy, safety and tolerability across a variety of patients, including those who were methotrexate naïve or had an inadequate response to methotrexate (MTX), patients who were intolerant to conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), and patients who failed or were intolerant to biologic disease-modifying anti-rheumatic drugs (DMARDS).[1-5]

- SELECT-EARLY was a 48-week trial in 947 patients with moderately to severely active rheumatoid arthritis who were naïve to methotrexate.
- SELECT-MONOTHERAPY was a 14-week monotherapy trial in 648 patients with moderately to severely active rheumatoid arthritis who had an inadequate response to methotrexate.
- SELECT-NEXT was a 12-week trial in 661 patients with moderately to severely active rheumatoid arthritis who had an inadequate response to conventional synthetic disease modifying anti-rheumatic drugs.
- SELECT-COMPARE was a 48-week trial in 1,629 patients with moderately to severely active rheumatoid arthritis who had an inadequate response to methotrexate.
- SELECT-BEYOND was a 12-week trial in 499 patients with moderately to severely active rheumatoid arthritis who had an inadequate response or intolerance to biologic disease-modifying anti-rheumatic drugs.

About RINVOQ® (upadacitinib)[8]
RINVOQ® (upadacitinib) 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. RINVOQ may be used as monotherapy or in combination with other nonbiologic DMARDs.

For important safety information, please consult the RINVOQ Product Monograph at www.abbvie.ca.

About AbbVie Care
Canadians prescribed RINVOQ will have the opportunity to be enrolled in AbbVie Care, AbbVie's signature care program. The program is designed to provide a wide range of customized services such as reimbursement and financial support, pharmacy services, lab work reminders and coordination, as well as personalized education and ongoing disease management support from a dedicated AbbVie Care nurse, throughout the treatment journey. For more information, consult www.abbviecare.ca.

About AbbVie
AbbVie is a global, research and development-based biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.ca and www.abbvie.com. Follow @abbviecanada and @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

-30-

Media:
Julie Lepsetz
AbbVie Canada
julie.lepsetz@abbvie.com
(514) 451-9427

References:

[1] Genovese MC, et al. Safety and efficacy of upadacitinib in patients with active rheumatoid arthritis refractory to biologic disease-modifying anti-rheumatic drugs (SELECT-BEYOND): a double-blind, randomised controlled phase 3 trial. Lancet. 2018 Jun 23;391(10139):2513-2524. doi: 10.1016/S0140-6736(18)31116-4. Epub 2018 Jun 13.

[2] Smolen JS, et al. Upadacitinib as monotherapy in patients with active rheumatoid arthritis and inadequate response to methotrexate (SELECT-MONOTHERAPY): a randomised, placebo-controlled, double-blind phase 3 study. Lancet. 2019. May 23. doi: 10.1016/S0140-6736(19)30419-2. Epub 2019 May 23.

[3] Fleischmann R, et al. Upadacitinib versus placebo or adalimumab in rheumatoid arthritis and an inadequate response to methotrexate: Results of a Phase 3, Double-Blind, Randomized Controlled Trial. Arthritis and Rheumatology. 2019. Jul 9. doi: 10.1002/art.41032.

[4] van Vollenhoven R, et al. A Phase 3, Randomized, Controlled Trial Comparing Upadacitinib Monotherapy to MTX Monotherapy in MTX-Naïve Patients with Active Rheumatoid Arthritis. 2018 ACR/ARHP Annual Meeting; 891.

[5] Cohen S, et al. Safety profile of upadacitinib in Rheumatoid Arthritis: Integrated analysis from the SELECT Phase 3 Clinical Program. EULAR 2019; THU0167.

[6] Arthritis Society, What is rheumatoid arthritis. Available at: https://arthritis.ca/about-arthritis/arthritis-types-(a-z)/types/rheumatoid-arthritis, Accessed December 11, 2019.

[7] Ajeganova S. and Huizinga T. Sustained remission in rheumatoid arthritis: latest evidence and clinical considerations. Ther Adv Musculoskelet Dis. 2017 Oct;9(10):249-262. doi: 10.1177/1759720X17720366.

[8] RINVOQ Product Monograph. Available at: http://www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/RINVOQ_PM.pdf. Accessed January 6, 2020.