PRESS RELEASE

AbbVie welcomes Therapeutic Goods Administration (TGA) Regulatory Approval of RINVOQ® (upadacitinib)[1]

SYDNEY AUSTRALIA, January 22, 2020 - AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that the Therapeutic Goods Administration (TGA) granted regulatory approval for RINVOQ® (upadacitinib), a once-daily, selective and reversible inhibitor of Janus Kinase 1 (JAK1), for the treatment of adult patients with moderate-to-severe active rheumatoid arthritis who have responded inadequately to, or who are intolerant to, one or more disease-modifying anti-rheumatic drugs (DMARDs).[1]

Rheumatoid arthritis (RA) affects nearly half a million Australians.[2,3] It typically begins in the smaller joints of the hands, wrists and feet, causing pain, stiffness, swelling and loss of function in the joints.[4,5,6] If not appropriately managed, ongoing inflammation can lead to irreversible joint damage and loss of function. [2,4,5,6] Beyond physical symptoms, rheumatoid arthritis also significantly impacts health-related quality of life, including emotional wellbeing and ability to perform daily activities.[7,8] It also represents a substantial economic burden to patients and society.[9]

Early detection and diagnosis are critical in being able to treat symptoms, manage pain, and prevent irreversible joint damage.[4] Scientific advances have improved therapies, moving from symptomatic relief through to slowing or preventing further joint damage.[4] Despite the availability of current treatments, many of these patients do not achieve their treatment goals[10,11] and therefore additional therapeutic options are needed.[4]

“An average of 10,000 new cases of Rheumatoid Arthritis are estimated to be diagnosed in Australia each year, with RA prevalence likely to rise to 700,000 Australians by 2032.[2] While significant treatment advances have been made, it is critical to ensure patients have access to new treatment options which work in different ways,” said Kirsten O’Doherty, Vice President and General Manager Australia and New Zealand.

“The TGA registration of RINVOQ is an important milestone for the rheumatoid arthritis community and we are pleased to be able to offer patients in Australia this additional treatment option. We are working to ensure access to this new treatment is available via the Pharmaceutical Benefits Scheme.”

Currently RINVOQ (upadacitinib) is not listed on the Pharmaceutical Benefits Scheme (PBS) for patients with Rheumatoid Arthritis.

About RINVOQ (upadacitinib)[1]

Discovered and developed by AbbVie, RINVOQ is a selective and reversible inhibitor of Janus Kinase 1 (JAK1) for the treatment of moderate to severe active rheumatoid arthritis.[12]

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Important Safety Information[1,13]

Therapy with RINVOQ should be started and monitored by a specialist with expertise in the management of rheumatoid arthritis.

RINVOQ must not be used if the patient has an allergy to upadacitinib or any of its ingredients, or if the patient has an active, serious infection. In addition, RINVOQ must not be used in combination with biologic disease-modifying anti-rheumatic drugs. Patients should tell their health care professional if they currently have an infection, have had an infection that keeps coming back, had herpes zoster infection, have had chicken pox, hepatitis or blood clots previously.

Prior to using RINVOQ, patients should be checked for tuberculosis (TB) infection. RINVOQ should not be given to patients with active TB. TB treatment may be required for patients with TB or have risks of having contracted TB.

Prior to initiating therapy with RINVOQ, completion of all appropriate immunisations should be considered according to current immunisation guidelines. However, RINVOQ should not be used with certain vaccines. Check this with the healthcare professional.

RINVOQ should be used with caution when certain other medications are being taken. Patient should inform their healthcare professional if they are taking any other medications.
Common side effects include nose or throat infections, nausea, high liver enzyme levels, cough, fever, stomach discomfort, and weight gain.

RINVOQ should not be used during pregnancy or breastfeeding.

Please review the Consumer Medicines Information here for further safety information on RINVOQ.

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.com. Follow @abbvie on Twitter, Facebook, LinkedIn or Instagram.

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