PRESS RELEASE

AbbVie welcomes registration of RINVOQ® (upadacitinib) for atopic dermatitis

SYDNEY AUSTRALIA, September 24, 2021 - AbbVie (NYSE: ABBV) today announced that RINVOQ® (upadacitinib), a Janus Kinase 1 (JAK1) inhibitor, has been registered in Australia for the treatment of adults and adolescents 12 years and older with moderate to severe atopic dermatitis who are candidates for systemic therapy.[1]

Atopic dermatitis is a chronic inflammatory skin condition and is one of the most common and most severe forms of eczema.[2,3] Caused by an overactive immune system, the condition results in inflammation in the skin and is characterised by a cycle of intense itching and scratching.[4] Scratching exacerbates the condition, and can result in cracked, scaly, oozing skin covering a significant portion of an individual's body.[4,5 6] Scratching for temporary relief often makes it worse by breaking down the outer layer of the skin which allows bacteria, viruses and allergens to enter.[7] Subsequently, the immune system reacts, and the rash and itch become more severe.[7]

Symptoms can significantly impact daily life,[2,4] especially for those with moderate to severe disease.[4,8] This burden can be persistent every day, not just during flare-ups.[4] Many patients report a significant impact on their physical, social and psychological well-being.[4,8] Unlike other forms of eczema, atopic dermatitis typically does not go away in a few days or weeks, and it often returns or flares up after periods of getting better.[3] Disease flare-ups and periods of worsening symptoms are different from person to person.

While data in Australia is limited, an estimated 6.3% of Australian adults (approximately 1.6 million) are thought to be living with atopic dermatitis,[9] with around one in five patients suffering from moderate to severe disease.[9] For up to 85 percent of people living with atopic dermatitis, the condition begins before they are five years old.[2] For many of these individuals, it resolves as they get older; however, it can persist into adulthood for some.[2]

There remains an unmet need for patients with atopic dermatitis in Australia, as currently available management strategies may not result in complete disease control.[10] As there is no cure for atopic dermatitis, the main goals in managing the disease are to reduce itch, minimise rash and limit impact on quality of life.[11] Management typically involves a multidimensional approach that includes patient and caregiver education, elimination of triggers and restoration of the barrier function of the skin via the use of topical moisturisers, in combination with medical therapies.[11] However the treatment plans largely depend on disease severity.[11]

AbbVie Australia Pty Ltd
Level 7, 241 O'Riordan St
Mascot, NSW, 2020
Australia

Date of preparation: September 2021
Document number: AU-RNQD-210093

Chris Stemple, Vice President and General Manager AbbVie Australia and New Zealand welcomed the registration saying, “The atopic dermatitis community face many challenges in relation to diagnosis and assessment of disease, as well as navigating the complexity of the disease and its treatment pathways. With many patients not achieving disease control, access to additional treatment options is critical.[11] This is what drives us forward and we’re committed to continued innovation and developing a deeper understanding of disease with the hope of making a difference to the lives of patients. We’re pleased to bring an additional treatment option to patients in Australia.”

Currently RINVOQ (upadacitinib) is listed on the PBS for severe active rheumatoid arthritis, severe active psoriatic arthritis and active ankylosing spondylitis (refer to the PBS schedule for full information). RINVOQ (upadacitinib) is not currently listed on the PBS for atopic dermatitis.

Important Safety Information[1,12]

Therapy with RINVOQ should be started and monitored by a specialist physician with expertise in the management of the indicated conditions.

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, have had herpes zoster infection, have had chicken pox, hepatitis or blood clots previously.

Prior to using RINVOQ, patients should be checked for current or previous exposure to 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, such as live vaccines. Check this with the healthcare professional.

RINVOQ should be used with caution when certain other medications are being taken. Patients should inform their healthcare professional if they are taking any other medications.

Some common side effects include nose or throat infections, nausea, high liver enzyme, blood creatine phosphokinase or cholesterol level increases, decreased neutrophil counts, cough, fever, stomach discomfort, and weight gain.

RINVOQ should not be used during pregnancy or breastfeeding.

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

AbbVie Australia Pty Ltd
Level 7, 241 O’Riordan St
Mascot, NSW, 2020
Australia

Date of preparation: September 2021
Document number: AU-RNQD-210093

NOTES TO EDITORS:

About RINVOQ (upadacitinib)[1]

RINVOQ contains the active ingredient upadacitinib, which is a JAK 1 inhibitor. JAK enzymes create signals in the body's immune system that result in inflammation.

RINVOQ works to block these signals, thereby reducing inflammation and the production of immune cells within the body.

Discovered and developed by AbbVie, RINVOQ is a selective inhibitor of Janus Kinase 1 (JAK1) for the treatment of:

- Moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to, one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ may be used as monotherapy or in combination with methotrexate or other conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs).[1]
- Moderate to severe active psoriatic arthritis in adult patients who have responded inadequately to, or are intolerant to one or more DMARDs. RINVOQ may be used as monotherapy or in combination with a non-biological DMARD.[1]
- Adults with active ankylosing spondylitis.[1]
- Adults and adolescents 12 years and older with moderate to severe atopic dermatitis who are candidates for systemic therapy.[1]

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. Our heritage in Australia reaches back more than 80 years and we employ more than 450 people with our therapies currently benefiting more than 30,000 Australians. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments. Recently, we acquired Allergan which immediately diversified our business across several therapeutic areas: Immunology, Oncology, Virology, Neuroscience, Eye Care and Aesthetics.

For further information please visit www.abbvie.com.au. Follow @abbvie_AU on Twitter, Facebook, Instagram or our LinkedIn page.

###

AbbVie Australia Pty Ltd
Level 7, 241 O'Riordan St
Mascot, NSW, 2020
Australia

Date of preparation: September 2021
Document number: AU-RNQD-210093

Media enquiries:

Sam Pearson
Senior Communications and Patient Relations Manager
+61 418 419 549
Sam.pearson@abbvie.com

References:

1. RINVOQ Approved Product Information – Available at: https://apps.medicines.org.au/files/veprinvo.pdf Accessed September 23, 2021
2. Nutten, S. Atopic Dermatitis: Global Epidemiology and Risk Factors. Ann Nutr Metab. 2015;66 Suppl 1:8-16. doi: 10.1159/000370220. Epub 2015 Apr 24.
3. National Eczema Foundation. Atopic Dermatitis. 2020. Available at: https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/. Accessed on September 9, 2021.
4. EFA. Atopic Eczema: Itching for Life Report. 2018. Available at: https://www.efanet.org/images/2018/EN_-_Itching_for_life_Quality_of_Life_and_costs_for_people_with_severe_atopic_eczema_in_Europe_.pdf. Accessed on September 9, 2021
5. AAAI. Eczema (Atopic Dermatitis) Overview. 2020. Available at: https://www.aaaai.org/Tools-for-the-Public/Conditions-Library/Allergies/Eczema-(Atopic-Dermatitis)-Overview. Accessed on September 9, 2021.
6. Berdyshev, E et al. Lipid abnormalities in atopic skin are driven by type 2 cytokines. JCI Insight. 2018. Feb 2018; 3(2): 1-15.
7. Murtota, H and Katayama I. Exacerbating factors of itch in atopic dermatitis. Allergology International. 2017; 66(1):8-13. https://doi.org/10.1016/j.alit.2016.10.005.
8. Silverberg, J. Comorbidities and the Impact of Atopic Dermatitis. Ann Allergy Asthma Immunol. 2019 Aug;123(2):144-151. doi: 10.1016/j.anai.2019.04.020. Epub 2019 Apr 26
9. Chidwick K, Busingye D, Pollack A, Osman R, Yoo J, Blogg S, Rubel D and Smith S. Prevalence, incidence and management of atopic dermatitis in Australian general proactive using routinely collected data from MedicineInsight. Australas J Dermatol. 2020; 61: e319-e327.
10. Simpson, E., et al. Patient burden of moderate to severe atopic dermatitis. J Am Acad Dermatol. 2016 Mar;74(3):491-8. doi: 10.1016/j.jaad.2015.10.043.
11. Hajar, T., et al. New and developing therapies for atopic dermatitis. Anais brasileiros de dermatologia vol. 93,1 (2018): 104-107. doi:10.1590/abd1806-4841.20187682.
12. RINVOQ Approved Consumer Medicines Information – Available at: https://medicines.org.au/files/vecrinvo.pdf. Accessed September 23, 2021