PRESS RELEASE

RINVOQ® (upadacitinib) Now Listed on the PBS for Australia's Most Common and Severe Form of Eczema, Atopic Dermatitis (AD)[1,2,3]

SYDNEY, AUSTRALIA, January 22nd 2022 – AbbVie (NYSE: ABBV) today announced that RINVOQ® (upadacitinib), a Janus Kinase 1 (JAK1) inhibitor, has been listed on the Pharmaceutical Benefits Scheme (PBS) for patients living with severe AD.[1] This includes patients with severe AD that affects their whole body, face or hands.[1]

Atopic dermatitis is a chronic inflammatory skin condition caused by an overactive immune system and is one of the most common and severe forms of eczema.[2,3] Approximately 1.6 million Australians are thought to be living with atopic dermatitis, with around one in five of these suffering from a moderate to severe form of the condition.[4] Unlike other types 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.[5] Stress, changes in temperature, sweat, dust, and allergies are all common triggers.[6]

Melanie Funk, Managing Director at Eczema Support Australia said, "Atopic dermatitis has a significant impact on quality of life.[7] The condition may cause physical discomfort, which in turn can cause insomnia, emotional distress, depression, embarrassment, and social stigma.[8] As a result, people may avoid work, social situations, and relationships.[8] We know that the last few years have been particularly challenging and that stressful circumstances can lead to more flare ups. Therefore, the availability of an additional treatment option for atopic dermatitis is timely and very welcomed by the community."

There remains an unmet need for people living with atopic dermatitis, as currently, available management strategies may not result in complete disease control.[9] As there is no cure for atopic dermatitis, the main goals in managing the disease are to reduce itch, minimise rash, and limit the impact on quality of life.[2,6]

Associate Professor Stephen Shumack, University of Sydney and Royal North Shore Hospital said, "Until recently, the treatment of severe atopic dermatitis relied on corticosteroids and systemic immunosuppressants.[4,6] Access to targeted therapies provides clinicians with additional treatment options to help alleviate the burden of this chronic condition. With the growing impact of stress on many patients' daily lives, now may be a good time for people with atopic dermatitis to assess their treatment options and find out what's best for them."

Chris Stemple, Vice President and General Manager AbbVie Australia & New Zealand, said, "We welcome the news today that RINVOQ has been listed on the PBS. People living with atopic dermatitis face many challenges navigating the complexity of their condition. We remain committed to innovation and developing a deeper understanding of the disease with the hope of making a difference to the lives of Australians living with this debilitating condition."

RINVOQ (upadacitinib) is also 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).

Important Safety Information[1]

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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 chickenpox, hepatitis, or blood clots previously.

Before 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.

Before initiating therapy with RINVOQ, completion of all appropriate immunisation 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 acne, upper respiratory tract infections, nose or throat infections, nausea, high liver enzyme, blood creatine phosphokinase or cholesterol level increases, decreased neutrophil counts, headache, cough, fever, stomach discomfort, and weight gain.

RINVOQ should not be used during pregnancy or breastfeeding.

For further safety information on RINVOQ please review the Consumer Medicines Information here or the Product Information here.

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NOTES TO EDITORS

About Atopic Dermatitis

Atopic dermatitis is more than a rash or itchy skin.[2] It is a chronic inflammatory condition and is one of the most common and most severe forms of eczema.[2,3]

The exact cause of atopic dermatitis is unknown.[6] It is driven by complex interactions between genetic and environmental factors that trigger an uncontrolled immune response, resulting in intense itch and a painful rash.[2] 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.[10] Subsequently, the immune system reacts, and the rash and itch become more severe.[10]

People with atopic dermatitis have an increased risk of other conditions, including asthma, allergic rhinitis,[11] and other immune-mediated inflammatory conditions.[12] They may also have an increased risk of cardiovascular disease, depression and anxiety, and neuropsychiatric diseases (ADHD, seizures, and headaches).[6, 12]

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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).
- 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.
- Adults with active ankylosing spondylitis.
- Adults and adolescents 12 years and older living with severe AD. This includes patients with severe AD that affects their whole body, face or hands.

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
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Note Regarding Spokespeople

No compensation was provided to Melanie Funk and Associate Professor Stephen Shumack, and the opinions expressed are their own. Melanie Funk and Associate Professor Stephen Shumack have been briefed by AbbVie on the approved use of this product.

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References

[1] RINVOQ Approved Product Information. Available at: https://apps.medicines.org.au/files/veprinvo.pdf Accessed November 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 January 18, 2022.

[4] Chidwick K, Businge D, Pollack A, Osman R, Yoo J, Blogg S, Rubel D and Smith S. Prevalence, incidence and management of atopic dermatitis in Australian general practice using routinely collected data from MedicineInsight. Australas J Dermatol. 2020; 61: e319-e327.
[5] Misery L, Finlay AY, Martin N, Boussetta S, Nguyen C, Myon E, Taieb C. Atopic dermatitis: impact on the quality of life of patients and their partners. Dermatology. 2007;215(2):123-9. doi: 10.1159/000104263. PMID: 17684374.
[6] Griffiths CE, van de Kerkhof P, Czarnecka-Operacz M. Psoriasis and Atopic Dermatitis. Dermatol Ther (Heidelb). 2017 Jan;7(Suppl 1):31-41. doi: 10.1007/s13555-016-0167-9. Epub 2017 Feb 1. PMID: 28150106; PMCID: PMC5289118.
[7] Gochnauer H, Valdes-Rodriguez R, Cardwell L, Anolik RB. The Psychosocial Impact of Atopic Dermatitis. Adv Exp Med Biol. 2017;1027:57-69. doi: 10.1007/978-3-319-64804-0_6. PMID: 29063431.
[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] Silverberg, J.L., et al. Comparative efficacy and safety of systemic therapies used in moderate-to-severe atopic dermatitis: a systematic literature review and network meta-analysis. Eur Acad Dermatol Venereol. 2021 Sep;35(9):1797-1810. doi: 10.1111/jdv.17351. Epub 2021 Jun 12. PMID: 33991374; PMCID: PMC8453983.
[10] 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.
[11] Weidinger, S. and Novak, N. Atopic Dermatitis. Lancet. 2016 Mar 12;387(10023):1109-1122. doi: 10.1016/S0140-6736(15)00149-X. Epub 2015 Sep 13.
[12] Anderson, Y., et al. Comorbidities of Atopic Dermatitis: Beyond Rhinitis and Asthma. Curr Dermatol Rep. 2017;6(1):35-41. doi: 10.1007/s13671-017-0168-7. Epub 2017 Jan 21.

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