PRESS RELEASE

New oral treatment listed on the PBS for arthritis of the spine and pelvis

SYDNEY AUSTRALIA, 1 August 2023 – Australian adults living with active non-radiographic axial spondyloarthritis (nr-axSpA), a form of inflammatory arthritis causing pain and restricting movement in the spine and pelvis will now have access to RINVOQ® (upadacitinib) on the Pharmaceutical Benefits Scheme (PBS).[1,2]

RINVOQ will be available on the PBS from 1 August 2023, enabling patients living with the condition to now have access to an affordable non-biologic disease modifying antirheumatic drug (DMARD) in the form of a tablet.[1.]

Approximately 30,000 Australians have nr-axSpA with early signs of the autoimmune disease presenting between the ages of 15 and 40 years.[3] While symptoms vary for each person, they tend to include stiffness and pain in the back and buttocks, tendons and ligaments and can go untreated for many years.[3,4]

Professor Andrew Östör, Rheumatologist at Melbourne Rheumatology welcomed the addition of an oral non-biologic DMARD for Australian patients: “It’s important for me as a rheumatologist to have a range of medications to work with, because each patient has unique needs and responds differently to medicines. Having another treatment option available on the PBS for nr-axSpA is good news for patients and doctors.

“My ultimate goal is to help people with nr-axSpA to lead normal, functional lives, with the best outcomes achieved with early diagnosis and management including medication, exercise, diet and nutrition.”

While the inflammation that characterises nr-axSpA can cause bone to grow within the joints of the spine over time, the damage progresses so slowly that it often does not show up on x-rays.[3] Formal diagnosis requires specialist tests including blood tests and other imaging, and it takes an

average of five to seven years for nr-axSpA and many visits to different healthcare professionals to be identified.[4]

“The creeping symptoms of nr-axSpA can increase so gradually that many people don’t realise the disease’s increasing effect and often put pain and stiffness down to other causes before obtaining a diagnosis. If people are experiencing unresolved pain in the spine and pelvis, it’s important they speak to a doctor. With the right diagnosis and support, patients have a much better chance of managing the impact of this type of arthritis on their daily lives and avoiding long-term complications,” commented **Jonathan Smithers, CEO, Arthritis Australia**.

Long-term comorbidities (complications or impacts) of nr-axSpA include: osteoporosis, heart disease, depression and anxiety and inflammatory bowel disease.[5,6,7]

Nathalie McNeil, General Manager, AbbVie Australia, said, “We welcome the news that RINVOQ will be accessible to people living with nr-axSpA through the PBS. We are proud to be able to provide a new treatment option to help patients live with this painful condition, which can come with many other health issues, and create a cycle of pain and poor quality of life. We remain committed to our mission at AbbVie to improve outcomes for patients with autoimmune inflammatory diseases.”

RINVOQ® is also listed on the PBS for severe active rheumatoid arthritis, chronic severe atopic dermatitis, severe psoriatic arthritis, ankylosing spondylitis and ulcerative colitis (refer to the PBS schedule for full information).[2]

Important RINVOQ® safety information[2]

Therapy with RINVOQ® should be initiated and monitored by a specialist physician (for example, a rheumatologist) well versed in the use of immunomodulatory therapeutic agents like RINVOQ, with expertise in the management of the indicated conditions such as non-radiographic axial spondyloarthritis.

RINVOQ® carries a boxed warning for patients with a history of cardiovascular disease or cardiovascular risk factors, current or past long-time smokers, patients who have had cancer including skin cancer and cancer of the lymph glands, and patients 65 years of age and older.

RINVOQ® must not be used if the patient has an allergy to upadacitinib or any of its other 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 such as adalimumab

or infliximab, or with potent immunosuppressants such as azathioprine, cyclosporin or tacrolimus.

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 immunisations should be considered according to current immunisation guidelines. However, RINVOQ® should not be used with live vaccines. Patients should check this with their doctor.

Patients should tell their doctor if they have an infection or have had an infection that keeps coming back. Patients should tell their doctor if they have or have had herpes zoster infection; chicken pox; hepatitis; any liver problems; any heart problems; high blood pressure; high cholesterol; any cancers (including skin cancers and lymphomas); any abnormal blood cell counts; or blood clots (or at increased risk of blood clots). If the patients have diabetes, they may be at increased risk of getting infections. Patients should also advise their doctor if they have unexplained stomach (abdominal) pain, have had diverticulitis (painful inflammation of small pockets in the lining of the intestine), or ulcers in the stomach previously.

RINVOQ® should be used with caution when certain other medications are being taken. Patients must inform their doctor if they are taking any other medications, including any they obtain without a prescription. In addition, patients must tell their doctor if they have any kidney problems. In these cases, the dosage may need to be modified accordingly.

Some common side effects include infections; abnormal laboratory tests; headache; dizziness; hypertension; cough; constipation; diarrhoea; nausea; vomiting; back pain; pyrexia; fall; lipid abnormalities; weight gain; abdominal pain; oropharyngeal pain; dyspepsia; acne; urticaria; fatigue; pyrexia; arthralgia; myalgia; eczema herpeticum.

RINVOQ® must not be used during pregnancy or breastfeeding.

For further safety information on RINVOQ® please review the Consumer Medicines Information here (for consumers) or the Product Information here for healthcare professionals.

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ABOUT RINVOQ®[2]

RINVOQ® contains the active ingredient upadacitinib, which is a Janus Kinase (JAK) 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. [2]

RINVOQ® is used to treat: [2]

- 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 aged 12 years and above who weigh at least 40 kg for the treatment of moderate to severe atopic dermatitis which is inadequately controlled with active topical pharmacotherapies and for whom systemic therapy is indicated.
- Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biological medicine.
- Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) change, who have responded inadequately to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).
- Adults with moderately to severely active Crohn's disease (CD), who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biological medicine.

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, and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com.au. Follow @abbvie_AU on Twitter, Facebook, Instagram or our LinkedIn page.

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