



## CONSUMER PRESS RELEASE

**EMBARGOED UNTIL 06:00 AEST, 1 DECEMBER 2023**

### **RINVOQ® (upadacitinib) now reimbursed for Australians living with Severe Crohn's disease<sup>1</sup>**

- *RINVOQ®*, a once daily tablet, has become available on the Pharmaceutical Benefits Scheme (PBS) for eligible patients living with severe active Crohn's disease (CD)<sup>1,2</sup>
- *It's the first new molecule for CD to be funded by the Government in seven years<sup>1,3</sup>*
- *Australia has one of the high rates in the world, impacting many in their 20s to 30s<sup>6</sup>*
- *Currently there is no cure for CD and severity of the disease is on the rise due to environmental & dietary factors<sup>7,8</sup>*

**SYDNEY, AUSTRALIA, 1 December 2023** – AbbVie (NYSE: ABBV), is pleased to announce RINVOQ® (upadacitinib), a once daily tablet, has been listed on the Pharmaceutical Benefits Scheme (PBS) for adult patients with severe Crohn's disease (CD), who have had an inadequate response, lost response or were intolerant to either conventional therapy or biological medicine.<sup>1</sup>

RINVOQ is a once daily oral tablet and the first new molecule to be listed on the PBS for CD in seven years.<sup>3</sup> Prior to this, the main approaches for managing the disease have been intravenous infusions or subcutaneous injections.<sup>9</sup>

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.<sup>2,9</sup>

According to data from a 2021 study, it is estimated that approximately 77,000 Australians have CD.<sup>4</sup> CD is one of two major types of inflammatory bowel disease (IBD).<sup>5,8</sup> Australia has one of the highest rates of CD in the world.<sup>6</sup>

CD can be found anywhere in the gastrointestinal tract, however it is more commonly diagnosed in the area between the small intestine and large intestine.<sup>8</sup> Symptoms of the disease include persistent diarrhoea, abdominal pain, rectal bleeding & unexpected weight loss.<sup>8</sup> Severity of CD is also on the rise, with up to 80% of people diagnosed with CD needing surgery at some point in their lives.<sup>9,10</sup>

A diagnosis of CD can occur at any age but is more common in young people from 20-30 years old.<sup>11-13</sup> The diagnosis journey can be challenging, with many receiving multiple misdiagnoses, trialling of many treatments and specialists as symptoms vary for everyone.<sup>14</sup> It can then typically take two years to find the optimal management plan to control the condition.<sup>15</sup>

**Leanne Raven, CEO of Crohn's & Colitis Australia** said, "Despite being described as an 'invisible disease' the impact of Crohn's disease cannot be overstated. The high prevalence of psychological distress has a significant impact on all aspects of life including ability to work, family and friendships. With over 50% experiencing distress and only a third of those with severe distress seeing a mental health practitioner many are not receiving the mental health support needed.<sup>16</sup> Given many receive their diagnosis at the prime of their life, having access to more treatment options that will improve the quality of life for this community is paramount, especially as there is currently no cure."

**Associate Professor Gregory Moore, Head of Inflammatory Bowel Disease at Monash Medical Centre Melbourne** says, “As prevalence and severity of Crohn’s disease continues to rise in our community, an expansion of treatment options is crucial. The accessibility of RINVOQ for individuals living with Crohn’s disease offers the clinical community an additional avenue for managing this challenging condition. Given the variability of symptoms among individuals this makes this news especially encouraging.”

**Nathalie McNeil, Vice President and General Manager of AbbVie Australia and New Zealand** added, “AbbVie has a long and established history of working collaboratively with the IBD community to help those living with the condition. We take great pride in our research and development capabilities, as they have significantly enhanced the efficiency and accessibility of bringing medicines to patients. We are so pleased to be able to extend our listing of RINVOQ, offering a new treatment option for people living with CD.”

RINVOQ® is also PBS listed for severe active rheumatoid arthritis, chronic severe atopic dermatitis, severe psoriatic arthritis, ankylosing spondylitis and moderately to severely active ulcerative colitis (refer to the PBS schedule for full information).<sup>2</sup>

For more information around CD and its management, it is important to speak to a healthcare professional around the treatment options that are available and appropriate to meet individual needs.

### **Important RINVOQ® safety information<sup>2</sup>**

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.

**-ENDS-**

## **ABOUT RINVOQ®<sup>2</sup>**

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.<sup>2</sup>

RINVOQ® is used to treat:<sup>2</sup>

- 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).

## **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](http://www.abbvie.com.au) Follow @abbvie\_AU on Twitter, Facebook, Instagram, or our LinkedIn page.

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