

## PRESS RELEASE

### **AbbVie's HUMIRA® (adalimumab) receives Health Canada approval for the extension of the Polyarticular Juvenile Idiopathic Arthritis indication for patients between 2 and 4 years**

- Polyarticular juvenile idiopathic arthritis (JIA) occurs in approximately 25 per cent of all JIA patients<sup>1</sup>
- HUMIRA was approved in Canada in 2012 for moderate to severe polyarticular JIA in patients aged 4 to 17 years

MONTREAL, December 9, 2015 – AbbVie (NYSE: ABBV), a global, research-based biopharmaceutical company, today announced that Health Canada has approved the extension of the HUMIRA indication for moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) to reduce signs and symptoms in patients between 2 and 4 years. HUMIRA was approved in Canada in 2012 for polyarticular juvenile idiopathic arthritis (JIA) in patients aged 4 to 17 years.

“This is exciting news that there is now an indication for the use of HUMIRA for the treatment of polyarticular JIA in children two to four years old,” said Dr. Earl Silverman, Division of Rheumatology, SickKids Hospital. “I’m pleased that the regulatory agency has given its blessing, and this indication will no doubt be very reassuring to parents of children living with polyarticular JIA. Hopefully this will be a precedent for other medications used in JIA now and in the future.”

JIA is one of the most common chronic childhood diseases.<sup>2</sup> It is estimated that as many as 24,000 Canadian children aged 18 and under live with a form of arthritis, or more than three out of every 1,000 kids.<sup>2</sup> Polyarticular JIA, which is one of several types of JIA, involves five or more joints and occurs in approximately 25 per cent of all JIA patients.<sup>1</sup> Symptoms include painful, swollen and tender joints, limping, morning stiffness, decreased activity and the reluctance to use an arm or leg. Early diagnosis and appropriate management of polyarticular JIA are important in managing this chronic disease.

"This is great news for Canadian families," said Janet Yale, president and CEO of The Arthritis Society. "This updated indication opens the door to earlier treatment for young patients, which in turn offers the potential for improved long-term prognosis."

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<sup>1</sup> Seo, P. (2013). Juvenile Idiopathic Arthritis. In *Oxford American Handbook of Rheumatology* (Second ed., p. 322). Oxford University Press.

<sup>2</sup> The Arthritis Society, Childhood Arthritis, <http://arthritis.ca/manage-arthritis/living-well-with-arthritis/living-well-in-alberta-nwt/childhood-arthritis>  
Accessed on November 30, 2015

HUMIRA will now be available to patients age 2 to 17 years living with polyarticular JIA, with the dose based on patient body surface area. HUMIRA is available for this patient population in a pediatric vial.

“AbbVie is pleased that children between the ages of 2 and 4 living with polyarticular JIA will now have HUMIRA as an additional treatment option,” said Stéphane Lassignardie, general manager, AbbVie Canada. “This approval speaks to the safety and efficacy of HUMIRA, and it represents our continued commitment to addressing the needs of people, including young children, living with a wide range of immune-mediated diseases.”

HUMIRA is also approved in Canada in adults for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease (CD), ulcerative colitis (UC) and psoriasis (Ps), as well as in children with Crohn's disease 13 to 17 years of age weighing more than 40kg.

### **About HUMIRA**

HUMIRA resembles antibodies normally found in the body. It works by blocking TNF- $\alpha$ , a protein that, when produced in excess, plays a central role in the inflammatory responses of many immune-mediated diseases.

HUMIRA is one of the most comprehensively studied biologics available. The overall clinical database for HUMIRA spans 18 years across 13 indications globally (8 in Canada), including more than 100 clinical trials with more than 28,000 patients. HUMIRA is approved in 87 countries and used by more than 940,000 patients worldwide.

Any medicines can have side effects. Like all medicines that affect the immune system, HUMIRA can cause serious side effects.<sup>3</sup> Before initiation of, during and after treatment with HUMIRA, patients should be evaluated for active or inactive tuberculosis infection with a tuberculin skin test. For further information, please see the HUMIRA Product Monograph<sup>3</sup> available at [www.abbvie.ca](http://www.abbvie.ca).

### **About AbbVie Care**

Canadians prescribed HUMIRA will have the opportunity to be enrolled in AbbVie Care, AbbVie's signature support program. The program is designed to provide a wide range of customized services including reimbursement and financial support, pharmacy services, lab work coordination, injection training, personalized education and ongoing disease management support throughout the treatment.

For more information, call 1-866-8-HUMIRA (486472) or consult [www.abbviecare.ca](http://www.abbviecare.ca).

### **Important Safety Information<sup>3</sup>**

HUMIRA is a TNF blocker medicine that affects the immune system and can lower the ability to

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<sup>3</sup> HUMIRA® (adalimumab) Product Monograph. Date of Revision: November 5, 2015

fight infections. **Serious infections have happened in people taking HUMIRA. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections.** People should be tested for TB before HUMIRA use and monitored for signs and symptoms of TB during therapy. People at risk of TB may be treated with medicine for TB before starting HUMIRA. Treatment with HUMIRA should not be started in a person with an active infection, unless approved by a doctor. HUMIRA should be stopped if a person develops a serious infection. People should tell their doctor if they live in or have been to a region where certain fungal infections are common, have had TB, hepatitis B, are prone to infections, or have symptoms such as fever, fatigue, cough, or sores.

For people taking TNF blockers, including HUMIRA, the chance of getting lymphoma or other cancers may increase. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers including HUMIRA, the chance of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life threatening if treated.

Other possible serious side effects with HUMIRA include hepatitis B infection in carriers of the virus, allergic reactions, nervous system problems, blood problems, certain immune reactions, including a lupus-like syndrome, liver problems, and new or worsening heart failure or psoriasis. The use of HUMIRA with other biologic DMARDS (e.g., anakinra, or abatacept), or other TNF antagonists is not recommended. People using HUMIRA should not receive live vaccines.

Common side effects of HUMIRA include injection site reactions (redness, rash, swelling, itching, or bruising), upper respiratory infections (including sinus infections), headaches, rash, and nausea.

HUMIRA is given by injection under the skin. The benefits and risks of HUMIRA should be carefully considered before starting therapy.

This is not a complete list of the Important Safety Information for HUMIRA. For additional important safety information, please consult the HUMIRA Product Monograph<sup>3</sup> at: [www.abbvie.ca](http://www.abbvie.ca).

### **About AbbVie**

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit [www.abbvie.ca](http://www.abbvie.ca) and [www.abbvie.com](http://www.abbvie.com). Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](https://www.facebook.com/abbvie) or [LinkedIn](https://www.linkedin.com/company/abbvie) page.

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