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PRESS RELEASE

AbbVie's HUMIRA® (Adalimumab) Approved by Health Canada to Treat Pediatric Patients with Chronic Non-infectious Anterior Uveitis

- *The approval marks HUMIRA as the only approved biologic treatment option in Canada for pediatric patients from two years of age with chronic non-infectious anterior uveitis who have had inadequate response to conventional therapy*
- *The approval is based on results from SYCAMORE, an investigator-initiated clinical trial, which showed that HUMIRA combined with methotrexate significantly delayed the time to treatment failure compared to methotrexate plus placebo in children with active JIA-associated uveitis*[1]
- *Juvenile idiopathic arthritis (JIA) is the most common systemic disorder associated with non-infectious uveitis in children, accounting for more than 75 percent of cases of pediatric anterior uveitis*[2]

MONTREAL, QC, February 20, 2019 — AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that Health Canada has approved HUMIRA® (adalimumab) for the treatment of chronic non-infectious anterior uveitis in pediatric patients from two years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. HUMIRA is now the only approved biologic treatment option for chronic non-infectious anterior uveitis in children aged two years and older in Canada.

"This approval marks an important milestone for pediatric uveitis patients and their caregivers who, up until this point, had no biologic treatment options available to them," said Stéphane Lassignardie, General Manager of AbbVie Canada. "This label expansion for HUMIRA further demonstrates AbbVie's dedication to addressing the unmet medical needs for both adult and pediatric patients living with serious immune-mediated inflammatory diseases."

Uveitis is an inflammation of the uvea, which includes the iris, choroid and the ciliary body in the eye.[3] If left untreated, it can lead to vision loss, including cataracts, glaucoma and cystoid macular edema (CME).[4,5] Severe vision loss has been estimated to occur in 25 to 30 percent of pediatric uveitis cases, making early diagnosis and treatment essential to preserve vision in children with the disease.[4,6] JIA is the most common systemic disorder associated with uveitis in children accounting for more than 75 percent of cases of pediatric anterior uveitis.2

"For many children, the diagnosis of uveitis carries a significant burden in terms of number of visits to the hospital, threat to the patient's vision and anxiety for the whole family," explained Dr. Eric Fortin, ophthalmologist at the University of Montreal Ophthalmology Center. "Having this approval for the indication of pediatric uveitis will hopefully lead to easier access to HUMIRA for those patients who need it. That is something that is very important both to me and my patients."

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"Pediatric uveitis is a debilitating and potentially blinding condition, which poses overwhelming challenges to children and their families," said Christina Pelizon, Medical Director, AbbVie Canada. "The SYCAMORE study showed that HUMIRA in combination with methotrexate significantly delayed the time to treatment failure compared with methotrexate plus placebo. These results demonstrate HUMIRA has the potential to help many children who have failed standard treatments preserve their eyesight from the ocular complications associated with chronic non-infectious anterior uveitis."

The SYCAMORE clinical trial is a randomized controlled study of the clinical efficacy and safety of HUMIRA combined with methotrexate versus methotrexate plus placebo for the treatment of active JIA-associated uveitis. It was sponsored by the University Hospitals Bristol NHS Foundation Trust and coordinated by the Clinical Trials Research Centre at the University of Liverpool. The Independent Data Safety and Monitoring Committee (IDSMC) recommended unmasking the trial early after 90 randomized patients with active JIA-associated uveitis because it showed that HUMIRA combined with methotrexate controlled ocular inflammation better and was associated with a significantly lower rate of treatment failure, defined according to several criteria, including multiple components of intraocular inflammation, than placebo.[1]

About the SYCAMORE Trial[1]

The SYCAMORE clinical trial was sponsored by the University Hospitals Bristol NHS Foundation Trust and coordinated by the Clinical Trials Research Centre at the University of Liverpool. The study was supported by grants from the National Institute for Health Research Health Technology Assessment Programme and Arthritis Research UK. In this multicenter, double-masked, randomized, placebo-controlled trial, researchers assessed the efficacy and safety of HUMIRA in children and adolescents two years of age and older who had active JIA-associated uveitis noninfectious anterior uveitis who were refractory to at least 12 weeks of methotrexate treatment.

Patients who were taking a stable dose of methotrexate were randomly assigned in a 2:1 ratio to receive either HUMIRA (at a dose of 20 mg or 40 mg, according to body weight) or placebo, administered subcutaneously every two weeks. Patients continued the trial regimen until treatment failure or until 18 months had elapsed. Including a 6 months off-study drug period, they were followed for up to two years after randomization. The primary endpoint was the time to treatment failure, defined as meeting at least one of the following criteria: multiple components of intraocular inflammation, worsening or development of ocular comorbidities, use of concomitant medications that were not allowed or that did not follow pre-specified criteria, and suspension of treatment for an extended period of time.

Study results showed that the addition of HUMIRA to methotrexate significantly delayed the time to treatment failure as compared with placebo, and the pre-specified stopping criteria were met after the enrollment of 90 of 114 patients. Researchers observed 16 treatment failures in 60 patients (27 percent) in the HUMIRA group versus 18 treatment failures in 30 patients (60 percent) in the placebo group (hazard ratio, 0.25; 99.9 percent confidence interval [CI], 0.08 to 0.79; P<0.0001 [the pre-specified stopping boundary]).

About HUMIRA

HUMIRA resembles antibodies normally found in the body. It works by blocking TNF-α, 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 20 years across 15 indications globally (11 in Canada), including more than 71 clinical trials with more than 23,000 patients. HUMIRA is approved in 90 countries and used by more than one million patients worldwide.

Any medicines can have side effects. Like all medicines that affect the immune system, HUMIRA can cause serious side effects.[7] 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[1]available at www.abbvie.ca.

Important Safety Information
HUMIRA is a TNF blocker medicine that affects the immune system and can lower the body's ability to 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 or 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 biologics 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, swelling, itching, pain or bruising), cough and cold symptoms, headache, rash, nausea, pneumonia, fever and abdominal pain.

HUMIRA is given by injection under the skin.

The benefits and risks of HUMIRA should be carefully considered before starting therapy.

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This is not a complete list of the Important Safety Information for HUMIRA. For additional important safety information, please consult the HUMIRA Product Monograph at www.abbvie.ca

About AbbVie Care
The AbbVie Care program is designed to provide a wide range of customized services including reimbursement and financial support, pharmacy services, lab work reminders and coordination, personalized education and ongoing disease management support throughout the treatment journey. For more information, consult www.abbviecare.ca.

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. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at abbvie.ca and abbvie.com. Follow @abbviecanada and @abbvie on Twitter, or view careers on our Facebook or LinkedIn page.

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[7] HUMIRA (adalimumab) Product Monograph. AbbVie Corporation. Last updated January 23, 2019.

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