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# PRESS RELEASE

## Health Canada Approves Label Update for AbbVie's HUMIRA® (adalimumab) Supporting Potential For Use During Breastfeeding and Use During Pregnancy if Clearly Needed

- *Updated label provides guidance that HUMIRA use can be considered while breastfeeding and should only be used during pregnancy if clearly needed*[1]
- *Approval is supported by postmarketing data, a prospective cohort registry analysis designed to monitor and evaluate the exposure to medication during pregnancy, as well as literature regarding lactation*[1]

**MONTREAL, QC, October 15, 2018** – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced that Health Canada has approved a label update for HUMIRA® (adalimumab) to include clinical and postmarketing safety data surrounding pregnancy and breastfeeding. This label update includes guidance that HUMIRA use can be considered while breastfeeding and should only be used during pregnancy if clearly needed.[1]

"While Abbvie continues to exercise appropriate due caution regarding the safety of its products, the recent label change for HUMIRA is reassuring for women living with inflammatory bowel disease (IBD), particularly because IBD most commonly affects individuals in their peak reproductive years," said Dr. Cynthia Seow, Associate Professor, Division of Gastroenterology and Hepatology, University of Calgary. "While HUMIRA should be used during pregnancy only if clearly needed, this label update cites data demonstrating a lack of pattern of major birth defects with the use of HUMIRA during pregnancy, and a statement on the relative safety of HUMIRA use whilst breastfeeding."

"This label update provides important, clinically meaningful information allowing women and their healthcare professionals to better understand the safety of HUMIRA during pregnancy and breastfeeding, and to make an informed treatment decision," said Christina Pelizon, Medical Director, AbbVie Canada. "Understanding how immune-mediated diseases impact patients at all stages of life drives the way we conduct research and generate evidence to advance the field of immunology."

The Health Canada label update is based on final data from a prospective cohort pregnancy exposure registry conducted by OTIS (Organization of Teratology Information Specialists) / MotherToBaby, the leading group of maternal health experts in evaluation of drugs during pregnancy in North America, as well as literature review regarding lactation.

The registry, conducted in the U.S. and Canada between 2004 and 2016, compared the risk of major birth defects in live-born infants in 69 women with rheumatoid arthritis (RA) and 152 women with Crohn's disease (CD) treated with adalimumab at least during the first trimester with 74 women with RA and 32 women with CD not treated with adalimumab during pregnancy. The proportion of major birth defects among live-born infants in the adalimumab-treated and untreated cohorts was 10% (8.7% RA, 10.5% CD) and 7.5% (6.8% RA, 9.4% CD), respectively.

The lack of pattern of major birth defects is reassuring and differences between exposure groups may have impacted the occurrence of birth defects. This study cannot reliably establish whether there is an association between adalimumab and the risk for major birth defects because of methodological limitations of the registry, including small sample size, the voluntary nature of the study, and the non-randomized design.

Adalimumab may cross the placenta into the serum of infants born to women treated with HUMIRA during pregnancy. Consequently, these infants may be at increased risk for infection. Administration of live vaccines to infants exposed to adalimumab in utero is not recommended for five months following the mother's last HUMIRA injection during pregnancy.

Limited information from case reports in the published literature indicates the presence of adalimumab in human milk at concentrations of 0.1% to 1% of the maternal serum level. Published data suggest that the systemic exposure of adalimumab to a breastfed infant is expected to be low because adalimumab is a large molecule and is degraded in the gastrointestinal tract. However, the effects of local exposure in the gastrointestinal tract are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for adalimumab and any potential adverse effects on the breastfed child from adalimumab or from the underlying maternal condition.

**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 14 indications globally (10 in Canada), including more than 100 clinical trials with more than 33,000 patients. HUMIRA is approved in 90 countries and used by more than 1 million patients worldwide.

Any medicines can have side effects. Like all medicines that affect the immune system, HUMIRA can cause serious side effects.[1] 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.

**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.

**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.

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

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**References:**

[1] HUMIRA (adalimumab) Product Monograph. AbbVie Corporation. Last updated August 28, 2018.