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# PRESS RELEASE

## AbbVie's HUMIRA® (Adalimumab) Receives First and Only Health Canada Approval for Moderate to Severe Hidradenitis Suppurativa

- *Hidradenitis suppurativa (HS) is a painful, chronic inflammatory skin disease*

**Montreal, Canada – January 6, 2016** – AbbVie, a global biopharmaceutical company, today announced that Health Canada approved HUMIRA® (adalimumab) for the treatment of adults with active moderate to severe hidradenitis suppurativa (HS), who have not responded to conventional therapy (including systemic antibiotics). This follows approval from the Food and Drug Administration (FDA) and the European Commission. HUMIRA is now the first and only Health Canada-approved therapy for the treatment of adults living with HS.

HS is a chronic, systemic, immune-mediated skin disease which affects between 1 to 3% of the global population however the diagnosis is often delayed or the condition is misdiagnosed with the true prevalence unknown.[1]

In general, HS has a greater impact on the quality of life of affected individuals compared to other dermatological conditions.[2] The average Canadian HS patient will see five doctors with over 17 visits spanning eight years before being diagnosed. HS is associated with intense pain, decreased mobility, and the deep-seated lesions (nodules or abscesses) may be accompanied by unpleasant odor and purulent drainage. The lesions are present under the arms, groin, and perianal area with the breasts being affected in female individuals. With time, the lesions can be clustered with residual scarring.[3]

Dr Bourcier, Dermatologist at Centre Hospitalier Universitaire Hopital Georges-L. Dumont in Moncton, said, "There isn't much awareness about HS so it's often misdiagnosed. This means there are many patients living and suffering with this disease. The approval of a new treatment is a huge step forward for those living with HS bringing hope to patients and their families."

Maria Goguen, who lives with HS, added, "I have lived with HS for many years and the impact on my life is huge. I was lucky to have finally found a doctor who not only knew about my disease but who was able to have me participate in a clinical trial for HUMIRA. Since being on this medication I have been able to find my passion for photography again, spend more quality time with my daughter, and get involved in doing activities like dancing, hiking and camping that I had to stop since having HS."

"Bringing a much needed medication to HS patients is extremely important for AbbVie in our mission to treat unmet medical needs and improve the quality of life for people living with HS. We are working very diligently to co-create an enhanced treatment path for both patients and dermatologists as currently HS

patients are often lost in the system and very often in emergency rooms," said Stéphane Lassignardie, General Manager, AbbVie Canada.

Health Canada's approval for the treatment of HS adds to the comprehensive record of clinical studies that HUMIRA has established over its 11 years of use in immunology in Canada. This latest Health Canada approval is based on the results of two pivotal Phase 3 studies, PIONEER I and PIONEER II, and represents the ninth approved indication for HUMIRA in Canada.

PIONEER I and PIONEER II included 633 patients with moderate to severe HS. Patients in these studies were randomly assigned to receive either HUMIRA or placebo in addition to daily use of topical antiseptic. Both studies showed that more patients given HUMIRA had reductions in the total number of abscesses and inflammatory nodules than patients given placebo. No new safety risks were identified in these trials. More information on PIONEER I and PIONEER II is available at www.clinicaltrials.gov (NCT01468207 and NCT01468233, respectively).

**Important Safety Information**[4]

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, 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 [4] at www.abbvie.ca

**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 18 years across 13 indications globally (9 in Canada), including more than 100 clinical trials with more than 28,000 patients. HUMIRA is approved in 90 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.[4] 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[4] available at www.abbvie.ca.

**About AbbVie Care**

Canadians prescribed HUMIRA will have the opportunity to be enrolled in AbbVie Care, AbbVie's signature care program. The 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 and beyond.

For more information, call 1-866-8-HUMIRA (486472) or consult www.abbviecare.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.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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**References**

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2 Wolkenstein P, et al. J Am Acad Dermatol. 2007;56(4):621-623.

3 The Canadian Hidradenitis Suppurativa Foundation - www.hs-foundationcanada.org

4 HUMIRA (adalimumab) Product Monograph. AbbVie Corporation. (December 31, 2015).