



News

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**ABBOTT'S HUMIRA<sup>®</sup> (ADALIMUMAB) APPROVED IN  
CANADA FOR TREATMENT OF ANKYLOSING  
SPONDYLITIS**

*– Canada approval marks third for HUMIRA in treating autoimmune  
diseases –*

Montreal, Canada, November 7, 2006 – Abbott announced that it has received approval from Health Canada to market HUMIRA<sup>®</sup> (adalimumab) as a treatment for active ankylosing spondylitis (AS) in Canada. AS is a chronic disease of the spinal skeleton and large peripheral joints that causes inflammatory back pain and stiffness, but can also be associated with other inflammatory diseases of the skin, eyes and intestines. In its severe form, AS over time can result in complete spinal fusion, causing extreme physical limitation. It is estimated that AS affects between 150,000 and 300,000 Canadians (as many as one in 100).

# **ABBOTT'S HUMIRA® (ADALIMUMAB) APPROVED IN CANADA FOR TREATMENT OF ANKYLOSING SPONDYLITIS**

This is the third in a series of autoimmune diseases targeted for HUMIRA therapy. HUMIRA is also approved in Canada for the treatment of moderately to severely active rheumatoid arthritis and active psoriatic arthritis.

"This approval of HUMIRA in Canada is important in the treatment of ankylosing spondylitis, a debilitating disease that strikes young, mostly male patients in their thirties and forties," said Walter P. Maksymowych, M.D., Professor of Medicine at the University of Alberta. "Treatments like HUMIRA are changing how we can treat AS. HUMIRA has been shown to significantly reduce the pain and inflammation caused by AS and substantially improve function and reduce disability."

HUMIRA will be available immediately to patients with ankylosing spondylitis in Canada.

Unlike many other rheumatic conditions, AS affects mostly young men, and commonly begins before the age of 35. AS is difficult to diagnose in its early stages and is one of the most overlooked causes of persistent back pain in young adults.

## **Clinical Trial Results**

The approval of HUMIRA for the treatment of AS is based on data from the ATLAS (Adalimumab Trial Evaluating Long-Term Efficacy and Safety in AS) trial.

ATLAS was a randomized, placebo-controlled, double-blind, Phase III study conducted in Europe and the United States. Results showed that HUMIRA was successful in reducing pain and inflammation in patients with AS – the study's primary endpoint. Other findings demonstrated the efficacy of HUMIRA in many patients in reducing disease activity and improving physical function and physical quality of life.

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"Today's approval of HUMIRA as a treatment for active ankylosing spondylitis marks another milestone for Abbott, and more importantly for patients, in providing new treatment options for this potentially debilitating autoimmune disease," said Rebecca Hoffman, M.D., divisional vice president, Immunology Development, Abbott. "Thousands of Canadians with rheumatoid arthritis and psoriatic arthritis have been prescribed HUMIRA. Now Canadians with AS have the option of HUMIRA as well."

The safety profile for patients with ankylosing spondylitis treated with HUMIRA® 40 mg every other week was similar to the safety profile seen in patients with rheumatoid arthritis. In the ATLAS trial, a similar rate of treatment emergent adverse events leading to discontinuation of study drug was observed among placebo-treated (1.9 percent) and HUMIRA-treated (1.4 percent) patients. The overall incidence of adverse events reported by patients treated with HUMIRA was higher than the placebo-treated patients. The most common adverse events included nasopharyngitis, injection site reactions and headache.

## **About Ankylosing Spondylitis**

Ankylosing spondylitis (AS), or arthritis of the spine, is an autoimmune disorder in which a human protein, tumor necrosis factor-alpha (TNF- $\alpha$ ), has been suggested to play a role in the disease development. AS is a form of arthritis known as spondyloarthritis, which is a group of closely linked rheumatic diseases that can cause pain in the spine and joints as well as ligaments and tendons. AS is a chronic disease that primarily affects the spine causing back stiffness and potential deformity over time.

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## **Important Safety Information**

The most common adverse events seen in the two placebo-controlled clinical trials in ankylosing spondylitis (HUMIRA vs. placebo) included headache (4.5 percent vs. 2.6 percent), injection site reaction (3.3 percent vs. 0.7 percent), nasopharyngitis (3.3 percent vs. 0.0 percent), and injection site pain (2.4 percent vs. 2.0 percent). As with any treatment program, the benefits and risks of HUMIRA should be carefully considered before initiating therapy.

Patients must be monitored closely for infections, including tuberculosis (TB), before, during and after treatment with HUMIRA. Treatment should not be initiated in patients with active infections until infections are controlled. Patients who develop new infections while using HUMIRA should be monitored closely. HUMIRA should not be used by patients with active TB or other severe infections such as sepsis and opportunistic infections. HUMIRA should be discontinued if a patient develops a serious infection until their infection is controlled. Physicians should exercise caution when considering the use of HUMIRA in patients with a history of recurrent infection or with underlying conditions that may predispose patients to infections.

TNF antagonists, including HUMIRA, have been associated in rare cases with exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Prescribers should exercise caution in considering the use of HUMIRA in patients with pre-existing or recent-onset central nervous system demyelinating disorders.

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There have been very rare cases of certain kinds of cancer in patients taking HUMIRA or other TNF blockers.

## **About HUMIRA**

### **Rheumatoid Arthritis**

HUMIRA (adalimumab) is indicated for reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). HUMIRA can be used alone or in combination with methotrexate (MTX) or other DMARDs.

When used as first-line treatment in recently diagnosed patients who have not been previously treated with methotrexate (MTX), HUMIRA should be given in combination with MTX. HUMIRA can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is contraindicated.

### **Psoriatic Arthritis**

HUMIRA (adalimumab) is indicated for reducing the signs and symptoms of active arthritis in adult psoriatic arthritis patients. HUMIRA can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.

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## **Ankylosing Spondylitis**

HUMIRA (adalimumab) is indicated for reducing the signs and symptoms in patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy.

To date, HUMIRA has been approved in 65 countries and prescribed to more than 150,000 patients worldwide. Clinical trials are currently underway evaluating the potential of HUMIRA in other autoimmune diseases.

## **About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs 65,000 people and markets its products in more than 130 countries.

Abbott Canada is headquartered in Saint-Laurent, Québec, and employs approximately 2,000 people. Its key businesses include nutritionals, pharmaceuticals, diabetes care products, diagnostics, point-of-care products and vascular products.

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