

FOR IMMEDIATE RELEASE



News

## Health Canada approves HUMIRA® (adalimumab) for treatment of Crohn's disease

*Canada has the world's highest reported incidence and prevalence of Crohn's disease<sup>1</sup> with more than 80,000 Canadian adults diagnosed<sup>2</sup>, most before age 40*

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**MONTRÉAL**, January 21, 2008 — Abbott announced today it has received Health Canada approval for HUMIRA® (adalimumab) as a treatment for reducing signs and symptoms, and inducing and maintaining clinical remission, of moderately to severely active Crohn's disease in adult patients who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

HUMIRA is the first and only fully human biologic treatment for Crohn's disease and the only biologic treatment for Crohn's disease to offer patients the convenience of self-injection every two weeks at or away from home. Crohn's disease is the fourth Health Canada approval in autoimmune diseases for HUMIRA.

"HUMIRA's approval gives Crohn's disease patients access to a treatment that may significantly impact their symptoms and reduce the rate of hospitalizations, and that allows them to self-administer their medication," said Dr. Charles Bernstein, a gastroenterologist in Winnipeg. "Self-administered medication of this type provides enhanced freedom for uninterrupted engagement in everyday activities such as school and work. There is an unmet need for this convenience."

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<sup>1</sup> Charles N. Bernstein, M.D., Andre Wajda, M.S., Lawrence W. Svenson, B.Sc., Adrian MacKenzie, B.Sc., Mieke Koehoorn, Ph.D., Maureen Jackson, M.Sc., Richard Fedorak, M.D., David Israel, M.D., and James F. Blanchard, M.D., Ph.D.: *The Epidemiology of Inflammatory Bowel Disease in Canada: A Population-Based Study*. American Journal of Gastroenterology 2006; 101:1559-1568 (Blackwell Publishing)

<sup>2</sup> Crohn's & Colitis Foundation of Canada

Crohn's disease is a serious chronic, inflammatory disease of the gastrointestinal (GI) tract that affects more than 80,000 Canadians. This is the highest reported prevalence of Crohn's disease in the world<sup>3</sup>. Within Canada, prevalence and incidence of Crohn's disease are highest in Nova Scotia, where the incidence rate in 2000 was 20.2 per 100,000 person-years and prevalence was 319 per 100,000 person-years<sup>4</sup>.

Crohn's disease affects people of all ages but it is primarily a disease of young adults, with onset typically before age 40. There is no known cause or cure for Crohn's disease and few treatment options exist for patients afflicted with the condition. As many as 75 percent of patients with Crohn's disease undergo surgery at least once for complications or disease resistance to treatment. Of those who undergo surgery to remove a portion of the intestines (resection), half experience a relapse within five years<sup>5</sup>.

Describing his experience with the disease, John Harvie, a HUMIRA clinical trial patient said, "Crohn's disease overwhelmed me and controlled my life. Treatment with HUMIRA gave me relief from my symptoms and I am back in control of my life, enjoying family and social activities I have not participated in for years."

Because Crohn's disease affects Canadians in their prime working years, it may have considerable impact on their employment. Canadians diagnosed with Crohn's disease are more likely to be nonparticipants in the work force than are people diagnosed with other chronic diseases<sup>6</sup>. In 1998, the indirect cost of nonparticipation in the work force as a result of inflammatory bowel disease, including Crohn's disease, exceeded \$104 million Canadian dollars<sup>7</sup>.

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<sup>3</sup> *Bernstein et al: Ibid*

<sup>4</sup> Person-years are the sum of the number of years that each member of a population has been afflicted with a specific disease.

<sup>5</sup> Abbott Laboratories news release: *HUMIRA receives FDA approval for treatment of Crohn's Disease*. February 27, 2007

<sup>6</sup> Teresa Longbardi, M.A., Philip Jacobs, Ph.D., Lieling Wu, M.Sc., and Charles N. Bernstein, M.D.: *Work Losses Related to Inflammatory Bowel Disease in Canada: Results from a National Population Health Survey*. American Journal of Gastroenterology 2003; 98: 844-849. (Blackwell Publishing)

<sup>7</sup> *Ibid*

**About HUMIRA for Crohn's Disease**

Health Canada approval of HUMIRA was based on data from three pivotal trials of HUMIRA in Canada, the United States and other countries. At 16 sites in Canada, 373 Canadians were among the 1,400 adult patients with moderately to severely active Crohn's disease who participated in these clinical trials. In Québec, 34 patients participated at four sites.

These trials evaluated efficacy and safety of HUMIRA in a diverse group of moderate to severe adult Crohn's disease patients, from those who were naive to biologic therapy, to patients who had previously lost response or were intolerant to the currently available biologic.

**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 has been approved in 67 countries and more than 190,000 people worldwide are currently being treated with HUMIRA. Clinical trials are currently under way evaluating the potential of HUMIRA in other immune-mediated diseases.

Any medicines can have side effects. Like all medicines that affect your immune system, HUMIRA can cause serious side effects<sup>8</sup>. Before initiation of, during and after treatment with HUMIRA, patients should be evaluated for active or latent tuberculosis infection with a tuberculin skin test. For further information, please see HUMIRA product monograph<sup>8</sup> available at [www.abbott.ca](http://www.abbott.ca).

**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.

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<sup>8</sup> Product Monograph. HUMIRA ® (adalimumab). Date of Revision: July 05, 2007.

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Headquartered in Montréal, Québec, Abbott Canada employs almost 2,000 people and is one of the "50 Best Employers in Canada", according to a survey by Hewitt Associates.

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