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News

Abbott seeks Health Canada approval of HUMIRA® for psoriasis

- *If approved, HUMIRA would offer a new, convenient treatment option to Canadians affected by moderate to severe psoriasis, a chronic autoimmune disease that attacks the skin.*
- *Promising results of two clinical trials, which included 500 Canadian patients at sites across Canada, support Abbott's submission to Health Canada. Psoriasis is the fifth autoimmune disease targeted for HUMIRA therapy in Canada.*
- *Painful and unsightly, the scaly raised, red skin lesions (plaques) of psoriasis may crack and bleed, impacting careers, social and personal relationships. Psoriasis, associated with depression, obesity and alcoholism, often results in social isolation and economic hardship.^{1,2}*

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MONTRÉAL, April 30, 2007— Abbott Canada announced today that it has filed a Supplemental New Drug Submission (SNDS) with Health Canada, seeking approval to market HUMIRA (adalimumab) as a treatment for moderate to severe chronic plaque psoriasis. More than 600,000 Canadians of all ages are affected by psoriasis.

Psoriasis is a non-contagious, chronic autoimmune disease that causes the body to attack itself and create raised, inflamed, scaly, red lesions known as plaques, which may crack and bleed. Psoriasis is more than skin lesions. It is painful and can impact many aspects of a person's life, from professional and social activities to personal relationships. People with psoriasis may also suffer from poor self-image and social isolation.

Abbott Canada's SNDS filing with the Biologics and Genetic Therapies Directorate, Health Canada, is based on results of two double-blind, placebo-controlled trials of HUMIRA: REVEAL and CHAMPION. In both trials, reduction in

¹ Kimball, Alexa B.; Jacobson, Christine; Weiss, Stefan; Vreeland, Mary G.; Wu, Ying: *The Psychosocial Burden of Psoriasis*. American Journal of Clinical Dermatology, 2005; 6 (6): 383-392

² Pearce, Daniel J.; Singh, Saurabh; Balkrishnan, Rajesh; Kulkarni, Amit; Fleisher, Alan B., Jr. & Feldman, Steven R.; *The negative impact of psoriasis on the workplace*. Journal of Dermatological Treatment. 2006; 17:24-28

disease activity was determined by the Psoriasis Area and Severity Index (PASI) score, which measures the extent and severity of psoriasis.

In Canada, REVEAL and CHAMPION trial sites were located in St. John's, Halifax, Québec, Montréal, Toronto, North Bay, Hamilton, Waterloo, London, Windsor, Calgary, Edmonton and Vancouver.

“This is fantastic news because it gives added hope to Canadians with psoriasis,” said Dr. Kim Papp, President of the Dermatology Association of Ontario, and President of Probit Medical Research, Waterloo, Ontario. “This submission for HUMIRA® in psoriasis brings patients closer to accessing a biologic treatment option that may provide clearance from the disfiguring, painful skin lesions that profoundly affect their lives. We expect our patients, their families and other dermatologists will welcome the results from the HUMIRA clinical trials and look forward to the convenience and ease of a self-administered injection.”

About HUMIRA Psoriasis Clinical Trials

- In REVEAL, a pivotal 52-week trial, the short-term and sustained clinical efficacy and safety of HUMIRA were evaluated in more than 1,200 patients from Canada and the United States with moderate to severe chronic plaque psoriasis. Patients experienced a significant reduction in the signs of their disease at 16 weeks when treated with HUMIRA; specifically, almost three out of four patients (71 percent) receiving HUMIRA achieved PASI 75 or better, compared to only 6.5 percent of patients receiving placebo. One in five (20 percent) patients receiving HUMIRA achieved PASI 100 (complete clearance), compared to less than 1 percent of patients receiving placebo.
- In CHAMPION, a 16-week study evaluating 271 psoriasis patients from Canada and Europe, twice the percentage (80 percent) of patients treated with HUMIRA achieved PASI 75 compared to patients treated with methotrexate (36 percent), a standard systemic treatment for psoriasis, and four times more than patients treated with placebo (19 percent). Nearly 17 percent of patients treated with HUMIRA achieved PASI 100 at week 16, compared to 7 percent of patients receiving methotrexate and 2 percent of patients receiving placebo. In addition, a mean PASI improvement of 57 percent was achieved at week four in patients receiving HUMIRA, compared to baseline.

"With almost 20 percent of patients achieving PASI 100, or complete clearance, in these two clinical trials, HUMIRA shows tremendous promise for physicians and people living with this condition, which has no cure," said Eugene Sun, M.D., vice president, Global Pharmaceutical Clinical Development at Abbott.

The adverse events observed in REVEAL and CHAMPION were similar to those observed in previous HUMIRA studies. The most commonly reported adverse events in HUMIRA psoriasis trials were upper respiratory tract infection, nasopharyngitis (inflammation of the nose and pharynx) and headache.

HUMIRA has almost ten years of clinical experience. More than 180,000 patients worldwide are currently being treated with HUMIRA. HUMIRA is also approved to treat psoriatic arthritis, a form of arthritis that affects up to 30 percent of people with psoriasis.

More Information About Psoriasis

Psoriasis is a chronic autoimmune disease that speeds the growth cycle of skin cells and results in thick scaly areas of skin. The most common form of psoriasis appears as red, raised areas of skin covered with flaky white scales, which may itch or burn. Psoriasis most commonly appears on the scalp, knees, elbows, lower back, hands and feet, though it can develop anywhere on the skin. It may even occur in the fingernails, toenails and in the joints. While psoriasis can occur in people of all ages, it typically appears in patients between the ages of 15 and 35. The severity of the disease varies from person to person. Currently, there is no cure for psoriasis.

Important Safety Information

Serious infections, sepsis, tuberculosis (TB) and rare cases of opportunistic infections, including fatalities, have been reported with the use of TNF-blocking agents, including HUMIRA. Many of these serious infections have occurred in patients also taking other immunosuppressive agents that in addition to their underlying disease could predispose them to infections. Treatment with HUMIRA should not be initiated in patients with active infections. TNF-blocking agents, including HUMIRA, have been associated with reactivation of hepatitis B (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Patients at risk for HBV infections should be evaluated for prior evidence of HBV infections before initiating HUMIRA. The combination of HUMIRA and anakinra is not recommended.

TNF-blocking agents, including HUMIRA, have been associated in rare cases with demyelinating disease and severe allergic reactions. Infrequent reports of serious blood disorders have been reported with TNF-blocking agents. More cases of malignancies have been observed among patients receiving TNF blockers, including HUMIRA, compared to control patients in clinical trials.

These malignancies, other than lymphoma and non-melanoma skin cancer, were similar in type and number to what would be expected in the general population. There was an approximately four fold higher rate of lymphoma in combined controlled and uncontrolled open-label portions of HUMIRA clinical trials. The potential role of TNF-blocking therapy in the development of malignancies is not known. Worsening congestive heart failure (CHF) has been observed with TNF-blocking agents, including HUMIRA, and new onset CHF has been reported with TNF-blocking agents. Treatment with HUMIRA may result in the formation of auto-antibodies and rarely, in development of a lupus-like syndrome.

The most frequent adverse events seen in the placebo-controlled clinical trials in rheumatoid arthritis (HUMIRA vs. placebo) were injection site reactions (20 percent vs. 14 percent), upper respiratory infection (17 percent vs. 13 percent), injection site pain (12 percent vs. 12 percent), headache (12 percent vs. 8 percent), rash (12 percent vs. 6 percent) and sinusitis (11 percent vs. 9 percent). Discontinuations due to adverse events were 7 percent for HUMIRA and 4 percent for placebo. As with any treatment program, the benefits and risks of HUMIRA should be carefully considered before initiating therapy.

In HUMIRA clinical trials for ankylosing spondylitis, psoriatic arthritis and Crohn's disease, the safety profile for patients treated with HUMIRA was similar to the safety profile seen in patients with rheumatoid arthritis.

About HUMIRA

HUMIRA is the only fully human monoclonal antibody approved in Canada for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). HUMIRA resembles antibodies normally found in the body. It works by blocking tumor necrosis factor alpha (TNF- α), a protein that when produced in excess, plays a central role in the inflammatory responses of many immune-mediated diseases. To date, HUMIRA has been approved in 67 countries and more than 180,000 people worldwide are currently being treated with HUMIRA.

Clinical trials are currently under way evaluating the potential of HUMIRA in other immune-mediated diseases. Abbott plans to begin trials of HUMIRA in children and adolescents with psoriasis later this year.

In Canada, HUMIRA, alone or in combination with methotrexate (MTX) or other DMARDs, 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). 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.

HUMIRA, in combination with methotrexate, is also approved for reducing the signs and symptoms of active arthritis in adult psoriatic arthritis patients who do not respond adequately to methotrexate alone as well as for reducing the signs and symptoms in patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy. In late 2006, Abbott filed for regulatory approval of HUMIRA in the treatment of Crohn's disease.

Abbott's Commitment to Immunology

Abbott is focused on the discovery and development of innovative treatments for immunologic diseases. The Abbott Bioresearch Center, founded in 1989 in Worcester, Mass., United States, is a world-class discovery and basic research facility committed to finding new treatments for autoimmune diseases.

More information about HUMIRA, including Canadian full prescribing information for RA, PsA and AS, is available on the Web site 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.

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

Abbott's news releases and other information are available on the company's Web sites at www.abbott.com and www.abbott.ca

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