Abbott's HUMIRA® (Adalimumab) Approved In Europe For Treatment Of Ulcerative Colitis (UC)

HUMIRA® Becomes First and Only Self-injectable Biologic Therapy for the Treatment of Moderately to Severely Active UC in Adults

Abbott Park, Illinois (NYSE: ABT) — Abbott today announced that the European Commission has approved HUMIRA® (adalimumab) for the treatment of moderately to severely active ulcerative colitis (UC) in adult patients who have had an inadequate response to conventional therapy. With this approval, HUMIRA becomes the first and only self-injectable biologic therapy for the treatment of moderately to severely active ulcerative colitis in adults. The approval also marks the seventh indication for HUMIRA in the European Union since the product's first approval in 2003.

UC is a chronic inflammatory bowel disease that causes ulcers in the colon[i] and may lead to life-threatening complications.[ii] It is estimated that UC affects up to 1.2 million people in the European Union.[iii] It is also estimated that up to one third will undergo surgical removal of the colon during their lifetimes[iv] – leaving patients with a permanent colostomy or ileal pouch.

"This is a difficult-to-treat chronic disease with limited treatment options," said William J. Sandborn, M.D., chief, Division of Gastroenterology at UC San Diego Health System and lead investigator. "A new therapeutic option used for the induction and maintenance of remission, with the convenience of self-administering at home is welcomed among this unique patient population."

"This approval represents an important new therapeutic option for people with UC," said Marco Greco, chairman of the European Federation of Crohn's & Ulcerative Colitis Associations. "Having one more option to treat this disease provides new hope that some patients will be able to achieve remission of their disease."

HUMIRA is also indicated for the treatment of several other inflammatory diseases, including moderately to severely active rheumatoid arthritis, active polyarticular juvenile idiopathic arthritis, moderate to severe chronic plaque psoriasis, and severely active Crohn's disease, when conventional treatment has failed. The new indication for moderately to severely active ulcerative colitis further supports the use of HUMIRA for the treatment of inflammatory bowel diseases.

"The approval of HUMIRA for the treatment of moderately to severely active ulcerative colitis further demonstrates HUMIRA's versatility in treating a wide range of immune-mediated inflammatory diseases," said John Leonard, M.D., senior vice president, Pharmaceuticals Research and Development, Abbott. "This marks an important milestone in Abbott's continued commitment to advance science and help improve the standards of care for patients."

The approval was based on two Phase III clinical trials involving more than 800 patients in 21 countries across the globe.

About UC

UC is a chronic inflammatory bowel disease that causes inflammation in the rectum and colon, resulting in diarrhea, rectal bleeding and abdominal cramping. Typically, people are diagnosed with UC in their mid-30s, though the disease can occur at any age.

The symptoms of UC tend to come and go, with varying periods of clinical stability punctuated by episodic flares of disease activity. Common symptoms include frequent loose bowel movements and rectal bleeding. Severe flares of UC can necessitate hospitalization and can be life-threatening. Treatment may include medication and surgery.

About HUMIRA® (adalimumab)

Globally, uses and prescribing information vary; please refer to the individual country label for complete information.

HUMIRA is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

HUMIRA is indicated for treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

HUMIRA in combination with methotrexate, is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate and for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

HUMIRA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. HUMIRA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.

HUMIRA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). HUMIRA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. HUMIRA has not been studied in children aged less than 4 years.

HUMIRA is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

HUMIRA is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. HUMIRA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

HUMIRA is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

Important Safety Information

HUMIRA is a TNF blocker that affects the immune system and can lower the ability to fight infections.

People treated with HUMIRA are at an increased risk for developing serious infections that may lead to hospitalization or death. Reported serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. 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. 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.

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.

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 anakinra or abatacept 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.

As with any treatment program, the benefits and risks of HUMIRA should be carefully considered before starting therapy.

About Abbott

Abbott (NYSE: ABT) 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 approximately 91,000 people and markets its products in more than 130 countries.

[i] National Institutes of Health Website.
http://www.nlm.nih.gov/medlineplus/colonicdiseases.html Last accessed March 14, 2012
[ii] Huber, W. Life-threatening complications of Crohn's disease and ulcerative colitis: a systematic analysis of admissions to an ICU during 18 years. Dtsch Med Wochenschr. 2010 Apr;135(14):668-74. Epub 2010 Mar 31
[iii] Molodecky, N. Increasing incidence and prevalence of the inflammatory bowel diseases with time, based on systematic review. Gastroenterology. 2012 Jan;142(1):46-54.e42; quiz e30. Epub 2011 Oct 14
[iv] Crohn’s and Colitis Federation of America website.
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