Abbott's HUMIRA® (Adalimumab) Approved In Europe For Expanded Treatment Of Crohn's Disease (CD)

- Approval Extends HUMIRA Indication to Include Moderately Active Crohn's Disease

ABBOTT PARK, Illinois, Aug. 30, 2012 /PRNewswire/ -- Abbott today announced that the European Commission (EC) has approved HUMIRA® (adalimumab) for the treatment of moderately active Crohn's disease (CD) in adult patients who have had an inadequate response to conventional therapy. HUMIRA has been approved for severely active CD in adults in the European Union (EU) since 2007.

Crohn's disease is a serious, chronic inflammatory bowel disease (IBD) of the gastrointestinal (GI) tract that affects up to one million people in Europe. CD affects people of all ages, but it is most often diagnosed in adolescents and young adults. Complications and disorders associated with moderate to severe disease can include rectal bleeding, fistulas (ulcers that form tunnels to surrounding tissues), anemia and fatigue – all of which can significantly affect a patient's quality of life. Those with severely active CD may have other serious symptoms such as evidence of intestinal tissue damage and abscesses (pockets of infection that cause swelling and inflammation).

"The approval of HUMIRA for the treatment of adult patients with moderate CD is an important step to improve treatment in patients suffering from active Crohn's disease," said Paul Rutgeerts, M.D., Ph.D., director, Multidisciplinary Department of Endoscopy and chair of the Inflammatory Bowel Diseases group at the University Hospital Gasthuisberg in Leuven, Belgium. "This label extension provides more patients access to a convenient, self-administered therapeutic option."

The approval is supported by four Phase 2/3 clinical trials which evaluated the use of HUMIRA to induce and maintain clinical remission in adult patients with moderately to severely active CD.

"With this label extension, physicians now have HUMIRA as another option to treat patients with this debilitating and progressive disease," said John Leonard, M.D., senior vice president, Pharmaceuticals Research and Development, Abbott. "This approval demonstrates Abbott's continued commitment to making HUMIRA available to more patients with inflammatory bowel diseases and other immune mediated disorders."

In addition to its approved uses in moderately to severely active CD, HUMIRA is indicated in Europe for the treatment of several other inflammatory diseases including: moderately to severely active rheumatoid arthritis, active and progressive psoriatic arthritis, active polyarticular juvenile idiopathic arthritis, moderate to severe chronic plaque psoriasis, moderately to severely active ulcerative colitis and severe axial spondyloarthritis. The label extension for moderately active CD further supports the use of HUMIRA for the treatment of IBD.

About CD

CD is a serious, chronic and debilitating inflammatory disease of the GI tract that affects millions of people worldwide. CD can affect people of all ages but most often is diagnosed in those between 15 and 35 years of age.

CD is characterized by periods in which the disease flares up, is active and causes symptoms such as cramping, weight loss and in some cases, rectal bleeding. These episodes can be followed by times of remission—periods in which symptoms disappear or decrease. Other common symptoms of the disease include diarrhea, abdominal pain and fever.

About HUMIRA

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 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 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 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.

HUMIRA is indicated for the treatment of adults with severe axSpA without radiographic evidence of ankylosing spondylitis, but with objective signs of inflammation by elevated c-reactive protein (CRP) and/or MRI who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs). HUMIRA is currently indicated for the treatment of adults with severe active AS who have had an inadequate response to conventional therapy.

Important Safety Information

HUMIRA is a TNF blocker medicine that affects the immune system and can lower the 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. 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, 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 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.

HUMIRA is given by injection under the skin.

The benefits and risks of HUMIRA should be carefully considered before starting therapy.

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 approximately 91,000 people and markets its products in more than 130 countries.

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