Abbott's HUMIRA® (Adalimumab) Receives U.S. FDA Approval For The Treatment Of Adult Patients With Moderate To Severe Ulcerative Colitis

- HUMIRA is now indicated to treat adult patients with moderate to severe ulcerative colitis who have had an inadequate response to immunosuppressants

- Approval makes HUMIRA the first and only self-administered biologic for use in UC and the first treatment approved for these patients in more than seven years

- UC is seventh approved indication for HUMIRA in the United States

ABBOTT PARK, Ill., Sept. 28, 2012 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved HUMIRA® (adalimumab) for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis (UC) when certain other medicines have not worked well enough. Combined with its approval to treat moderate to severe Crohn's disease, HUMIRA is now approved for the treatment of two primary diseases that comprise inflammatory bowel disease (IBD).

HUMIRA works by inhibiting tumor necrosis factor-alpha (TNF-alpha). The UC approval represents the seventh indication for this treatment in the U.S. and makes HUMIRA the first and only self-administered biologic treatment approved for use in this disease. It is not known if HUMIRA is effective in people with moderate to severe UC who have lost response to or could not tolerate anti-TNF medicines. HUMIRA can be self-administered after proper injection training is received and with proper physician monitoring.

"There is significant unmet medical need in this patient population, which has not seen a new treatment approved in more than seven years," said William J. Sandborn, M.D., division chief, Gastroenterology, University of California, San Diego. "This FDA approval is good news for patients and health care professionals who are seeking another option to manage the disease."

UC is a chronic disease that is marked by inflammation and ulceration in the lining of the colon or large intestine. It is estimated that approximately 700,000 people in the U.S. have UC. On average, people are diagnosed with UC in their mid-30s, though the disease can occur at any age. Symptoms include abdominal cramping, rectal bleeding, diarrhea, and urgency and frequency to have a bowel movement. The symptoms of UC tend to come and go, with periods of remission between flare-ups. Treatment may include medication and/or surgery.

It is also important that UC patients properly manage their nutrition because fluids, nutrients and electrolytes can be lost due to rectal bleeding and diarrhea. Additionally, 25 percent of UC patients will require surgery during the course of the disease.

"Since the first FDA approval of HUMIRA in late 2002, Abbott has continued to investigate the medication in multiple conditions with the goal of bringing this treatment option to more patients who may benefit from it," said John M. Leonard, M.D., senior vice president, Global Pharmaceutical Research and Development, Abbott. "This approval underscores Abbott's commitment to investing in and advancing our pipeline to benefit patients with IBD."

About the HUMIRA UC Phase 3 Clinical Program
Abbott's submission for HUMIRA was supported by results from two phase 3 studies, ULTRA 1, an 8-week study, and ULTRA 2, a 52-week study, both of which enrolled adult patients who had moderately to severely active UC despite concurrent or prior treatment with immunosuppressants (i.e., corticosteroids, azathioprine, or 6-mercaptopurine).

The primary endpoint of both studies was the proportion of patients achieving clinical remission at specified time points (week 8 in ULTRA 1 and weeks 8 and 52 in ULTRA 2). Remission was defined as a Mayo score of ≤ 2 and no individual subscore > 1. The Mayo score is calculated based on subscores of stool frequency, rectal bleeding, physician's global assessment and endoscopy. In the FDA-approved dose, both studies achieved their primary endpoints. The safety results from both studies were consistent with the known safety profile of HUMIRA and no new safety signals were identified.

Other Approved HUMIRA Indications
HUMIRA is a prescription medicine used:

To reduce the signs and symptoms of:

- **Moderate to severe rheumatoid arthritis (RA)** in adults. HUMIRA can be used alone, with methotrexate, or with certain other medicines. HUMIRA may prevent further damage to the bones and joints and may help the ability to perform daily activities.
- **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA)** in children 4 years of age and older. HUMIRA can be used alone, with methotrexate, or with certain other medicines.
- **Psoriatic arthritis (PsA)** in adults. HUMIRA can be used alone or with certain other medicines. HUMIRA may prevent further damage to the bones and joints and may help the ability to perform daily activities.
- **Ankylosing spondylitis (AS)** in adults.
- **Moderate to severe Crohn's disease (CD)** and to achieve and maintain clinical remission in adults who have not responded well to conventional treatments. HUMIRA is also for these adults who have lost response to or are unable to tolerate infliximab.

To treat moderate to severe chronic plaque psoriasis (Ps) in adults who are ready for systemic therapy or phototherapy, and

are under the care of a doctor who will decide if other systemic therapies are less appropriate.

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.

Full Prescribing Information for HUMIRA is available at http://www.rxabbott.com/pdf/humira.pdf.

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.

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

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