# ABBOTT RECEIVES POSITIVE OPINION FOR HUMIRA® IN ULCERATIVE COLITIS FROM EMA'S CHMP

Positive Opinion Based on Supporting Data from Two Phase III Clinical Studies

Abbott Park, Illinois.(NYSE: ABT) — Abbott today announced that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for HUMIRA® (adalimumab) in adults with moderate to severely active ulcerative colitis (UC) who have not responded to, cannot tolerate or have medical contraindications to conventional therapies. Based on the CHMP's positive opinion, a final decision from the European Commission is anticipated in the next few weeks. Upon final decision, HUMIRA will be the first and only self-injectable biologic therapy available for moderate to severe UC patients.

UC is a chronic inflammatory bowel disease that causes inflammation in the colon and may lead to life-threatening complications. There is no known cure for UC other than surgical removal of the colon. It is estimated that UC affects up to 1.2 million people in the European Union and approximately 25 percent of UC patients will undergo some type of surgery to treat their symptoms during their lifetimes.

"A diagnosis of ulcerative colitis can be devastating -- it can disrupt a patient's life and cause pain, bleeding and hospitalization," said John Leonard, M.D., senior vice president, Pharmaceuticals Research and Development, Abbott. "Today's positive opinion is a step forward in making HUMIRA available to patients with UC throughout the European Union and underscores our long-standing commitment to patients with IBD."

The positive opinion for HUMIRA for the UC indication was based on two Phase III clinical trials which evaluated clinical remission with HUMIRA in adult patients with moderate to severe UC. HUMIRA will be indicated for the 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.

**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. On average, 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**

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

**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.

Media:
Raquel Powers
+1 (847) 935-6563

Financial:
Liz Shea
+1 (847) 935-2211