ABBOTT PRESENTS PHASE 3 STUDY RESULTS FOR INVESTIGATIONAL USE OF HUMIRA® (ADALIMUMAB) IN PATIENTS WITH ACTIVE NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

First Phase 3 Study to Evaluate an Anti-TNF in Patients with Non-radiographic Axial Spondyloarthritis

Berlin — Abbott (NYSE: ABT) today announced results from the open-label extension of the Phase 3 ABILITY-1 investigational study of HUMIRA® (adalimumab), which assessed the improvement in signs and symptoms of disease for patients with active axial spondyloarthritis (axSpA) who have no X-ray evidence of structural damage. Results were presented at the European League Against Rheumatism (EULAR) 2012 Congress in Berlin, Germany.

ABILITY-1 is the first large, pivotal study to use the Assessment of SpondyloArthritis international Society (ASAS) criteria to classify non-radiographic axial SpA patients, and to evaluate an anti-tumor necrosis factor medication (anti-TNF) in treating patients with non-radiographic axSpA. ABILITY-1 used the ASAS 40 response criteria for the primary endpoint, which is a more stringent outcome measure than the ASAS 20 response criteria used in pivotal AS clinical trials. ASAS 40 is defined as at least a 40 percent improvement from baseline using the ASAS criteria.

The initial 12-week results from this study showed that a significantly higher percentage of HUMIRA patients, compared to those receiving placebo, achieved ASAS 40 (36.3 percent vs. 14.9 percent, $P<0.001$). Following this 12-week, double-blind period, 67 percent of HUMIRA patients who continued into the open-label extension and had data available for the analysis at 68 weeks (n=144) achieved ASAS 40.

AxSpA can be a debilitating condition that primarily presents with chronic back pain and stiffness, and can be accompanied by the presence of arthritis, inflammation in the eye and/or gastrointestinal tract. People with non-radiographic axSpA can have similar signs and symptoms as ankylosing spondylitis (AS) – including inflammation in the back joints that can lead to severe, chronic pain and discomfort – but do not have X-ray evidence of structural damage. AxSpA is most often seen in younger individuals and can go unrecognized for years.

"It often takes years to be diagnosed with non-radiographic axial SpA, and a patient suffering the debilitating effects of the disease has likely spent several more years trying what few conventional therapies are available," said Joachim Sieper, M.D., Head of Rheumatology, Campus Benjamin Franklin of the Charitè University Hospital, Berlin, Germany. "In this trial, we are encouraged to see that of the patients who received HUMIRA up to week 68, which was approximately three-quarters of those who initiated the trial, more than two-thirds achieved at least a 40 percent improvement in the ASAS criteria, an important clinical milestone for this underserved patient population."

Patients were also evaluated for level of disease activity according to the ankylosing spondylitis disease activity score (ASDAS), a measure used to assess disease activity in spondyloarthritides. In this group, 47 percent of patients achieved an inactive disease state, defined by an ASDAS score of less than 1.3.

"Biologics like HUMIRA have advanced the care for patients who may have dealt with unresolved disease symptoms for a variety of immunological conditions," said John Medich, Ph.D., divisional vice president, clinical development, Immunology, Abbott. "Abbott continues to explore new indications for HUMIRA, such as non-radiographic axSpA, that would potentially provide rheumatologists with more treatment options to choose from and help even more patients around the world."

Spondyloarthritis (SpA) is a group of diseases that share common clinical, radiographic and genetic features. SpA can be categorized according to which part of the body is mainly affected – axial or peripheral. ASAS developed improved classification criteria for axial and peripheral SpA designed to facilitate identification and classification of people with a spondyloarthritis who share similar symptoms. Criteria for axial SpA incorporate the use of magnetic resonance imaging (MRI), in addition to traditional X-rays, for visualizing sacroiliitis (inflammation of the sacroiliac joint which connects the lower spine and pelvis), one of the hallmarks of axial spondyloarthritis.

HUMIRA is not approved for the treatment of spondyloarthritides other than ankylosing spondylitis and psoriatic arthritis.

About ABILITY-1

ABILITY-1 is an ongoing, multi-country, Phase 3 study designed to evaluate the efficacy and safety of HUMIRA in axSpA patients without radiographic sacroiliitis. Eligible patients were randomized 1:1 to receive either HUMIRA (40 mg every other week, n=91) or placebo (n=94) for 12 weeks, followed by the open-label extension phase in which all patients could receive HUMIRA (40 mg every other week) for up to an additional 144 weeks. During the open-label extension phase of the study, both the investigator and the patient knew that the patient was receiving HUMIRA.

At week 12, more than twice as many HUMIRA patients (36 percent) compared to those receiving placebo (15 percent) achieved ASAS 40 (P<0.001), and significantly more patients achieved the secondary endpoint of ASDAS inactive disease state (24.2 percent for HUMIRA patients versus 4.3 percent for those receiving placebo, P<0.001). After week 12, 179 patients (87 HUMIRA and 92 placebo) entered into the open-label period, and 144 patients had data available for the week 68 analysis (69 from original HUMIRA group and 75 from original placebo group). Baseline demographics and disease characteristics were comparable between patients who entered the open-label period and those of patients who were initially randomized.

Results on clinical endpoints at week 68 of the open-label period of the study included:

- 80 percent of patients achieved at least 20 percent improvement in the ASAS criteria (ASAS 20)
- 67 percent of patients achieved at least 40 percent improvement in the ASAS criteria (ASAS 40)
- 65 percent of patients achieved at least 50 percent improvement in the Bath Ankylosing Spondylitis Disease Activity Index criteria (BASDAI 50)
- 49 percent of patients achieved at least a 20 percent improvement in five of six assessment areas (ASAS 5/6) (e.g., Bath Ankylosing Spondylitis Functional Index [BASFI], total back pain, patient global assessment [PtGA] of disease activity, inflammation [questions 5 and 6 of the BASDAI], lateral lumbar flexion from Bath Ankylosing Spondylitis Metrology Index [BASMI] and acute phase reactants)
- 47 percent of patients achieved ASDAS inactive disease
- 36 percent of patients achieved ASAS partial remission

Safety was assessed in terms of adverse events. As of week 68 of the study, among patients who had at least one dose of HUMIRA, there were three serious infections (1.6 events/100 patient years), which included one case of tuberculosis. There was one death due to suicide but was assessed by the investigator as not related to the study drug.

About HUMIRA® (adalimumab)

USES

HUMIRA (adalimumab) is a prescription used to reduce the signs and symptoms of ankylosing spondylitis in adults.

HUMIRA is used alone or with certain other medicines to reduce the signs and symptoms of psoriatic arthritis in adults. It may prevent further damage to bones and joints and may help with the ability to perform daily activities.

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.

This is not a complete list of the Important Safety Information for HUMIRA. For additional important safety information, please click for the Full Prescribing Information and Medication Guide.

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.

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