

# **ABBOTT TO PRESENT WIDE RANGE OF INVESTIGATIONAL EFFICACY, SAFETY AND HEALTH OUTCOMES DATA ON HUMIRA® (ADALIMUMAB) AT THE ANNUAL MEETING OF THE EUROPEAN LEAGUE AGAINST RHEUMATISM - (U.S.)**

Data Highlight HUMIRA Research in Multiple Rheumatologic Diseases and Abbott's Continued Commitment to Science

Abbott Park, Illinois (NYSE: ABT) — Abbott scientists and independent researchers will highlight the latest investigational research findings on HUMIRA® (adalimumab) at the European League Against Rheumatism (EULAR) Congress in Berlin, Germany, from 6-9 June, 2012. The presentations include two of the longest open-label extension studies in rheumatoid arthritis (RA), featuring long-term data for disease activity and radiographic inhibition. Data will also be presented on investigational indications in axial and peripheral spondyloarthritis (SpA), moderate to severe polyarticular juvenile idiopathic arthritis (JIA), ankylosing spondylitis (AS) and health economics research.

"Data presented at this year's EULAR highlight Abbott's commitment to continue to expand our understanding of the efficacy and safety of HUMIRA and address the needs of patients and physicians across a broad spectrum of rheumatologic diseases," said John Medich, Ph.D., divisional vice president, Clinical Development, Immunology, Abbott. "Specifically, data highlighting the use of HUMIRA for long-term treatment of RA and new data in investigational indications like axial and peripheral SpA will be presented, reinforcing Abbott's ongoing investment in research in the rheumatology space."

## **Presentation Highlights**

Data being presented at EULAR include the comprehensive 10-year data for treatment of moderate to severe, long-standing RA in the DE019 trial and in the DE020 follow-up study. DE020 will be presented in a publication, while DE019 will be presented as a poster on 9 June.

Data will also be presented for ABILITY-I, the first, multi-national Phase 3 study evaluating the use of an anti-tumor necrosis factor (anti-TNF) medication in patients with active non-radiographic axial SpA – a debilitating condition closely related to AS that primarily presents with chronic back pain and stiffness, and can be accompanied by the presence of arthritis, and inflammation in the eye and/or gastrointestinal tract. There is currently no approved treatment for non-radiographic axial SpA. Results from 68 weeks of treatment with HUMIRA will be shown, highlighting not only the initial clinical responses in the 12-week, placebo-controlled trial, but also the responses over an additional year of treatment. These data will be presented as a poster on 7 June.

The initial results will be presented from ABILITY-2, the first Phase 3 study investigating the use of an anti-TNF medication in patients with active peripheral SpA that don't have a diagnosis of psoriatic arthritis (PsA). This patient population is characterized by peripheral arthritis (asymmetric, lower limb or both), enthesitis (painful inflammation where a tendon or ligament attaches to bone) or dactylitis (a painful and swollen digit), in addition to the presence of other features (family history of SpA, history of inflammation in the eye, diagnosis of other immune-mediated inflammatory diseases, sacroiliitis on MRI). There is currently no approved treatment for non-PsA peripheral SpA. Data following 12-weeks of treatment with HUMIRA will be shown as a poster on 7 June.

Additionally, clinical and patient-reported outcomes will be presented from OPTIMA, the first global prospective trial using a treat-to-target philosophy in the treatment of moderate to severe RA. Treat-to-target is focused on achieving a clearly defined treatment goal within a set duration of time and adjusting the treatment if the target is not met. This approach is aligned to EULAR and American College of Rheumatology (ACR) rheumatoid arthritis treatment recommendations.

A comprehensive list of EULAR abstracts is available at [www.eular.org](http://www.eular.org). Specific abstracts related to HUMIRA or the disease states that it helps to treat include the following (all times are CET):

## **Rheumatoid Arthritis**

- Final 10-year Results of an Open-label Extension of a Phase 3 Trial of Combination Therapy with Adalimumab Plus Methotrexate in Patients with Long-standing Rheumatoid Arthritis; E. Keystone, et al
  - Abstract SAT0127; Poster; 9 June, 2012; 10:15 a.m.; Location: Poster Area
- Results Following 10 Years of Treatment with Adalimumab in Follow-up Trial; M. Weinblatt, et al
  - Abstract AB0479; Publication only
- Study Evaluating the Long-Term Effectiveness and Safety of Adalimumab in Patients with Moderate Versus Severe Rheumatoid Arthritis; G. Burmester, et al
  - Abstract FRI0159; Poster; 8 June, 2012; 11:45 a.m.; Location: Poster Area
- Results from the OPTIMA Study Evaluating Long-term Disease Control in Early, Moderate to Severe Rheumatoid Arthritis with Adalimumab and Methotrexate; P. Emery, et al

- Abstract FRI0171; Poster; 8 June, 2012; 11:45 a.m.; Location: Poster Area

### **Ankylosing Spondylitis/Spondyloarthritis**

- Week-68 Results from an Open-label Extension of a Phase 3 Study Evaluating the Efficacy and Safety of Adalimumab in Patients with Non-radiographic Axial Spondyloarthritis; J. Sieper, et al
  - Abstract THU0275; Poster; 7 June, 2012; 11:45 a.m.; Location: Poster Area
- Results from a Phase 3 Study on the Efficacy and Safety of Adalimumab in Patients with Peripheral Spondyloarthritis; P. Mease, et al
  - Abstract THU0280; Poster; 7 June, 2012; 11:45 a.m.; Location: Poster Area

### **Juvenile Idiopathic Arthritis**

- Results from a Phase 3b Study Evaluating the Efficacy and Safety of Adalimumab in Children with Active Polyarticular Juvenile Idiopathic Arthritis Aged 2 to 4 Years or > 4 Years Weighing <15 Kg; D. Kingsbury, et al
  - Abstract FRI0337; Poster; 8 June, 2012; 11:45 a.m.; Location: Poster Area

### **Long-Term Safety Across Diseases**

- Results from an Analysis Evaluating the Long-term Safety of Adalimumab in Patients with Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Psoriasis and Crohn's Disease; G. Burmester, et al
  - Abstract SAT0130; Poster; 9 June, 2012; 10:15 a.m.; Location: Poster Area

### **Health and Economic Outcomes**

- Results from the OPTIMA Study Related to Adalimumab and Patient-reported Outcomes and Work Productivity in Early Rheumatoid Arthritis Patients; A. Kavanaugh, et al
  - Abstract AB0450; Publication only
- Study Related to the Use of Anti-TNF Therapy and Cardiovascular Event Risk in Rheumatoid Arthritis; M. Nurmohamad, et al
  - Abstract OP0002; Oral Presentation; 6 June, 2012; 4:15 p.m.; Location: Hall 5.2 B
- Analysis of Randomized Trials Related to Adalimumab and the Risk of Major Adverse Cardiovascular Events in Rheumatoid Arthritis; G. Burmester, et al
  - Abstract FRI0145; Poster Tour; 8 June, 2012; 12:15 p.m.; Location: Poster Area Hall 2.2
- Results from a Study Estimating Prevalence and Gender Distribution of Axial Spondyloarthritis Among Patients in US Rheumatology Practices; S. Rao, et al
  - Abstract FRI0406; Poster Tour; 8 June, 2012; 12:15 p.m.; Location: Poster Area Hall 4.2

### **General Disease State**

- Results from an Analysis of Registry Data Comparing the Disease Burden of Patients with Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis and the Implications on Treatment; J. Sieper, et al
  - Abstract OP0266; Oral Presentation; 6 June, 2012; 9:50 a.m.; Location: Hall 5.2 B
- Results from an Analysis Evaluating Adherence to Subcutaneous vs. Oral Disease-Modifying Antirheumatic Drugs (DMARDs) in Rheumatoid Arthritis; M. Bergman
  - Abstract AB1376; Publication only
- Results from an Analysis of Registry Data Regarding Factors Associated with Work Status and Missed Work Days in Rheumatoid Arthritis; L. Harrold, et al
  - Abstract SAT0469; Poster; 9 June, 2012; 10:15 a.m.; Location: Poster Area

### **About HUMIRA® (adalimumab)**

#### **Uses**

HUMIRA (adalimumab) is a prescription medicine used alone, with methotrexate, or with certain other medicines to reduce the signs and symptoms of moderate to severe rheumatoid arthritis in adults. It may prevent future damage to bones and joints and may help with the ability to perform daily activities.

HUMIRA is used alone, with methotrexate, or with certain other medicines to reduce the signs and symptoms of moderate to severe polyarticular juvenile idiopathic arthritis in children 4 years of age and older.

HUMIRA is 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.

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

### **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 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 lifethreatening 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.

International Media:

Javier Boix  
(847) 393-5065

U.S. Media:

Derin Denham  
(847) 937-2889

Financial:

Elizabeth Shea  
(847) 935-2211

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