

Abbott's HUMIRA (adalimumab) Shows Long-Term Improvement In

ABBOTT PARK, Illinois, March 13 /PRNewswire/ --

- Two Sub-Analyses from the CHARM Trial Evaluated Fistula Closure and Quality Of Life in Patients with Fistulas from Crohn's Disease

Abbott announced today the first two-year data for Crohn's disease patients with fistulas, which show that more than half of patients receiving HUMIRA(R) (adalimumab) had continued fistula healing. These data were presented at the European Crohn's and Colitis Organization (ECCO) Annual Meeting in Lyon, France. Fistulas are tunnels that form between the intestine and other parts of the body and are considered one of the most painful complications of Crohn's disease. Fistula healing in these studies was defined as complete cessation of fistula drainage.

Fistulas are a serious complication of Crohn's disease that can lead to invasive surgery, said Jean-Frederic Colombel, M.D., professor, Gastroenterology, Hopital Huriez, Lille, France. Medical treatments that can promote fistula healing are important for gastroenterologists and patients suffering from fistulizing Crohn's disease -- a very difficult-to-treat patient population.

The results were taken from two sub-analyses of fistula patients from Abbott's 854-patient, one-year Phase III CHARM trial for HUMIRA. Patients were followed through a second year of therapy into a non-placebo controlled, ongoing open-label extension (OLE) trial. Results showed:

-- Fistula healing was sustained with HUMIRA treatment. More than half of patients (60 percent) experienced fistula healing at one year with HUMIRA treatment, and 76 percent had continued fistula healing one more year. -- Seventy-one percent (50 of 70 patients) had at least a 50 percent reduction in the number of draining fistulas after treatment with HUMIRA. -- Adverse event rates among patients with fistulas were consistent with those seen in previous trials of HUMIRA in rheumatoid arthritis and Crohn's disease. -- More than half had a high quality-of-life score that correlates clinical remission over two years. This was measured with an Inflammatory Bowel Disease Questionnaire (IBDQ), a quality-of-life tool that assesses the impact of chronic medical illness on physical, emotional, and social well-being. Specifically, 54 percent had IBDQ scores greater than 170 at 56 weeks (26 of 48 patients) and 60 percent at 116 weeks (29 of 48 patients). -- An IBDQ score greater than 170 correlates with clinician remission, which is measured by the Crohn's Disease Activity Index (CDAI) and defined as a CDAI score of less than 150.

HUMIRA's ability to heal, and keep healed, a majority of fistulas among patients studied reinforces that HUMIRA is an effective and convenient treatment option for severe and active Crohn's disease, said Rebecca Hoffman, M.D., divisional vice president, HUMIRA clinical development, Abbott.

About the CHARM Trial

CHARM was a 56-week trial that enrolled 854 patients with moderate to severe Crohn's disease and evaluated HUMIRA for the maintenance of clinical remission. Following a four-week open label induction period, the 778 patients still participating in the trial were randomized to either HUMIRA (40 mg every other week or weekly), or placebo. The co-primary endpoints evaluated the maintenance of clinical remission at weeks 26 and 56 for the HUMIRA 40mg every other week and 40mg every week groups compared to those on placebo. A significantly greater percentage of patients treated with HUMIRA maintained clinical remission at one year compared to placebo.

The data presented at ECCO included patients from CHARM who were followed through one year in an ongoing open-label extension trial (OLE) and one additional year. The analyses pooled data from both HUMIRA doses and evaluated the subgroup of patients from CHARM who had fistulas at baseline and enrolled into the OLE for further evaluation. Patients were analyzed for the percentage of healed fistulas and percentage with greater than or equal to 50 percent fistula response at 12, 18, and 24 months. Quality of life measures evaluated included IBDQ at weeks 56, 96, and 116.

In each trial, clinical remission was measured by a CDAI score of less than 150. CDAI is a weighted composite score of eight clinical factors that evaluate patient wellness, including daily number of liquid or very soft stools, severity of abdominal pain, levels of general well-being and other measures. In these sub-analyses, fistula healing was defined as a closure of all fistulas that were draining at baseline at 6, 12, 18 and 24 months. Fistula response was defined as a decrease from baseline in the number of draining fistulas of more than 50 percent over these time periods.

About Crohn's Disease

Crohn's disease is a chronic autoimmune disease characterized by inflammation in the gastrointestinal tract. It affects people of all ages but it is primarily a disease of young adults, with onset typically before age 40. Common symptoms of the disease include diarrhea, cramping, abdominal pain, weight loss and fever. Complications include intestinal obstruction, fistulas (ulcers that form tunnels to surrounding tissues), and malnutrition. Over the course of their disease, at least 75 percent of patients with Crohn's will undergo surgery at least once for complications or disease resistant to

treatment. Of those who undergo surgery to remove a portion of their intestines (resection), half will experience a relapse within five years.

HUMIRA for Crohn's Disease

Three pivotal trials have studied the effect of HUMIRA, the only fully human monoclonal antibody for the treatment of Crohn's disease, in more than 1,400 adult patients with moderately to severely active Crohn's disease. The CLASSIC I, CHARM and GAIN trials supporting the indication for Crohn's disease evaluated the efficacy and safety of HUMIRA in a diverse group of adult Crohn's disease patients, from those who were naive to anti-tumor necrosis factor (TNF) therapy, to patients who had previously lost response to or were unable to tolerate infliximab, another anti-TNF agent for treatment of Crohn's disease.

Important Safety Information

Globally, prescribing information varies; refer to the individual country product label for complete information.

Serious infections, sepsis, rare cases of tuberculosis (TB), and opportunistic infections, including fatalities, have been reported with the use of TNF antagonists, including HUMIRA. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease could predispose them to infections. Patients must be monitored closely for infections, including tuberculosis, before, during and after treatment with HUMIRA. Treatment should not be initiated in patients with active infections until infections are controlled. HUMIRA should not be used by patients with active TB or other severe infections such as sepsis and opportunistic infections. Patients who develop new infections while using HUMIRA should be monitored closely. HUMIRA should be discontinued if a patient develops a new serious infection until infections are controlled. Physicians should exercise caution when considering use of HUMIRA in patients with a history of recurring infection or with underlying conditions that may predispose patients to infections.

TNF-blocking agents have been associated with reactivation of hepatitis B (HBV) in patients who are chronic carriers of the virus. Some cases have been fatal. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating HUMIRA.

The combination of HUMIRA and anakinra and/or abatacept are not recommended.

TNF antagonists, including HUMIRA, have been associated in rare cases with demyelinating disease and serious allergic reactions. Rare reports of pancytopenia including aplastic anaemia have been reported with TNF-blocking agents. Adverse events of the haematologic system, including medically significant cytopenia have been infrequently reported with HUMIRA.

More cases of malignancies including lymphoma have been observed among patients receiving a TNF antagonist compared with control patients in clinical trials. The size of the control group and limited duration of the controlled portions of studies precludes the ability to draw firm conclusions. Furthermore, there is an increased background lymphoma risk in rheumatoid arthritis patients with long-standing, highly active, inflammatory disease, which complicates the risk estimation. During the long-term open-label trials with HUMIRA, the overall rate of malignancies was similar to what would be expected for an age-, gender- and race-matched general population. With the current knowledge, a possible risk for the development of lymphomas or other malignancies in patients treated with a TNF antagonist cannot be excluded. All patients, and in particular patients with a medical history of extensive immunosuppressant therapy or psoriasis patients with a history of PUVA treatment, should be examined for the presence of non-melanoma skin cancer prior to and during treatment with HUMIRA.

In clinical studies with another TNF antagonist, a higher rate of serious congestive heart failure (CHF) related adverse events including worsening CHF and new onset CHF have been reported. Cases of worsening CHF have also been reported in patients receiving HUMIRA. Physicians should exercise caution when using HUMIRA in patients who have heart failure and monitor them carefully. HUMIRA should not be used in patients with moderate or severe heart failure.

The most frequently reported adverse event (greater than 1/10 patients) at least possibly causally related to HUMIRA is injection site reaction (including pain, swelling, redness or pruritus). Other common adverse events (reported by greater than 1/100 patients) at least possibly causally related to HUMIRA include lower respiratory infections (including pneumonia, bronchitis), viral infections (including influenza, herpes infections), candidiasis, bacterial infection (including urinary tract infections), upper respiratory infection, dizziness (including vertigo), headache, neurologic sensation disorders (including paraesthesias), cough, nasopharyngeal pain, diarrhoea, abdominal pain, stomatitis and mouth ulceration, nausea, hepatic enzymes increased, rash, pruritus, musculoskeletal pain, pyrexia and fatigue (including asthenia and malaise).

About HUMIRA

HUMIRA is the only fully human monoclonal antibody approved for the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), psoriasis, ankylosing spondylitis (AS) and Crohn's disease in the United States and Europe. HUMIRA resembles antibodies normally found in the body. It works by blocking tumor necrosis factor alpha (TNF-

To date, HUMIRA has been approved in 73 countries and more than 250,000 people worldwide are currently being treated with HUMIRA. Clinical trials are also under way evaluating the potential of HUMIRA in ulcerative colitis.

In Europe, 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. HUMIRA is also indicated 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 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 adults with severe, active ankylosing spondylitis who have had an inadequate response to conventional therapy.

HUMIRA is indicated for treatment of severe, 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. For induction treatment, HUMIRA should be given in combination with corticosteroids. HUMIRA can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inappropriate.

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.

Abbott's Commitment to Immunology

Abbott is focused on the discovery and development of innovative treatments for immunologic diseases. The Abbott Bioresearch Center, founded in 1989 in Worcester, Mass., United States, is a world-class discovery and basic research facility committed to finding new treatments for autoimmune diseases.

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 68,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at <http://www.abbott.com>.

Latest physiotherapy techniques substantive details of the book

General Catalog (excerpt)

Chapter I gives an overview chapter II of the third mushroom physiotherapy and other physical therapy treatments Chapter IV of the synergies in scientific research methods in physical therapy physical therapy Chapter V of Chapter VI of the surface anatomy of the reactions and physical therapy treatment seventh child physical therapy Integrative Medicine in the first chapter and the DC iontophoresis therapy Chapter 2 Chapter 3 of low-frequency electrical therapy, therapy IF Chapter IV therapy Fifth deepen the movement of high-frequency electric static therapy based on infrared light therapy treatments visible UV irradiation therapy ultraviolet therapy photosensitive blood therapy magnetic field therapy laser therapy treatment

outlined the role of the magnetic field and magnetic treatment device types Jue I Fou bed of the side effects of magnetic therapy and clinical application of ultrasonic Chapter 1 Chapter 2 basis of the physics of ultrasound and the biophysical characteristics of the mechanism of the third mushroom Chapter IV of chapter V Original acoustic treatment equipment and technology indications and contraindications biofeedback outlined in the application of medical biofeedback therapy procedures and pay attention to matters of biofeedback therapy evaluation and prospect of Chapter I gives an overview chapter II section paraffin therapy Three other hyperthermia therapy cold Chapter 1 Chapter 2 Chapter 3 Cryotherapy cryosurgery response and management outlined in the spa room of the building and equipment Hydrotherapy 8. In the system of law spa bath therapy other Hydrotherapy first chapter external counterpulsation therapy Chapter II limb pressurized air ion therapy Chapter 1 Chapter II drug therapy ion therapy anatomical knowledge and mechanical movement and joint activities in the name of the measurement exercise therapy Categories of exercise on the body s physiological role of exercise prescription for exercise therapy room and exercise therapy and exercise therapy indications and contraindications traction therapy is vacuum therapy of acupuncture and massage therapy, cupping therapy, music therapy and music therapy climate and forest bath therapy Solarium, air Bath, swimming holes in sand bath therapy and medical treatment first chapter disease physical therapy Chapter II diseases of the nervous system of physical therapy Chapter III surgical diseases of physical therapy gynecological diseases in Chapter IV of chapter V pediatric physical therapy diseases physical therapy section VI skin diseases orthopedic physical therapy Chapter VII of the disease physical therapy eye disease Chapter VIII of the physical therapy Chapter IX ENT diseases physical therapy Chapter 10 dental disease physical therapy first chapter Tun

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About the Author

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This article focuses on exercises and modalities commonly used as physical therapy treatment for the patients who have nonspecific.

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