

FOR IMMEDIATE RELEASE



News

## Abbott's HUMIRA<sup>®</sup> (adalimumab) Honored with Prestigious Galen Prize for Innovation in Patient Care

*Prix Galien USA Names HUMIRA Best Biotechnology Product*

ABBOTT PARK, Ill., Sept. 27, 2007 — Abbott, a leader in the treatment of autoimmune diseases, has received the 2007 Galen Prize for Best Biotechnology Product for HUMIRA<sup>®</sup> (adalimumab), the first approved fully human antibody. HUMIRA is approved for use in the treatment of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and moderate to severe Crohn's disease. The Galen Prize, considered an equivalent to the Nobel Prize and awarded by Prix Galien USA, is one of the highest accolades in the pharmaceutical and biomedical industry recognizing excellence in medical and scientific research and innovation.

This is the first year in which the award, founded in France in 1970 and recognized as an international research honor, has been expanded to recognize scientific innovation from U.S. pharmaceutical and biotechnology companies specifically. Abbott won the prestigious Prix Galien international award in 1999 for developing one of the first protease inhibitors for the treatment of HIV.

"Abbott is extremely honored to be a Galen Prize recipient, as it recognizes our diligence in the discovery and development of innovative treatments for immunologic diseases," said John Leonard, M.D., vice president, Global Medical and Scientific Affairs, Abbott. "HUMIRA has become an important treatment option for many patients dealing with these diseases."

HUMIRA resembles antibodies normally found in the body and works by specifically blocking tumor necrosis factor alpha (TNF- $\alpha$ ), a protein that when produced in excess, plays a central role in the inflammation associated with autoimmune diseases. HUMIRA is a fully-human self-administered biologic and 190,000 patients worldwide are currently being treated.

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"HUMIRA represents years of dedicated research as part of our commitment to improve the human condition," said Jochen Salfeld, Ph.D., divisional vice president, Biologics Research, Abbott Bioresearch Center, who played an instrumental role in the development of HUMIRA. "We believe that the potential exists for HUMIRA to be effective in other diseases that have significant unmet needs and we're continuing to pursue that research in hopes of providing relief to patients worldwide."

**About Prix Galien USA**

Founded in 1970 by French pharmacist Roland Mehl to recognize his country's outstanding medical accomplishments, the award, named in honor of Galen, the Greek father of medicine and pharmacology, has evolved into Europe's leading honor for medical research and development achievement and is considered an equivalent to the Nobel Prize. With the addition of the United States award, Prix Galien is now in 11 countries. Consistent with the tradition of its founders, national judging panels must include top scientists who are undisputed in their clinical achievements and ability to evaluate cutting-edge medicine.

**Important Safety Information About HUMIRA**

Serious infections, sepsis, tuberculosis (TB) and opportunistic infections, including fatalities, have been reported with the use of TNF-blocking agents, including HUMIRA. Many of these serious infections have occurred in patients also taking other immunosuppressive agents that, in addition to their underlying disease, could predispose them to infections. Infections have also been reported in patients receiving HUMIRA alone. Treatment with HUMIRA should not be initiated in patients with active infections. TNF-blocking agents, including HUMIRA, have been associated with reactivation of hepatitis B (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Patients at risk for HBV infections should be evaluated for prior evidence of HBV infections before initiating HUMIRA. The combination of HUMIRA and anakinra is not recommended and patients using HUMIRA should not receive live vaccines.

More cases of malignancies have been observed among patients receiving TNF blockers, including HUMIRA, compared to control patients in clinical trials. These malignancies, other than lymphoma and non-melanoma skin cancer, were similar in type and number to what would be expected in the general population.

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There was an approximately 3.5 fold higher rate of lymphoma in combined controlled and uncontrolled open-label portions of HUMIRA clinical trials. The potential role of TNF-blocking therapy in the development of malignancies is not known. TNF-blocking agents, including HUMIRA, have been associated in rare cases with demyelinating disease and severe allergic reactions. Infrequent reports of serious blood disorders have been reported with TNF-blocking agents.

Worsening congestive heart failure (CHF) has been observed with TNF-blocking agents, including HUMIRA, and new onset CHF has been reported with TNF-blocking agents. Treatment with HUMIRA may result in the formation of autoantibodies and rarely, in development of a lupus-like syndrome.

The most frequent adverse events seen in the placebo-controlled clinical trials in adults with rheumatoid arthritis (HUMIRA vs. placebo) were injection site reactions (20 percent vs. 14 percent), upper respiratory infection (17 percent vs. 13 percent), injection site pain (12 percent vs. 12 percent), headache (12 percent vs. 8 percent), rash (12 percent vs. 6 percent) and sinusitis (11 percent vs. 9 percent). Discontinuations due to adverse events were 7 percent for HUMIRA and 4 percent for placebo. As with any treatment program, the benefits and risks of HUMIRA should be carefully considered before initiating therapy.

In HUMIRA clinical trials for ankylosing spondylitis, psoriatic arthritis and Crohn's disease, the safety profile for adult patients treated with HUMIRA was similar to the safety profile seen in adult patients with rheumatoid arthritis.

### **About HUMIRA**

In the United States, HUMIRA is approved by the Food and Drug Administration (FDA) for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.

HUMIRA is indicated for reducing the signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function in patients with psoriatic arthritis. HUMIRA can be used alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs).

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HUMIRA is also approved for reducing signs and symptoms in patients with active ankylosing spondylitis.

Earlier this year, HUMIRA was approved for reducing the signs and symptoms and inducing and maintaining clinical remission in adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, and reducing the signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

Clinical trials are currently under way evaluating the potential of HUMIRA in other immune-mediated diseases.

**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 supporting research and development of biologic treatments. Abbott Biotechnology Limited, which opened earlier this year in Barceloneta, Puerto Rico, United States, is the main production facility for Abbott's anti-TNF treatment and one of the world's largest centers for production of monoclonal antibodies.

More information about HUMIRA, including full prescribing information, is available on the web site [www.HUMIRA.com](http://www.HUMIRA.com) or in the United States by calling Abbott Medical Information at 1-800-633-9110.

**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 65,000 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 [www.abbott.com](http://www.abbott.com).

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