



Arthritis Foundation Statement on Rituximab for Rheumatoid Arthritis

Summary

The U.S. Food and Drug Administration's (FDA) approval of rituximab (Rituxan®) in combination with methotrexate to reduce the signs and symptoms of rheumatoid arthritis (RA) brings a new treatment option to adult patients with moderately-to-severely active RA who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. The Arthritis Foundation applauds the FDA's decision and believes that new RA therapies targeting key pathways responsible for the disease will better enable physicians to both reduce patients' disease symptoms and their risk of disability.

Full Statement

On February 28, 2006, the FDA approved an expanded indication for rituximab, a biologic agent that selectively targets immune cells involved in RA. Rituximab was approved in 1997 for the treatment of CD20-positive, B-cell, non-Hodgkin's lymphoma (NHL) and has shown significant benefits in RA clinical trials. Rituximab is the first RA treatment that targets and selectively depletes CD20-positive B-cells, which are involved in the joint inflammation that occurs in RA.

Phase III clinical trial results of rituximab were recently presented at the American College of Rheumatology Annual Scientific Meeting in November 2005. In the study, also known as REFLEX, patients who received one course of treatment of rituximab with methotrexate had statistically significant improvements through six months in the number of swollen and tender joints and disease activity measures such as pain, compared to those who received placebo and methotrexate. This research showed improvements in patients who had an inadequate response to prior treatment with one or more TNF antagonist therapies, bringing hope to this difficult-to-treat patient population.

"Rituximab provides an important treatment option to improve the quality of life of people with RA, one of the most serious and debilitating forms of arthritis," said John H. Klippel, M.D., president and CEO, Arthritis Foundation. "Enormous progress has been made in the treatment of RA over the past decade; however, many patients cannot tolerate or do not respond adequately to the anti-TNF agents that are currently available. Rituximab expands the treatment options for these patients."

Rituximab is administered as a treatment course of two intravenous infusions. In clinical trials for RA, the most common adverse events observed in patients treated with rituximab were infusion reactions and infections. Severe infusion reactions, which typically occur during the first infusion, have been reported in patients treated with rituximab, some with fatal outcomes in patients with NHL.

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About RA

RA is one of the more serious forms of arthritis and affects 2.1 million Americans. It is characterized by the inflammation of the synovium – the membrane lining the joint – which causes pain, stiffness, warmth, redness and swelling. The inflamed synovium can invade and damage bone and cartilage, leading to deformities of the joint, loss of joint movement, and limitations of activities requiring use of the joint. The disease usually begins in middle age, but can start at any age, including childhood. RA affects two to three times more women than men.

For More Information

The Arthritis Foundation offers a number of resources to assist people with RA in finding information about treatments and managing their activities, including a free consumer brochure on RA and a free *Arthritis Today* Drug Guide, as well as books such as *The Arthritis Foundation's Guide to Good Living with Rheumatoid Arthritis* and *The Essential Guide to Arthritis Medications*. For more information, contact the Arthritis Foundation at 800-568-4045 or www.arthritis.org.