Seven Years of Follow-Up Data Available on Etanercept

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San Antonio — The safety and efficacy of etanercept have held up over time, with large cohorts of rheumatoid arthritis patients having been followed for as long as 7 years.

In a poster session at the annual meeting of the American College of Rheumatology, Michael E. Weinblatt, M.D., reported long-term efficacy results for two groups of American patients: 207 who at baseline had a history of having RA for 3 years or less and 644 who had long-standing disease that failed at least one disease-modifying antirheumatic drug.

The median length of exposure to etanercept in the early RA group was 5.5 years; in the long-standing RA group, it was 5.6 years. All patients had received dosages of 25 mg twice weekly by subcutaneous injection.

"Significant improvements in multiple measures of disease activity have been achieved with etanercept therapy," he said. (See box.)

Concomitant medications were permitted during the extension studies, but most patients have been able to stop taking corticosteroids and methotrexate while receiving etanercept, said Dr. Weinblatt, professor of medicine, Harvard Medical School, Boston.

Patients who had received etanercept at any dose were included in the long-term safety analyses. Of this larger cohort, which included 558 early-disease patients and 884 long-standing disease patients, 323 (58%) and 391 (44%) of the early and long-standing disease patients, respectively, remain on the drug.

A total of 10% of the early disease group and 12% of the long-standing disease group discontinued the drug because of adverse effects.

There have been 28 deaths, including 4 from malignancy and 4 from cardiac disease, whereas 53 deaths were expected. There also have been 11 cases of sepsis but no cases of tuberculosis or opportunistic infections, Dr. Weinblatt said.

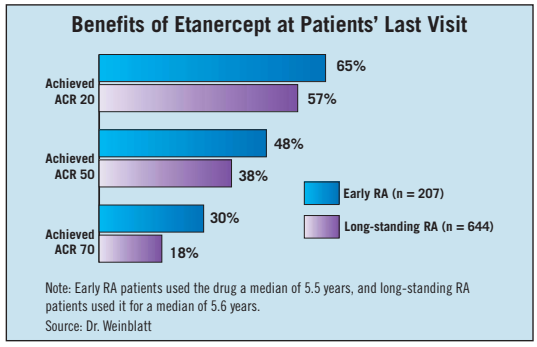
In a separate poster session, Larry W. Moreland, M.D., reported on a larger cohort of patients from North America and Europe who had been taking the drug. "Serious adverse events, infections, malignancies, and deaths do not increase over 7 years of treatment," he said.

Analysis of data from that cohort of 2,054 patients, representing 7,382 patient-years of etanercept exposure, found that the rates of serious adverse events and serious infections were similar to those seen in control groups in previous trials. Rates of malignancies were similar to what was expected, with 67 observed and 61 expected.

A total of 42 patients died. "This death rate was lower than expected, as 53 deaths were expected in North America alone," said Dr. Moreland, who holds the Anna Lois Waters Chair of Medicine in Rheumatology at the University of Alabama, Birmingham.

Of concern, however, are nine cases of lymphoma diagnosed in North America and one diagnosed in Europe. The incidence is higher than expected in the general population, and additional studies are needed to understand if this finding is related to etanercept or if it reflects the elevated risk of lymphoma inherent in patients with RA, Dr. Moreland said.

Both studies were funded by Immunex Corp., a subsidiary of Amgen Inc., and by Wyeth Research. ■



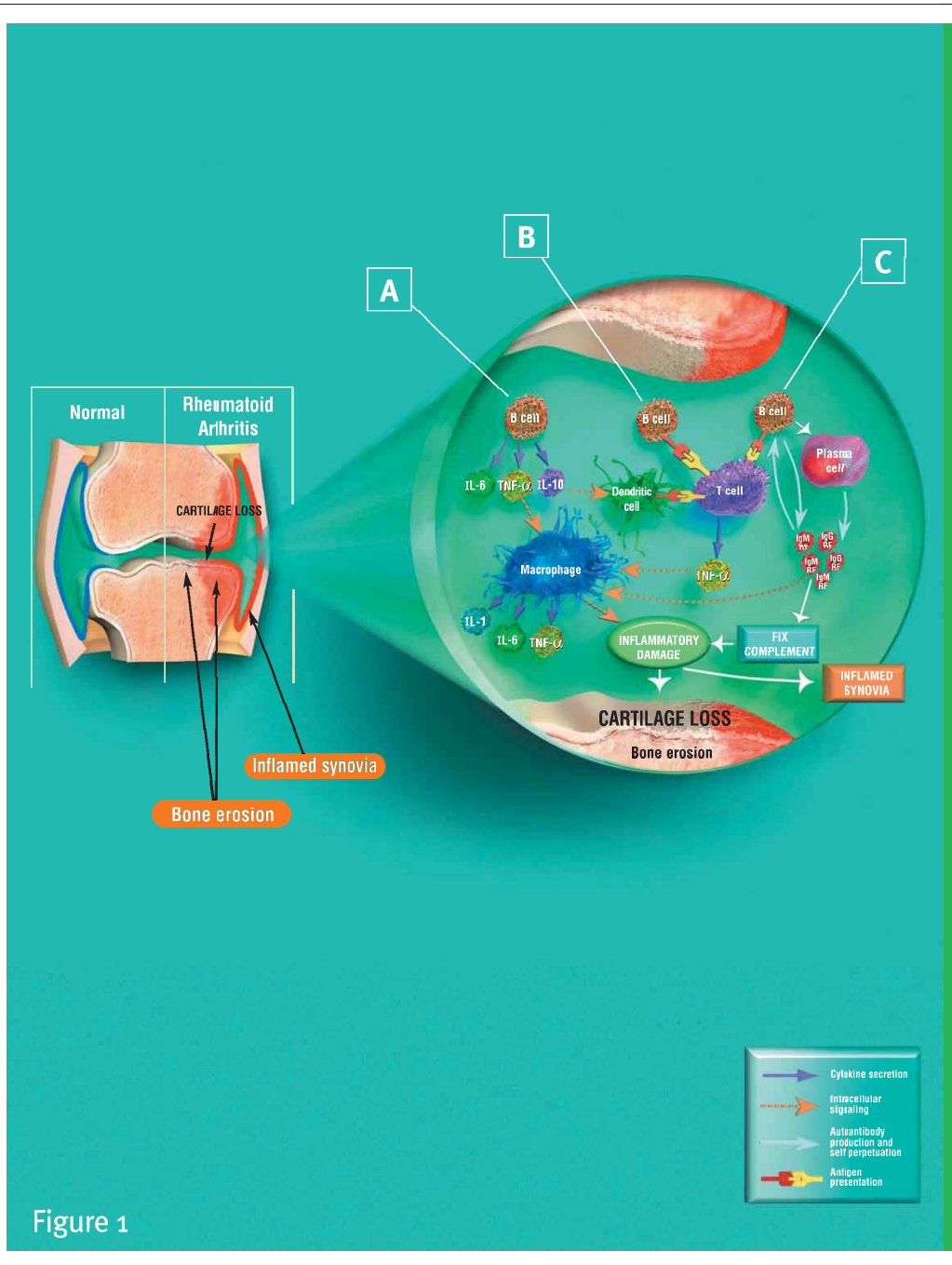


Figure 1