Certolizumab/Methotrexate Combo Proves Effective for RA

BY JEFF EVANS
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BARCELONA — Treatment of rheumatoid arthritis with a combination of certolizumab pegol and methotrexate improved symptoms in a significantly greater proportion of patients than methotrexate alone, according to the results of a phase III trial.

In the 52-week, multicenter, random¬ized, double-blind trial, about 60% of pa¬tients who received dosing regimens with either 200 mg or 400 mg of certolizumab pegol (Cimzia) and methotrexate achieved an American College of Rheumatology (ACR) 20 level of response at 24 weeks on an intent-to-treat basis, compared with only 14% of those who received placebo plus methotrexate.

An ACR 20 level of response is achieved when there is 20% improvement in the number of tender and swollen joints as well as a 20% improvement in at least three of five other parameters.

The mean age of the arthritis patients in the current trial, which was called RAPID 1, had to have had an inadequate re¬sponse to methotrexate therapy alone for at least 6 months prior to the start of the study. Dr. Edward C. Keystone reported at the annual European Congress of Rheumatology.

CERTOLIZUMAB PEGOL IS A HUMANIZED MONOCLONAL FAB' FRAGMENT CONJUGATED TO POLYETHYLENE GLYCOL, WHICH PROLONGS THE TIME OF THE DRUG REMAINS IN THE BLOODSTRAIN.

Rapid 1 trial tested the lipophilized formulation of the drug, whereas the RAPID 2 trial evaluated the liquid form of the drug.

The 397 patients who were assigned to the 200-mg arm initially received a 400-mg loading dose of certolizumab pegol at 0, 2, and 4 weeks, followed by 200 mg every 2 weeks. The 394 individuals in the 400-mg arm received 400 mg every 2 weeks.

The 201 placebo¬treated patients followed the same schedule as the 400¬mg group. If the patients did not reach an ACR 20 response by 16 weeks, they en¬tered an open-label extension in which they received 400 mg certolizumab pegol every 2 weeks, Dr. Keystone said.

At baseline, patients averaged 52 years of age, 6 years of RA, 13 mg/week methotrex¬ate, 1.1 treatment failures on disease-mod¬ifying antirheumatic drugs other than methotrexate, a Disease Activity Score of 7, and about 30 tender and 20 swollen joints.

Most patients who achieved an ACR 50 or ACR 70 response on the combination regimen did so by 16 weeks.

DR. KEYSTONE

On an intent-to-treat basis, similar per¬centages of patients who took the 200-mg and 400-mg certolizumab pegol dosages achieved an ACR 50 level of response (37% and 40%, respectively) or ACR 70 level of response (21% in each of the groups).

ACR 50 and 70 responses occurred in 8% and 3%, respectively, of patients in the placebo group.

Most patients who achieved either an ACR 50 or ACR 70 level of response did so by 16 weeks, which is earlier than has been seen with other anti-TNF agents, Dr. Keystone said.

About 80% of placebo-treated patients withdrew from the study, compared with about 25% of 400-mg patients and 30% of 200-mg patients.

Treatment-emergent adverse events, in¬cluding serious events, occurred at similar rates between the groups.

There was a trend toward more non¬serious and serious infections in the cer¬tolizumab-pegol-treated groups.

The trial also had a primary end point of Total Modified Sharp Score at the end of 52 weeks, but Dr. Keystone did not re¬port on it at the meeting.

The MRI images on the left (T1) and on the right (STIR) show erosions of the lunate and scaphoid bones.

A normal x-ray is shown for comparison.

The MRIs can also help keep patients on the right treatment schedule as the 210-mg or ACR 70 level of response did not by 16 weeks, which is earlier than has been seen with other anti-TNF agents, Dr. Keystone said.

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