

Etanercept Seems Safe in JIA Patients Under Age 4

BY MITCHEL L. ZOLER

COPENHAGEN — Treatment with etanercept was safe and effective in 33 patients younger than 4 years old with juvenile idiopathic arthritis in a pilot, open-label study presented at the annual European Congress of Rheumatology.

Although this is the second report of etanercept's being safely used to treat juvenile idiopathic arthritis (JIA) in children younger than 4 years, etanercept must still be considered an investigational drug for this indication until results are available from a double-blind, controlled study, said Dr. Claudia Bracaglia, a pediatric rheumatologist at Bambino Gesù Children's Hospital in Rome.

"Our study was observational. It's absolutely necessary to characterize the role of etanercept in a double-blind, controlled study, which we are planning to do," Dr.



Etanercept can offer 'remission with a significantly improved quality of life' to children with JIA.

DR. BRACAGLIA

Bracaglia said in an interview. "In our patients, etanercept meant the difference between patients having active disease and having remission with a significantly improved quality of life."

She presented data from a series that included 24 girls and 9 boys with JIA who were unresponsive to at least one disease-modifying antirheumatic drug. Methotrexate was the most commonly tried drug (31 patients); two patients were first tried on cyclosporine. In all, 8 (24%) patients had systemic-onset JIA, 18 (55%) had oligoarticular-onset JIA (5 with persistent and 13 with extended disease), 6 (18%) had polyarticular onset and were rheumatoid factor negative, and 1 patient (3%) presented with psoriatic arthritis.

The younger children received the same etanercept dosage (0.8-1.0 mg/kg once a week) that's been shown to be safe and effective in older children. Patients received etanercept for an average of 23 months (range, 6-86 months).

After 6 months, 27 patients (82%) attained an ACR Pediatric 30 response. At their last observation, 28 patients (85%) had an ACR Pediatric 30 response.

After 6 months, 25 patients (76%) had an ACR Pediatric 50 response, which extended to 28 patients (85%) by the time of the last assessment. After 6 months, 16 patients (48%) had an ACR Pediatric 70 response, which extended to 24 patients (73%) by last observation.

Of the five nonresponders, three had systemic-onset JIA. These five patients stopped etanercept because of lack of efficacy, and switched to another biologic drug. One patient switched to a different anti-tumor necrosis factor agent, and four switched to a drug aimed at blocking interleukin-1.

Four patients (12%) developed a major adverse event. One became infected by cytomegalovirus; three patients were infected by varicella zoster virus. One patient with a varicella zoster infection required hospitalization for necrotizing fasciitis. None developed tuberculosis, an opportunistic infection, or malignancy.

In response to the findings of varicella complications in these youngest JIA patients, the treatment protocol at Bam-

bino Gesù Children's Hospital requires that all children receive the varicella vaccine before starting methotrexate, Dr. Bracaglia noted.

She presented data on etanercept use in 158 JIA patients between the ages of 5 and 20 years who had not responded to methotrexate. Of these, 117 were female.

Over an average treatment course of 23 months, 80% achieved an ACR Pediatric 30, 70% achieved an ACR Pediatric

50, and 50% achieved an ACR Pediatric 70. Serious complications were more common in these older children, with 22% having to be hospitalized to manage the complications, many of which involved gastrointestinal problems. Despite the high hospitalization rate, none of the children discontinued etanercept because of the complications.

Dr. Bracaglia declared no conflicts of interest. ■

