Registry: JIA Patients Tolerate Etanercept Well

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VIENNA — Only 4% of etanercept-treated patients with juvenile idiopathic arthritis who were enrolled in a real-world clinical practice registry discontinued the biologic agent because of adverse events, Gerd Horneff, M.D., reported at the annual European congress of rheumatology.

Updated results from the German Etan-

ercept Juvenile Idiopathic Arthritis (JIA) Registry indicate that while the range of adverse events encountered in clinical practice is greater than reported earlier in the smaller, highly selective randomized trials, the drug's safety profile remains reassuring.

Indeed, nearly twice as many registry participants discontinued etanercept due to disease remission as for adverse events, noted Dr. Horneff of Martin Luther University, Halle, Germany.

He reported on 451 JIA patients with a total of 671 patient-years of follow-up on etanercept (Enbrel) in pediatric rheumatology practices in Germany and Austria

During this time, 128 adverse events were reported in 93 patients; 3 were life threatening. Another 30 were classified as serious.

The life-threatening adverse events consisted of a case of bacterial pneumonia requiring mechanical ventilation, a

thyroid cancer diagnosed 11 months after starting etanercept therapy, and a case of Stevens-Johnson syndrome in a patient who was also taking OCs. Following discontinuation of the OCs, etanercept was reinstituted without incident, the physician said at the congress, sponsored by the European League Against Rheumatism.

Twenty percent of the patients received etanercept monotherapy. The remaining 80% took etanercept plus methotrexate, a combination that provided synergistic efficacy at the cost of added toxicity. Excluding the 18% of registry participants with systemic JIA, a no-



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toriously difficult to treat condition, the complete remission rate among patients with other forms of JIA was 35% with combination therapy, compared with 13% with etanercept alone. Roughly onesixth of patients in each group experienced adverse events; however, the number of such events per affected patient was significantly greater in the combined therapy group.

Dr. Horneff noted that while the focus of his presentation was on the safety data, an earlier report from the German registry addressed etanercept's efficacy in the clinical practice setting (Ann. Rheum. Dis. 2004;63:1638-44).



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