Ustekinumab Bests Etanercept in Psoriasis Study

BY DOUG BRUNK

Ustekinumab at a dose of 45 or 90 mg at baseline and again at week 4 was more effective than a 50-mg dose of etanercept twice weekly in a 12-week randomized study of patients with moderate to severe psoriasis.

The findings "are generally consistent with those of previous studies," researchers led by Dr. Christopher E.M. Griffiths reported. "The high level of efficacy of ustekinumab treatment that we observed was achieved with only two injections during the 12-week period, as compared with twice-weekly injections of etanercept, which may be important for improved treatment compliance."

For this phase III study, 903 patients with moderate to severe arthritis were randomly assigned to one of three treatment groups: 45 mg ustekinumab at baseline and week 4 (209 patients), 90 mg of ustekinumab at baseline and week 4 (347 patients), or 50 mg etanercept twice weekly for 12 weeks (347 patients)..

Ustekinumab (marketed as Stelara by Centocor Ortho Biotech Services) blocks interleukin-12 and interleukin-23 while etanercept (marketed as Enbrel by Amgen and Wyeth) blocks tumor necrosis factor (TNF)–alpha.

The primary end point was the proportion of patients who achieved at least 75% improvement in the Psoriasis Area and Severity Index (PASI) at week 12 (N. Engl. J. Med. 2010;362:1118-28).

A total of 68% of patients in the 45-mg ustekinumab arm and 74% in the 90-mg ustekinumab arm achieved at least a 75% in the PASI score at week 12, compared with 57% of those in the etanercept arm.

Similarly, 65% of patients in the 45-mg ustekinumab arm and 71% of those in the 90-mg ustekinumab arm had cleared or minimal disease based on the physician's global assessment score, compared with 49% in the etanercept arm. ■

Disclosures: *The study was supported by Centocor Research and Development. The investigators disclosed conflicts with a number of pharmaceutical companies, including Centocor, Amgen, and Wyeth.*

MY TAKE

Comparison Was Long Overdue

This is the first study to directly compare two biologic agents for the treatment of moderate to severe psoriasis. We have been assuming that ustekinumab was better than etanercept for patients with moderate to severe psoriasis based upon individual clinical trials, but this study now provides proof.

For situations in which insurance companies have a tiered approval process whereby etanercept failure is a condition for ustekinumab use, this study is unlikely to change that requirement. For insurance companies that do not have a tiered approval process, this study could logically lead to treatment guidelines that support initial use of ustekinumab without prior use of etanercept.

Clinicians who provide care to patients with moderate to severe psoriasis have cautious optimism for ustekinumab in terms of its long-term safety profile. However, we really don't know for sure what that long-term safety profile is going to be. Accordingly, some of my colleagues will argue for the use of etanercept over ustekinumab from a safety point of view until more is known.

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