

Session Two

Etanercept Treatment in Children and Adolescents with Plaque Psoriasis

Dr. Richard Langley

9:35 am - 9:50 am
Friday, April 11

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Treating PsO in children is challenging. Patients (pts) may not respond to or tolerate conventional agents, and neither topical nor systemic therapies have been well-studied in children. Although there are published case reports on the use of biologics in children with promising results, this is the first clinical study assessing etanercept (ETN) in children with PsO. In this 48-wk study, 211 children (4 to 17 yrs) with PsO involving $\geq 10\%$ body surface area and PASI score ≥ 12 were randomly assigned 1:1 in a 12-wk double-blind (DB), placebo (Pbo)-controlled treatment period to once-weekly subcutaneous Pbo or ETN 0.8 mg/kg (≤ 50 mg), followed by 24 wks of open-label (OL) ETN, then a 12-wk randomized DB withdrawal-retreatment period. Pts who did not achieve PASI 50 at wk 24 or PASI 75 at wk 36 could add topical standard of care therapy. The primary endpoint was PASI 75 response at wk 12. Further endpoints included, but were not limited to, PASI 75 at other time points, PASI 50, PASI 90, static Physician's Global Assessment (PGA), and safety measures.

Baseline demographics and disease characteristics were similar across treatment arms. At wk 12, 57% of ETN pts achieved PASI 75, compared with 11% of those who received Pbo

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($P < 0.001$); proportions of pts who achieved PASI 50, PASI 90, and PGA clear-almost clear were also significantly greater in the ETN arm than the Pbo arm. Differences in PASI 75 between treatment arms were observed by wk 4. At wk 24, percentages of pts who achieved PASI 75/PGA clear-almost clear were 62%/56% for the original Pbo arm and 69%/57% for the original ETN arm. PASI 75 response was maintained through week 36; 56% (original Pbo arm) and 53% (original ETN arm) had PGA clear-almost clear. Proportions of pts with PASI 50 and PASI 90 at wks 24 and 36 increased in both groups compared with wk 12. Exposure-adjusted rates of non-infectious adverse events (431/100 pt-yr Pbo, 288/100 pt-yr ETN) and infections (308/100 pt-yr Pbo and 229/100 pt-yr ETN), were comparable between the 2 groups; most events were mild or moderate. Upper respiratory tract infection, headache, and nasopharyngitis were the most common events. During the withdrawal period, no pt experienced PsO rebound or change of PsO morphology.

In this study, ETN was well-tolerated and provided significant and sustained improvement in disease severity in children and adolescents with moderate to severe plaque PsO.

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