Pediatric Rheumatology

Oral presentation

7.5 Safety data from over 1,200 patients-years of methotrexate and/or etanercept treatment in children with polyarticular or systemic juvenile rheumatoid arthritis

EH Giannini*[1], NT Ilowite[2], DJ Lovell[1], CA Wallace[3], CE Rabinovich[4], A Reiff[5], G Higgins[6], B Gottlieb[7], Y Chon[8], SW Baumgartner[8] and S-L Lin[8]

Address: [1]Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, [2]Albert Einstein College of Medicine, Bronx, NY, USA, [3]Children's Hospital and Reginal Medical Center, Seattle, WA, USA, [4]Duke University Medical Center, Durham, NC, USA, [5]Childrens Hospital of Los Angeles, Los Angeles, CA, USA, [6]Ohio State University and Children's Hospital, Columbus, OH, USA, [7]Schneider Children's Hospital, New Hyde Park, NY, USA and [8]Amgen, Thousand Oaks, CA, USA

* Corresponding author

from 15th Paediatric Rheumatology European Society (PreS) Congress
London, UK. 14–17 September 2008

Published: 15 September 2008

Pediatric Rheumatology 2008, **6**(Suppl 1):S15 doi:10.1186/1546-0096-6-S1-S15

This abstract is available from: http://www.ped-rheum.com/content/6/S1/S15

Background

Etanercept has approval for use in children with polyarticular juvenile rheumatoid arthritis (JRA). Here we evaluate the safety of etanercept in children with polyarticular or systemic JRA.

Methods

This 3-year, open-label, non-randomized registry included patients age 2–18, with a diagnosis of polyarticular or systemic JRA. Patients treated with methotrexate (MTX), etanercept (ETN), or methotrexate/etanercept in combination (MTX/ETN) were eligible. Co-administration of non-biologic DMARDs was allowed. MTX was administered at 0.3 to 1 mg/kg/wk and etanercept was administered at 0.4 mg/kg (max 25 mg) twice weekly or 0.8 mg/kg (max 50 mg) weekly.

Results

602 patients enrolled; 198 received MTX, 105 received ETN, and 299 received MTX/ETN. A total of 33%, 31%, and 35% of patients have completed the 3-year registry for a total of 388, 210, and 610 subject-years of exposure for the MTX, ETN, and MTX/ETN groups, respectively. In the MTX, ETN, and MTX/ETN groups, 18%, 8%, and 19% discontinued due to insufficient therapeutic effect while 2%, 2%, and 0.3% discontinued due to adverse events. The rates of serious adverse events and medically important infections per 100 patient-years were 4.4, 7.6, 5.7 and 1.3, 1.9, and 2.1 for patients receiving MTX, ETN, or MTX/ETN. One case of lupus (MTX) and 2 cases of sepsis (ETN and MTX/ETN) were reported. No cases of lymphoma, malignancy, tuberculosis, or death were reported.

Conclusion

These data suggest etanercept is safe as a long-term, continuous therapy for treatment of JRA.

Funded by Immunex, a wholly-owned subsidiary of Amgen Inc., and by Wyeth Pharmaceutical.