



## Arthritis News

**Media Contact:** Tammy McCoy  
(404) 633-3777 (until Oct. 15)  
(210) 582-7010 (Oct. 16–Oct. 21)  
[tmccoy@rheumatology.org](mailto:tmccoy@rheumatology.org)

**Embargoed for Release at  
6:15 PM ET, Sunday Oct. 17, 2004**

### **EARLY TRIAL TREATMENT RESULTS FOR CHILDREN WITH SEVERE ARTHRITIS ENCOURAGING**

SAN ANTONIO, TEXAS—Preliminary results of a one-year study of adalimumab (HUMIRA™) indicate that this treatment for adults with rheumatoid arthritis also may provide rapid and substantial responses in children with juvenile idiopathic arthritis, according to research presented this week at the American College of Rheumatology Annual Scientific Meeting in San Antonio, Texas.

In a multi-center international (centers in the U.S. and Europe ) Phase III study, children ages four to 17 years with active arthritis who had failed to respond to methotrexate alone were given adalimumab injections subcutaneously (similar to an insulin injection) every other week. Each child was examined at regular intervals to assess disease activity (e.g., number of swollen joints, tender joints, joints with limitation of motion and joint pain as well as lab testing) and tolerance to the therapy. Of the 171 children enrolled in the study, 155 children completed the 16-week open-label study.

Overall, 91 percent (142 of the 155) of participants demonstrated significant clinical improvement by meeting the ACR Pediatric 30 level of response (this is a standard criteria of disease activity developed by the American College of Rheumatology), while 70 percent (109 of the 155) demonstrated profound improvement by meeting the ACR Pediatric 70 level of response. The 52 percent of patients taking adalimumab in combination with methotrexate showed more rapid and substantial improvement than did the group taking only adalimumab.

Adalimumab has already been shown to reduce signs and symptoms of rheumatoid arthritis, as well as inhibit radiographic progression (that is, damage to joints seen on an X-ray) of the disease and improve physical function in adults who have had a poor response to one or more disease-modifying anti-rheumatic drugs (DMARDs). During the 16-week study of children with arthritis, the drug also proved generally safe and was well-tolerated. If results continue to prove positive across extended year-long testing, adalimumab could become an additional treatment option to reduce symptoms for children with juvenile idiopathic arthritis. Juvenile idiopathic arthritis (commonly called juvenile rheumatoid arthritis in the U.S.) is a chronic condition causing joint inflammation in about one in every 1,000 children. The disease can cause severe joint damage if not effectively treated.

“The early results of this study are promising,” said Daniel J. Lovell, MD, Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, and an investigator in the study. “If borne out in the double-blind, randomized, controlled part of the study (on-going at this time), adalimumab will be established as an excellent treatment for children with significant arthritis.”

The American College of Rheumatology is the professional organization for rheumatologists and health professionals who share a dedication to healing, preventing disability and curing arthritis and related rheumatic and musculoskeletal diseases. For more information on the ACR’s annual meeting, see [www.rheumatology.org/annual](http://www.rheumatology.org/annual).

###

## Preliminary Data from the Study of Adalimumab in Children with Juvenile Idiopathic Arthritis (JIA)

Daniel J. Lovell<sup>1</sup>, Nicola Ruperto<sup>2</sup>, Steven Goodman<sup>3</sup>, Andreas Reiff<sup>4</sup>, Alberto Martini<sup>2</sup>, Edward H. Giannini<sup>1</sup>, Allen R. Radin<sup>5</sup>, Valluri S. Rao<sup>5</sup>, George Spencer-Green<sup>5</sup>. <sup>1</sup>Cincinnati Children's Hospital Medical Center, Cincinnati, OH; <sup>2</sup>PRINTO-IRCCS G Gaslini, Genova, Italy; <sup>3</sup>Arthritis Associates of South Florida, DelRay Beach, FL; <sup>4</sup>Children's Hospital Los Angeles, Los Angeles, CA; <sup>5</sup>Abbott Laboratories, Parsippany, NJ

**Objectives:** Adalimumab has been shown to inhibit signs and symptoms and radiographic progression in adult patients with rheumatoid arthritis. The present study was undertaken to evaluate the efficacy and safety of adalimumab in subjects with JIA.

**Subjects and Methods:** This was a multi-center, Phase III, randomized, double-blind, placebo-controlled study with a 16-week open-label lead-in period. Active treatment was 24 mg of adalimumab/M2 BSA subcutaneously every other week. Concomitant methotrexate (MTX) treatment was allowed. Eligible subjects were between 4 and 17 years of age and had polyarticular course juvenile idiopathic arthritis with a minimum of 5 swollen joints and 3 joints with limitation of motion (LOM). Efficacy assessments were performed at baseline, and weeks 2, 4, 8, 12, and 16, and included swollen joint count (o-66, SJC), pain on passive motion joint count (POM), LOM joint count, physician's and parent's global assessment of subject's overall well-being, Childhood Health Assessment Questionnaire (CHAQ), and C-reactive protein (CRP). Safety information was collected at regular intervals at patient visits on standard case report forms.

**Results:** Eighty percent (80%) of the subjects were female with a mean age of 11.4 yrs; 52% were taking concomitant MTX. To date, of the 171 subjects who enrolled, 155 completed the 16-week open-label lead-in period. In these 155 patients, response was rapid, with 67% and 77% of subjects achieving an ACR<sub>30</sub> response after 2 and 4 weeks of treatment, respectively. At week 16, 77 of 81 (95%) patients on concomitant MTX, and 65 of 74 (88%) patients on monotherapy had achieved an ACR<sub>30</sub> response and were eligible to enroll in the blinded portion of the study.

### Efficacy outcomes<sup>1</sup>

	Adalimumab with MTX (n=81)	Adalimumab without MTX (n=74)
ACR <sub>30</sub>	95%	88%
ACR <sub>50</sub>	94%	80%
ACR <sub>70</sub>	82%	59%
Active Joints <sup>2</sup>	-78%	-80%
SJC <sup>2</sup>	-83%	-75%
POM <sup>2</sup>	-100%	-86%
LOM <sup>2</sup>	-71%	-72%
Parent's VAS <sup>2</sup>	-72%	-66%
Physician's VAS <sup>2</sup>	-76%	-80%
CHAQ <sup>2</sup>	-75%	-67%
CRP <sup>2</sup>	-78%	-50%

<sup>1</sup>Observed, for patients eligible to enroll in double-blind study at 16 weeks

<sup>2</sup>Median percent change from baseline.

From safety data available to date, the most common adverse events observed during the study were infections (predominantly mild upper respiratory infections). Three subjects experienced serious adverse events of pneumonia, genital herpes, and acute gastritis. No tuberculosis or opportunistic infections were reported.

**Conclusions:** In this interim analysis of a 1-year study, adalimumab provided rapid and substantial responses in children with JIA and was generally safe and well-tolerated DURING the 16-week study period.

**Disclosure:** D.J. Lovell, Abbott Laboratories 5; Amgen 5, 8; Wyeth 8; Centocor 5; Bristol Myers Squibb 5; N. Ruperto, None; S. Goodman, None; A. Reiff, Merck 5, 8; Amgen 5, 8; Immunex 5, 8; Wyeth 5, 8; A. Martini, None; E.H. Giannini, Abbott Laboratories 2, 5; A.R. Radin, Abbott Laboratories 3; V.S. Rao, Abbott Laboratories 3; G. Spencer-Green, Abbott Laboratories 3.

**Author disclosure legend**—*Authors' disclosures of third-party relationships are listed in numeric format according to the following listing:*  
None—Nothing to disclose; 1—Stock options or bond holdings in a for-profit corporation or self-directed pension plan; 2—Research grants; 3—Employment (full or part-time); 4—Ownership or partnership; 5—Consulting fees or other remuneration (payment); 6—Non-remunerative positions of influence such as officer, board member, trustee or public spokesperson; 7—Receipt of royalties; 8—Speakers bureau.