3 studies confirm the value of etanercept therapy in treating juvenile idiopathic arthritis

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Three new studies have individually shown the anti-TNF (tumour necrosis factor) therapy etanercept to be effective, with a good safety profile, in children under four years of age with juvenile idiopathic arthritis (JIA), and associated with improved Health-Related Quality of Life (HRQoL) in a substantial proportion of children with JIA.

The first study, conducted in Italy, showed entanercept to be effective, with a good safety profile, in children under four years of age (an as yet unlicensed patient population for the treatment). Thirty-three patients under four years of age with unresponsive JIA (24 female, 9 male) were treated with etanercept for an average of 23 months. After the first 6 months of treatment, 82% achieved the ACR Pedi 30* response and 48% achieved the ACR Pedi 70* response. There was a low rate of mild adverse events, whilst one patient temporarily suspended treatment following hospitalisation for an infection.

The second study, conducted in The Netherlands, from the Arthritis and Biological in Children (ABC) project, observed impressive improvements in the Health-Related Quality of Life (HRQoL) of 53 patients with previously refractory (unresponsive) JIA in seven Dutch centres during entanercept use of at least 27 months. These comprised both disease-specific improvements (inflamed joints, functional impairment, erythrocyte sedimentation rate (ESR), a laboratory marker of inflammation) (p50% improvement, and ACR Pedi 70 represents a

>70% improvement.

Further details on the three studies are outlined below:

1. Safety and efficacy of etanercept in a cohort of juvenile idiopathic arthritis (JIA) patients under four years of age. (OP-0137)

Thirty-three patients with unresponsive JIA under four years of age in a single centre were treated with etanercept for a mean of 23 months (range 6-86), with all receiving other concurrent drug treatments. Efficacy (using ACR Pediatric 30, 50 and 70 criteria for improvement) and safety end points were recorded at each hospital visit.

The ACR Pedi 30 response was reached by 82% (27) after 6 months and 85% (28) at the last observation. The ACR Pedi 50 response was reached by 76% (25) at 6 months and 85% (28) at the last follow-up, and the ACR Pedi 70 response was reached by 48% and 73% respectively.

Four patients (12%) developed mild adverse events: including one case of cytomegalovirus infection and three varicella zoster virus (VZV) infections. One patient experienced a serious adverse event and was hospitalised for a necrotising fasciitis during VZV infection. No cases of tuberculosis, opportunistic infections or malignancies were reported.

2. Major improvements in health-related quality of life during the use of etanercept in patients with refractory juvenile idiopathic arthritis. (THU0426)

In 53 JIA patients, who previously did not respond to other second-line drugs, data were collected to evaluate HRQoL during treatment with

etanercept. HRQoL was measured by the Childhood Health Assessment Questionnaire (CHAQ), Child Health Questionnaire (CHQ) and Health Utilities Index mark 3 (HUI3) before start and after 3, 15 and 27 months. At the same time-points, information on JIA disease activity variables were also collected, including; physician's global assessment through the Visual Analogue Scale (VAS), number of active and limited joints and erythrocyte sedimentation rate. Linear mixed models were used to assess outcomes over time.

Significant improvements in HRQoL were seen during the 27 month study period. The disease specific CHAQ, including the VAS pain and VAS well-being scores showed a significant improvement on all domains (p