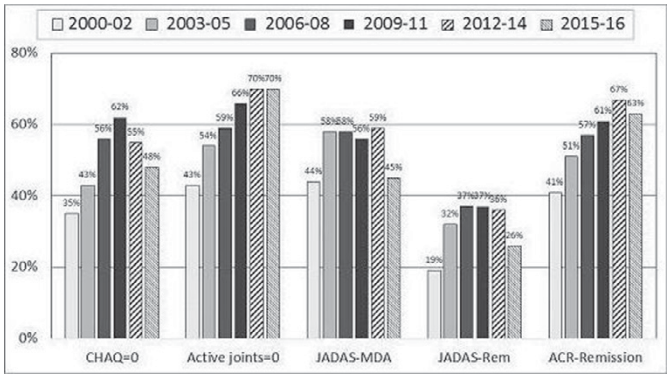

Conclusions: In recent years, children have been treated earlier, received less concomitant treatment with NSAIDS, corticosteroids as well as DMARDs. More recent cohort of patients had less severe disease at baseline, but also showed a markedly better outcome already at one year of treatment reflected by higher rates of patients with no active joint, a CHAQ DI of 0, a JADAS-MDA, and ACR-Remission. These data suggest that early disease control and better pre-selection of patients who need biologics are important to improve outcome and safety in children with JIA.

Disclosure of Interest: G. Horneff Speakers bureau: Abbvie, Pfizer, Roche, Novartis, MSD, K. Minden Speakers bureau: Abbvie, Pfizer, Roche, Genzyme, Pharm-Allergan, I. Foeldvari: None declared, G. Ganser: None declared, J. Haas: None declared, J. Brunner: None declared, I. Becker: None declared

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OP0197 **EVALUATION OF A DOSING REGIMEN FOR TOCILIZUMAB IN PATIENTS YOUNGER THAN TWO YEARS OF AGE WITH SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

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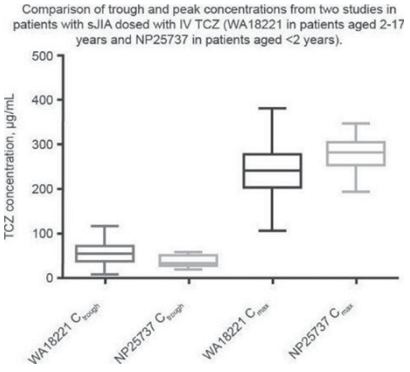
Background: Tocilizumab (TCZ) is approved for the treatment of systemic juvenile idiopathic arthritis (sJIA) based on clinical trials in patients (pts) ≥2 years of age. This study (NP25737) is the first for a biologic in sJIA pts <2 years of age.

Objectives: To evaluate the pharmacokinetics (PK), pharmacodynamics (PD), efficacy, and safety of TCZ in sJIA pts <2 years of age in a phase 1 trial.

Methods: Pts with uncontrolled sJIA and symptoms for ≥1 month prescreening who failed treatment with corticosteroids and NSAIDs and had no history of allergy to TCZ or other biologics received open-label TCZ 12 mg/kg intravenously (IV) every 2 weeks (dose calculated at each visit based on body weight). Pts were treated up to week 12 and could continue until the age of 2 years or were treated for 1 year from baseline. End points included PK (primary) at week 12, PD and efficacy (exploratory), and safety. Comparison was made to exposures from a previous trial in sJIA pts ≥2 years of age (WA18221) that was the basis for approval of TCZ in sJIA.

Results: Eleven pts were enrolled; median (range) age was 16 (10–22) months and weight was 10.40 (6.8–11.5) kg. Serum TCZ concentrations, estimated using population PK analysis, peaked immediately after infusion; median (range) maximum concentration was 282 (195–347) μg/mL (steady state reached by week 12), and median (range) trough concentration was 34.3 (19.2–59.7) μg/mL. Peak and trough exposures were within the exposure range in older children (244 [109–382] to 54.3 [10.9–117] μg/mL; Figure). Observed mean±SD soluble IL-6 receptor levels were 47.65±16.40 ng/mL at baseline and 927.83±148.07 ng/mL at day 71. CRP levels were 250.81±425.11 mg/L and 2.80±3.56 mg/L, respectively. ESR levels were 59.40±27.47 mm/h and 2.00±1.00 mm/h, respectively. Mean±SD Juvenile Arthritis Disease Activity Score-71 improved from 22.27±10.09 at baseline to 3.66±4.66 at day 71. By week 12, 10 pts had 32 adverse events (AEs) and 4 withdrew due to AEs. Infections or infestations were the most frequently reported AEs (10 events, 9 pts). Five serious AEs (SAEs) occurred; 3 pts had SAEs of hypersensitivity that led to withdrawal; 1 of these pts then experienced SAEs of foot and mouth disease and sJIA flare after study withdrawal. No actual cases of MAS were reported, but 2 pts had laboratory abnormalities indicative of MAS according to 2016 criteria.[1] No deaths occurred during the study.

Conclusions: TCZ exposures achieved in this study fell within the range of the previous trial in sJIA pts ≥2 years of age. This study provides evidence that TCZ is effective in sJIA pts <2 years of age, achieves PK and efficacy similar to those



demonstrated previously in older pts, and has a similar AE safety profile, but there was a higher incidence of serious hypersensitivity events and suspected MAS.

References:

[1] Ravelli A et al. Ann Rheum Dis. 2016;75:481–9.

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THURSDAY, 15 JUNE 2017

Barrier free employment for young people with RMDs

OP0198-PARE **FIT FOR WORK ONLINE: SUPPORTING EMPLOYEES WITH RMDS, EMPLOYERS AND HEALTHCARE PROFESSIONALS**

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Background: Seven million working days are lost each year in Ireland due to RMDs, such as back & neck pain or stiffness, arthritis, and limb pain. This is therefore a significant problem which obviously impacts on both employers, employees and healthcare professionals. That is why Arthritis Ireland has developed *Fit for Work Online* - an eLearning programme which focuses on the issues that face these three groups.

Objectives: The objective of the project was to develop an online educational programme to provide information, guidance and support to employees, employers and healthcare professionals on working with RMDs.

Methods: In 2015 Arthritis Ireland began its developments of an online education programme "*Fit for Work Online*" which focuses on the tripartite relationship between the employee, employer and healthcare professional.

3 video lessons were developed as part of this eLearning programme.

- The first lesson is aimed at employees who are living with an RMD
- The second lesson is aimed at employers who have a staff member who is living with an RMD (and finally)
- The third has been developed for health professionals to update them on current guidance around RMDs and ongoing employment

A key message in all 3 videos is that *working is good for your health.*

Since employment has been shown to boost health and happiness, it is crucial, whenever possible, that people who are living with an RMD, remain in employment, or return to work, as soon as they can. That is the central message of this eLearning programme.

A number of issues were addressed in the development of this programme in order to convey these important issues:

- Firstly, employees who are living with an RMD are encouraged to take control of their condition. People living with an RMD are encouraged to consider practical steps and issues which would support them in staying in, or returning to, work.
- Secondly, from an employer's perspective, in addition to concerns about the welfare of their employees, there are other issues to consider, and it is natural for instance to be concerned about the possible impact of any health condition on their employees' performance & reliability, and consequently on their business. Adaptations, supports, flexibility and so on need to be considered.
- Finally, health professionals need to encourage, advise and facilitate people who are living with RMDs to remain in, or return to work.

Results: The *Fit for Work Online* programme will go live in February 2015. It is planned that a report on the first four months of the programme's delivery and implementation will be available at EULAR 2017 in Madrid.

Conclusions: The direct cost of RMDs at work in Ireland is estimated to be