Conclusion: This study has identified that within CYP initiating ETN, similar response clusters are evident to those previously identified following MTX. This commonality suggests a new framework for understanding treatment response, beyond a simple responder/non-responder analysis at a set point, which applies across multiple drugs despite different mechanisms of action and previous unfavourable treatment outcomes. Understanding both clinical factors associated with, and biological mechanisms underpinning, these clusters would aid stratified medicine in JIA.

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OP0163

COMPARATIVE ANALYSIS OF ETANERCEPT BIOSIMILAR AND ORIGINATOR USE IN CLINICAL PRACTICE: DATA FROM THE GERMAN BIKER-REGISTRY

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Background: In 2017, 2 Etanercept biosimilars became approved. Comparative studies performed in adult patients with rheumatoid arthritis, ankylosing spondylitis or psoriasis by extrapolation led to approval for juvenile idiopathic arthritis (JIA).

Objectives: So far there is limited experience with Etanercept biosimilars in JIA: The large national data base of the BIKER-registry was used to describe experience with Etanercept biosimilars in clinical practice.

Methods: In this retrospective analysis patients exposed to ETA were identified in the German BIKER-registry and grouped into cohorts according to initiation of treatment after 2017, use of the originator and of biosimilars. The course of JADAS10, Physician global assessment VAS 0–100-mm, Parent/patient global assessment VAS 0–100-cm, Active joint count 0–71, truncated at 10, ESR and CHAQ-DI was analyzed. Descriptive statistics was used for demographic, clinical data, drug exposure, adverse events (AEs) and events of special interest (ESI).

Results: Until 31.10.2020, 2917 JIA patients were reported to have received Etanercept. Since January 1 2017, in 39 centres treatment with Etanercept was started in 439 patients (377 (85.9%) started with the originator and 62 (14.1%) started a Biosimilar). Biosimilars were prescribed in 17 centres (44%). In 12 centres (31%), Etanercept biosimilars were used first line in 62 patients. In 17 centres (44%), 63 patients switched for the originator to a biosimilar. 3 patients reswitched from the biosimilar to the originator. 4 patient switched from a biosimilar to the originator. 22 centres (56%) had not prescribed a biosimilars so far. In not a single centre, initiation of a biosimilar was more frequent than of the originator.

The patients' characteristics and disease activity parameters were widely comparable. Patients receiving biosimilar first line were slightly older at disease onset and had a longer disease duration. Patients receiving biosimilar first line had more often rheumatoid factor (RF) negative polyarthritis while extended oligoarthritis was more frequent in the originator cohort. In the switching cohort, more patients had extended oligoarthritis and fewer had RF negative polyarthritis and ERA JIA.

No difference in disease activity parameters was noted, neither at baseline, during the course of treatment nor at last observation upon treatment. A decrease of the JADAS10 indicates improvement in both groups (Figure 1). At the time of switching, 68% had JADAS minimal disease activity (MDA) and 43% were in JASDAS remission. At month 6 and 12 these numbers increased to 74%/65% and 62%/50%.

In total, 66 adverse events (AE) were reported in 45 patients upon biosimilar treatment.

33 patients had 1, 5 patients 2, 5 patients had 3 and 2 reported 4 events. Adverse event of special interest were hypersensitivity n=1, injection site reaction n=1, new onset of psoriasis n=1, celiac disease n=1, Crohn's disease n=1, elevated transaminases n=2, depression n=1 and disease deterioration (arthritis flare) in n=21. In 20 patients, the etanercept biosimilar was discontinued.

Conclusion: This analysis is the first attempt to present a large data sample on JIA patients exposed to Etanercept biosimilars. Biosimilar were used in a minority of patients and by a minority of centers although no difference in efficacy or safety was noted from our analysis. Until today, the use of the originator is by far exceeding the use of biosimilars. The prescription of a biosimilar either first line or by switching from the originator is limited to a part of centres. Differences in efficacy between first line biosimilar users and originator users could not be observed. Also, after switching, no loss of efficacy was observed.

JADAS 10

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OP0164

LONG-TERM SAFETY OF ANAKINRA IN PATIENTS WITH SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS FROM THE PHARMACHILD REGISTRY

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Background: Systemic juvenile idiopathic arthritis (SJIA) is characterized by extra-articular manifestations, as fever and rash, and rarely associated by a potentially lethal complication as macrophage activation syndrome (MAS). Anakinra is a recombinant human interleukin (IL)-1 receptor antagonist whose efficacy and safety profile has been studied for patients with SJIA.

Objectives: To evaluate the long-term safety profile of anakinra in patients with SJIA.

Methods: Data from patients with SJIA enrolled in the Pharmachild registry before 30 September 2018 and treated with anakinra were analyzed. The study

endpoints were the occurrence of non-serious adverse events (AEs) of at least moderate severity and serious AEs (SAEs), including macrophage activation syndrome (MAS), and the duration of anakinra treatment with reasons for discontinuation. All endpoints were analyzed overall, by 6 month-time windows and in different treatment sets represented by those patients continuously treated with anakinra for at least 12, 18 and 24 months (set-12, -18, -24, respectively).

Results: 306 patients were enrolled. 46%, 34% and 28% of them had been treated for at least 12, 18 and 24 months, respectively. 201 AEs, mostly represented by infections, were reported for 509.3 patient-years (py) with an overall incidence rate (IR) of 39.5/100 py. Among 56 SAEs (IR 11.0/100 py), (Table 1) 23.2% were infections and 19.6% MAS episodes. The IR of AEs was higher during the first 6 months of anakinra, followed by decreasing IR in the different long-term treatment sets. Treatment discontinuation occurred in 76% of patients, most in the first 6 months, due to inefficacy (43%), remission (31%) or AEs/intolerance (15%). No deaths or malignancies occurred during anakinra treatment.

Table 1. Number of SAEs and incidence rates (95% CI) by overall PT decreasing order and time window in the complete set (events with a frequency >1 by overall SOC and >1 by overall PT were reported) Only time windows <13 months were reported in the present table.

SOC	Time window		1-6 months		7-12 months		Overall
	N		306		194		306
	Patient-time (years)		117.3		80.2		509.3
PT	n	Rate (95% CI)		Rate (95% CI)		Rate (95% CI)	
		n		n		n	
All	All	33	28.1 (19.1-41.5)	4	5.0 (1.9-13.2)	56	11.0 (7.9-15.2)
Infections and infestations	All	7	6.0 (2.9-12.4)	1	1.2 (0.2-8.8)	13	2.6 (1.4-4.8)
	Pneumonia	2	1.7 (0.4-6.8)	1	1.2 (0.2-8.8)	4	0.8 (0.3-2.1)
Immune system disorders	All	7	6.0 (2.8-12.5)	1	1.2 (0.2-8.8)	11	2.2 (1.1-4.1)
	Haemophagocytic lymphohistiocytosis	7	6.0 (2.8-12.5)	1	1.2 (0.2-8.8)	11	2.2 (1.1-4.1)
Injury, poisoning and procedural complications	All	5	4.3 (1.8-10.2)	-	-	9	1.8 (0.9-3.4)
	Infusion related reaction	1	0.9 (0.1-6.0)	-	-	2	0.4 (0.1-1.6)
	Injection related reaction	4	3.4 (1.3-9.1)	-	-	6	1.2 (0.5-2.6)
Metabolism and nutrition disorders	All	3	2.6 (0.8-7.9)	-	-	4	0.8 (0.3-2.1)
Skin and subcutaneous tissue disorders	All	3	2.6 (0.8-7.9)	1	1.2 (0.2-8.8)	4	0.8 (0.3-2.1)
Blood and lymphatic system disorders	All	1	0.9 (0.1-6.1)	-	-	2	0.4 (0.1-1.6)
General disorders and administration site conditions	All	1	0.9 (0.1-6.1)	1	1.2 (0.2-8.8)	2	0.4 (0.1-1.6)
Investigations	All	2	1.7 (0.4-6.8)	-	-	2	0.4 (0.1-1.6)
Nervous system disorders	All	1	0.9 (0.1-6.0)	-	-	2	0.4 (0.1-1.6)
Surgical and medical procedures	All	1	0.9 (0.1-6.0)	-	-	2	0.4 (0.1-1.5)

Abbreviations: SAE, serious adverse event; SOC, system organ class; PT, preferred term, MedDRA version 21.1; N, number of patients ever treated with anakinra during the time window irrespectively of the length of any unexposed periods; 95% CI, 95% Confidence Interval.

Conclusion: The results of the present study confirm the long-term safety profile of anakinra in SJIA patients and show a decreasing overall incidence rate of AEs over time.

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OP0165 RISK FOR UVEITIS EVENTS AFTER WITHDRAWAL OF DISEASE MODIFYING ANTIRHEUMATIC DRUGS IN THE TREATMENT OF PATIENTS WITH EXTENDED OLIGOARTHRITIS OR RHEUMATOID FACTOR NEGATIVE POLYARTHRITIS

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Background: Juvenile idiopathic arthritis (JIA) associated uveitis is an extra-articular manifestation of the JIA disease that may cause vision-threatening complications and an uncontrolled uveitis may even lead to blindness. Uveitis occurs in up to 20% of patients with JIA, depending on the JIA category. The majority of patients develop uveitis within the first two years after JIA symptom onset, but uveitis can continue into adulthood.

Objectives: The main objective of this study was to analyze the risk for uveitis events after discontinuing disease-modifying antirheumatic drugs (DMARD) in patients with extended oligoarthritis and rheumatoid factor (RF)-negative polyarthritis.

Methods: Data of the two ongoing multicenter biologic registers: German Biologics in Pediatric Rheumatology (BiKeR) and the Juvenile arthritis Methotrexate/Biologics long-term Observation (JuMBO) were used to analyze the adverse event (AE) and events of special interest (ESI) reports about uveitis events during treatment and after discontinuation of DMARDs. Biker started recruitment of children and adolescent patients with JIA exposed to biological (b) or conventional (cs) DMARD's in 2001. The patients were further followed in JuMBO after reaching the age of 18 or transitioning to an adult rheumatologist. Disease characteristics, treatment data, AE's and ESI's were reported by the pediatric or adults rheumatologist, respectively.

Results: A total of 2,041 patients with RF-negative polyarthritis (n=1,280) or extended oligoarthritis (n=761) were included into the analyses. The mean follow-up of this study was 76 years (SD 5.3). About half of the patients were enrolled in BiKeR with start of etanercept (1,137, 55.7%), followed by 635 (31.1%) patients with start of methotrexate (MTX) monotherapy or adalimumab (ADA, n=198, 9.7%). A history of uveitis was reported for 238 (11.7%) patients