of a positive IFN-score, confirming an activation of this inflammatory pathway, may guide the clinicians in the management of these patients and may support therapeutic decisions

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FRI0543

EFFICACY AND SAFETY OF INTRAVENOUS GOLIMUMAB IN PATIENTS WITH JUVENILE IDIOPATHIC ARTHRITIS: RESULTS FROM A PHASE 3 OPEN-LABEL STUDY

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Objectives: To assess efficacy & safety of intravenous golimumab in pediatric patients with active polyarticular course juvenile idiopathic arthritis despite methotrexate therapy through 28 weeks of treatment.

Methods: A multicenter, Phase 3, single arm, open-label trial was conducted using intravenous golimumab at a dose of 80mg/m² given at weeks 0 & 4, then every 8 weeks thereafter, in pediatric patients ages 2-17 years old with active polyarticular course juvenile idiopathic arthritis despite methotrexate therapy. Patients received commercial MTX weekly at same BSA-based dose as at time of study entry. All the results below are based on full analysis set which includes all patients who received at least 1 dose of study agent.

Results: 180 patients were screened (130 enrolled, 127 treated) with the first patient screened on 22Dec2014; last patient first treated 26Dec2017, & last patient's Wk28 visit was 09Jul2018.

Proportion of JIA ACR 30,50,70, & 90 responders at Wk28 was 83.5%,79.5%,70.1%, & 46.5%, respectively. 29.1% of patients met criteria for inactive disease at Wk28. Median change from baseline for JASDAS 10, 27, & 71 was -14.20, -16.60, & -20.32, respectively at Wk28. JADAS 10, 27, & 71 minimal disease activity was met by 15% of patients at Wk28.

Proportion of patients experiencing at least 1 treatment-emergent AE through Wk28 was 77.2%. MedDRA system organ class with highest incidence of AEs was Infections & infestations (57.5%); most commonly reported AE upper respiratory tract infection (17.3%), then nasopharyngitis (15.0%). Six patients experienced serious AEs through Wk28: Herpes zoster disseminated, Infective exacerbation of bronchiectasis, Sepsis, Varicella, Mycosis fungoides, & Suicidal ideation. These events resulted in permanent discontinuation of intravenous golimumab, except for Varicella.

Conclusion: Intravenous golimumab delivered at a dose of 80mg/m² at weeks 0 & 4, then every 8 weeks thereafter and appears to be effective in these patients with a safety profile similar to other TNF inhibitor therapies.

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EFFICACY AND SAFETY OF CANAKINUMAB IN SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS – EXPERIENCE USING DATA OF THE BIKER REGISTRY

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Background: Canakinumab is approved for the treatment of systemic juvenile idiopathic arthritis (sJIA) older than 2 years.

Objectives: The aim of the German Biologics Registry (BiKeR) is the surveillance of JIA patients exposed to biologics.

Methods: Baseline demographics and disease activity parameters were documented. Efficacy was determined using the JADAS and the proposed criteria for inactive disease on medication. Safety assessments were based on reports of adverse events (AE). All reports have been coded according to MedDRA®.

Results: 48 sJIA patients with 82.5 patient-years (PY) of exposure to Canakinumab were recorded in the German BiKeR registry. The total observation time (from date of first dose until last follow-up, censored, if another biologic was started) was calculated with 109.9 PY.

The cohort treated with Canakinumab had experienced long disease duration of 2.9+/-3.8 years (mean +/- SD). 21 (44%) were pre-treated with methotrexate, 10 (21%) with Etanercept, 3 (6%) with Adalimumab, 18 (38%) with Anakinra and 19 (40%) with Tocilizumab. Concomitantly, 9 (18.8%) received methotrexate, 22 (45.8%) NSAIDs and 23 (48%) systemic corticosteroids.

At last follow up upon treatment, 48%/44%/42%/38% of patients reached PedACR30/50/70/90 improvement. 8 patients (16.7%) had inactive disease according to the Wallace criteria. The median (IQR1-IQR3) JADAS10 score decreased from 12.6 (6.2-15.8) at baseline to 0.5 (0.0-2.8). During ongoing treatment, approximately 82% of patients achieved a JADAS defined minimal disease activity; while 64% reached a JADAS defined remission at last follow-up.

125 adverse events (AE) were recorded (114 events/100PY [95% CI 96-136]). Of these, 22 qualified as serious adverse events (SAE) (20/100PY [13-30]). 100 AEs were observed during exposure or up to 90 days follow up after the last exposure to Canakinumab (121/100PY [99-147]). 19 qualified as SAE (23/100PY [15-36]).

Adverse Events of Special Interest were serious and medically important infection (n=4), cytopenia (n=4), macrophage activation syndrome (n=3). There was no opportunistic infection, intestinal perforation, anaphylaxis or other hypersensitivity, thrombotic event, evolving autoimmune disease, cardiac or cerebral event, bleeding, malignancy, or death. A total of 38 patients (79%) discontinued treatment, 8 (17%) due to lack of efficacy, 16 (33%) due to remission and 2 (4%) because of intolerance.

Conclusion: The current analysis adds to the established safety profile of Canakinumab and demonstrates that safety was comparable and consistent with the overall AE profile of Canakinumab in paediatric patients. MAS occurred in three sJIA patients and might be a JIA-associated feature. Infections were the most frequent AE, but only two serious infections were reported. No new safety signals specific to the paediatric population were identified for Canakinumab; the risk profile of Canakinumab remains positive for the approved paediatric indication sJIA.

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