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**THU0191**

**NOVEL FORMULATION OF CT-P13 FOR SUBCUTANEOUS ADMINISTRATION IN PATIENTS WITH RHEUMATOID ARTHRITIS: INITIAL RESULTS FROM A PHASE III/III RANDOMISED CONTROLLED TRIAL**

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**Background:** While the treatment with intravenous (IV) CT-P13, an infliximab biosimilar, is effective and well tolerated, a new subcutaneous (SC) CT-P13 formulation (CT-P13 SC) is developed to provide additional, more convenient treatment options and opportunities for self-injection.

**Objectives:** To find the optimal dose of CT-P13 SC and to evaluate efficacy, PK and safety over the first 30 weeks in patients with rheumatoid arthritis.

**Methods:** This study consists of 1 cohort with CT-P13 IV, and 3 cohorts with 3 different doses of CT-P13 SC injected biweekly. All enrolled patients initially received CT-P13 IV at Weeks 0 and 2 and patients who received 2 full doses and displayed no safety concerns were randomly assigned to receive either CT-P13 SC or IV at Week 6. Using part 1 result, PK-PD modelling was conducted for the 3 SC regimens.

**Results:** A total of 50 patients were enrolled, of whom 48 patients were randomly assigned into 4 cohorts. Overall, the efficacy results of CT-P13 SC up to Week 30 were comparable to those of CT-P13 IV. Disease improvement by DAS28 and ACR20 were comparable across all 4 cohorts, regardless of the route of administration or dosage of CT-P13 (table 1). The safety profiles in CT-P13 SC cohorts were generally comparable to CT-P13 IV. One of the 2 patients who experienced a hypersensitivity reaction became allergic to Infliximab during the study period. One injection site reaction was grade 1 or 2. The proportion of ADA (positive) was lower in the SC cohorts.

**Treatment continuation in patients enrolled with SB4 or oETN who were bionaive until enrollment.**

**Conclusions:** CT-P13 SC showed comparable efficacy and safety with CT-P13 IV. The preliminary results suggest CT-P13 SC as a future alternative treatment of infliximab.

**REFERENCES:**


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**THU0192**

**RETENTION RATES FOR ETANERCEPT: COMPARING THE ORIGINAL WITH A BIOSIMILAR**

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**Background:** Since the first approval of a biosimilar in 2015, the number of biosimilars approved for the treatment of rheumatoid arthritis (RA) in Germany has been increasing. Until now, there are just a few analyses investigating retention rates of biosimilars and the respective originators.

**Objectives:** To compare treatment survival on SB4 to the originator etanercept (oETN) using real-world data.

**Methods:** We used data gathered until December 2017 from the prospective, longitudinal RABBIT (Rheumatoid Arthritis: Observation of biologic therapy) cohort. RA patients are enrolled in RABBIT when they start a biologic, biosimilar or new csDMARD treatment. For comparative analyses, patients starting SB4 either as enrollment or during follow-up were compared to patients enrolled with oETN since 2015. The drug survival rates during the first six months were analysed in biologic naive patients prior to enrollment using Kaplan-Meier curves.
Results: Overall, 283 patients were included in the register starting SB4 and 369 with oETN. Another 355 patients who had already been enrolled in RABBIT switched to SB4 during follow up. Compared to oETN patients, those enrolled with SB4 had slightly lower disease duration (8 vs. 9 years) and significantly fewer patients had three or more comorbidities (40% vs. 47%, p<0.04). 88% (n=250) of patients enrolled with SB4 and 86% (n=317) enrolled with oETN were bionaive. Out of all patients who started SB4 during follow up, 40% had been treated with oETN, and 39% with another biologic before switching. 21% had received csDMARD or no drug treatment before treatment start. Kaplan-Meier curves show comparable retention rates over 6 months for SB4 and oETN (figure 1). Adjusting the curves for disease duration and comorbidities had no significant influence on the results. 8% (n=20) of bionaive SB4 patients and 17% (n=54) of bionaive oETN patients stopped treatment during the first 90 days. Additional 6% (n=14, SB4)/15% (n=46, oETN) stopped the treatment within 180 days after enrolment. The reasons for discontinuation of both treatments were adverse events (AE) in 59% (n=20, SB4)/49% (n=49, oETN) and loss of response in 26% (n=9, SB4)/31% (n=31, oETN). The most common cause for discontinuation within 180 days due to AE were skin reactions at the injection site in 35% (7 of 20) of SB4, and 49% (24 of 49) of oETN patients.

Conclusions: The retention rates for bionaive patients starting either the biosimilar SB4 or the originator oETN were similar. The distribution of adverse events was also comparable. A selection bias cannot fully be ruled out since patients on oETN had more comorbidities.

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THU0193 EFFICACY AND SAFETY OF BCD-055 (INFlixIMAB BIOSIMILAR) IN RHEUMATOID ARTHRITIS. RESULTS OF BCD-055–3/LIRA PHASE 3 CLINICAL STUDY

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Background: Equivalent efficacy of BCD-055 and infliximab (INF) innovator has been previously established (the primary endpoint: ACR20 at Wk14)

Objectives: The impact of BCD-055 and INF innovator on RA activity has been analysed within 14 week study period. DAS28-CRP,1 CDAI and SDAI were evaluated. Additionally, safety data has been collected.

Methods: The study was conducted as international multicenter randomised double-blind placebo controlled study. The study enrolled 426 adults with active RA. Patients were randomised into 2 study arms in 2:1 ratio to receive BCD-055 or INF innovator in dose of 3 mg/kg. In the analysed period of the study, patients received the iv infusions on Wk0, Wk2, Wk6, Wk14.

Results: Efficacy: BCD-055 and INF innovator showed similar impact on RA activity: in both groups significant decline of DAS28-CRP was observed (figure 1). This result corresponds to positive CDAI and SDAI dynamics (table 2). Medians of CDAI/SDAI on screening indicated high RA activity, while on Wk 14 – moderate activity. Analyses of inflammatory markers (ESR and C-reactive protein) revealed pronounced decline in ESR and CRP levels by Wk 2. No further elevation has been observed.

Safety: No differences in safety profiles of BCD-055 and INF innovator has been shown. One of the most frequent AEs were arterial hypertension, anaemia, neutropenia and increase of transaminases. Number of patients with binding and neutralising antibodies also did not differ between groups. Babs were detected in 6.83% patients in BCD-055 arm and in 7.81% in INF innovator arm (p=0.888), Nab were observed in 1.61% and 0.78% patients in same arms (p=0.666).

Abstract THU0193 – Table 1. SDAI, CDAI dynamics.

<table>
<thead>
<tr>
<th>SDAI</th>
<th>BCD-055 (n=280)</th>
<th>INF innovator (n=138)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>42.46 [35.15–51.11]</td>
<td>41.22 [34.21–47.52]</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.00000</td>
<td>&lt;0.00000</td>
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</table>

Abstract THU0193 – Table 2. Summarised safety data

<table>
<thead>
<tr>
<th>Percentage of patients with</th>
<th>Any AE/SAE</th>
<th>Therapy-related AEs</th>
<th>Any SAE</th>
<th>Grade 3–4 AEs</th>
<th>Therapy-related grade 3–4 AEs</th>
<th>Therapy-discontinuation due to AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCD-055 (n=280)</td>
<td>53.57% (150)</td>
<td>26.43% (74)</td>
<td>2.14%</td>
<td>10.00%</td>
<td>5.71%</td>
<td>2.50%</td>
</tr>
<tr>
<td>INF innovator (n=138)</td>
<td>44.93% (62)</td>
<td>24.64%</td>
<td>1.45%</td>
<td>5.80%</td>
<td>4.35%</td>
<td>2.90%</td>
</tr>
<tr>
<td>p-value</td>
<td>0.119</td>
<td>0.784</td>
<td>1.00</td>
<td>0.966</td>
<td>0.722</td>
<td>0.757</td>
</tr>
</tbody>
</table>

Table 1

Any AE/SAE 53.57% (150) 44.93% (62) 0.119
Therapy-related AEs 26.43% (74) 24.64% 0.784
Any SAE 2.14% 1.45% 1.00
Grade 3–4 AEs 10.00% 5.80% 0.966
Therapy-related grade 3–4 AEs 5.71% 4.35% 0.722
Therapy-discontinuation due to AE 2.50% 2.90% 0.757

Conclusions: Treatment with BCD-055 and INF innovator leads to significant decline in RA activity and inflammatory markers by Wk14, which corresponds with previous results of ACR20 assessment1. Both drugs are well tolerated with no differences in safety profiles. The frequency of ADA formation is also comparable.