OBJECTIVE: To assess the safety and effect of switching from reference rituximab (RTX ref) to rituximab biosimilar (RTX bs) BCD-020 in patients with RA in real clinical practice according to the data from MUAR.

METHODS: Patients with RA who treated by RTX bs, at the onset and then switched to RTX ref (BCD-020) were enrolled in the study. For all patients were performed: swollen and tender joints count, ESR, CRP, biochemistry and immunologic blood analyses. Assessment of dynamic of DAS28, RAPID3, HAG-DI was performed. The great attention was given to the therapy safety assessment. RTX ref effectiveness and safety profile was assessed at the moment of switching; data for RTX bs (BCD-020) were collected earlier than 6 months after switching.

RESULTS: 46 patients with RA were enrolled, 80.5% were women; the mean age 59.5±12.2 years; 91.3% were RF-positive, 63% - ACCPA-positive, the disease activity at the moment of switching was moderate, the mean DAS28 was 3.5. The duration of RTX ref therapy until switching was 36.8 ± 26.8 months; the duration of the follow-up period for BCD-020 biosimilar was 12.1 ± 6.18 months. In 43.5% of patients, previously inefficiency or intolerance of other biologics was discovered. The proportion of patients who received concomitant therapy with glucocorticoids or methotrexate (MTX) was 45.7% and 43.5%, respectively. The mean MTX dose was 13.6 mg/wk. The mean dose of RTX ref/BCD-020 was 1000 mg. The stability dynamic of clinical parameters was retained after switching to biosimilar (Tab.1) without significant difference between the rituximab products (p>0.05).

Table 1. Comparison of Efficiency Parameters for the Reference Rituximab and Biosimilar BCD-020

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference rituximab</th>
<th>Biosimilar BCD-020</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAS28 (ESR)</td>
<td>3.39</td>
<td>3.34</td>
</tr>
<tr>
<td>HAG-DI</td>
<td>1.48</td>
<td>1.44</td>
</tr>
<tr>
<td>RAPID3</td>
<td>12.9</td>
<td>12.8</td>
</tr>
</tbody>
</table>

The safety profile of RTX ref and RTX bs (BCD-020) was also similar. None of the patients discontinued BCD-020 therapy for reasons related to safety or inefficiency.

CONCLUSION: Within the framework of routine clinical practice, switching from reference rituximab to BCD-020 biosimilar is not accompanied by a change in safety and efficacy profile of the therapy and does not pose a risk of discontinuation, which is coherent with the results of the registration clinical trial for BCD-020. [3]

REFERENCES:

Disclosure of Interests: Galina Lukina Speakers bureau: Novartis, Pfizer, UCB, Abbvie, Biocad, MSD, Roche, Ekaterina Koltsova: None declared, Evgeniya Shmidt: Speakers bureau: MSD, Novartis, Pfizer, Karine Lytkina Speakers bureau: Novartis, Eli Lilly, Pfizer, UCB, Abbvie, Biocad, MSD, JonssonJonsson, Evgeny Zhilyaev Speakers bureau: Novartis, UCB, Pfizer, Biocad, Abbvie, MSD, Roche
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