Golimumab (GLM) has shown its efficacy and tolerability in various randomized clinical trials. Systemic data for GLM regarding health-economic parameters in daily clinical practice are essential not only for pharmaceutical companies but also for cost-benefit analyses in Germany.

Background: Golimumab (GLM) has shown its efficacy and tolerability in various randomized clinical trials. Systemic data for GLM regarding health-economic parameters in daily clinical practice are essential not only for pharmaceutical companies but also for cost-benefit analyses in Germany.

Objectives: This prospective NIS was designed to evaluate the impact of GLM therapy on work productivity and daily activities as well as Quality of Life (QoL) in patients with RA, AS or PsA in Germany under routine settings over an observational period of 24 months, plus an additional voluntary extension period of 12 months (total 24 months) to collect long-term data on health-economic parameters.

Methods: GO-ART was an observational prospective study on patients with RA, AS or PsA (biologic-naïve and biologic-experienced) who started treatment with GLM at 63 sites of Germany.

The primary endpoint was the change in work productivity/activity impairment as measured by Work Productivity and Activity Impairment (WPAI) questionnaire from baseline, measured primarily at month 3 and secondarily at months 6, 12 and 24. As secondary endpoint the change in quality of life (RAQoL for RA patients, ASQoL for AS patients and NAPPA-QoL for PsA patients) was assessed.

Results: 748 patients (RA=250, PsA=249, AS=249) started GLM therapy. The primary efficacy endpoint was analyzed in the modified intention-to-treat (mITT) subset of 493 patients (RA=158, PsA=157, AS=178) with RA, AS or PsA (biologic-naïve and biologic-experienced) who started treatment with GLM at 63 sites of Germany.

Conclusion: Treatment with GLM provided sustained improvement in WPAI and QoL in patients with RA, PsA and AS over the observational period of 24 months. All scores in the WPAI showed a significant (p<0.05) reduction in mean score values in each indication. GLM leads to an improvement of work productivity and daily activities in patients already within the first 3 months of treatment.

Table 1: WPAI - Changes in the 4 domain scores from baseline to Months 3, 12 and 24 (mITT)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Baseline</th>
<th>Month 3</th>
<th>Month 12</th>
<th>Month 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Productivity (on-the-job productivity)</td>
<td>52%</td>
<td>44%</td>
<td>36%</td>
<td>34%</td>
</tr>
<tr>
<td>Presenteeism</td>
<td>2%</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Activity impairment</td>
<td>18%</td>
<td>15%</td>
<td>12%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Disclosure of Interests: Ines Klaudius Employee of: MSD Sharp & Dohme GmbH, Klaus Krueger: None declared, Astrid Remstedt: None declared, Astrid Stiehe Consultant for: Biogen, Celgene, Chugai, Hexal, Janssen, Lilly, MSD, Novartis, Pfizer, UCB

as an ETN biosimilar. There is limited evidence on outcomes of transition from originator to biosimilar in a multi-country real-world setting.

**Objectives:** To provide real-world evidence on outcomes of transition from ETN to SB4 in routine clinical practice at EU sites.

**Methods:** Eligible patients had RA or axSpA and had initiated SB4 in routine clinical practice following a minimum of 6 months treatment with a stable dose of originator ETN, at clinics in France, Germany, Italy, and Spain. Data were captured from patient records prospectively and/or retrospectively for 6 months following transition. Outcome measures include clinical characteristics, disease scores (DAS-28 for RA, BASDAI) and clinical management.

**Results:** Analysis of 533 eligible patients (347 RA, 186 axSpA) demonstrated no clinically significant difference in disease score from baseline to 6 months post-transition; mean individual change was 0.0 (95% CI -0.3, 0.2) at 6 months post-transition in RA and axSpA subjects respectively. Regarding dose regimen, 73.5% and 63.4% of RA and axSpA subjects transitioned from ETN 50mg QW to SB4 50mg QW; by 6 months post-transition, 73.5% and 63.4% of subjects were receiving SB4 50mg QW.

**Disclosure of Interests:** Klaus Krueger: None declared, Carlo Selmi Shareholder of: Biogen, Employee of: Biogen International GmbH sponsored and funded this study.

**References:**
