Treatment Approach For Non-Hodgkin’s Lymphoma Patients Since First Biosimilars Of Rituximab Approved In EU5

Special Clinical Science Symposium: The Arrival of Biosimilars

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Rituximab (as monotherapy or in combination with other compounds) is the most frequently prescribed drug to treat and manage NHL patients.

February 2017: EMA approves the first mAb biosimilar of rituximab, Truxima™, followed by:

- Rixathon®
- Riximo®
- Blitzima® (CT-P10)
- Ritemvia® (CT-P10)
- Rituzena® (CT-P10)

*Rixathon and Riximo: same molecule, approved under two different names
*Blitzima, Ritemvia, Rituzena: same molecule, approved under different names
STUDY OBJECTIVE

Analysis of prescription patterns among main treaters of NHL patients to determine...

Potential shift from branded to mAb biosimilars

Clinical drivers of changes in prescribing:
are some patients perceived as more suitable for mAb biosimilars?
METHODOLOGY AND SAMPLE
STUDY METHODOLOGY AND SAMPLE

• METHODOLOGY: multi-centre medical chart study - physicians report online medical charts of NHL patients seen in consultation and treated with anti-cancer drug at the time of reporting

• PHYSICIAN SAMPLE: 97 physicians, personally responsible for prescribing anti-cancer drug treatment to NHL patients

• PATIENT SAMPLE: total of 640 medical charts of NHL patients, distributed in the following countries: France (117), Germany (73), Italy (117), Spain (136) and the UK (197)

• TIMEFRAME for data collection: July to September 2017
RESULTS
INITIAL UPTAKE OF BIOSIMILARS: GREATER IN GERMANY AND THE UK

- Among the 640 NHL patients reported in the EU5, 77% were reported as treated with a regimen including rituximab.
- Prescribing of rituximab biosimilars was highest in Germany and the UK (14% and 13% of patients versus branded version, respectively).

<table>
<thead>
<tr>
<th>Total EU5 countries</th>
<th>France</th>
<th>Germany</th>
<th>Italy</th>
<th>Spain</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=</td>
<td>640</td>
<td>117</td>
<td>73</td>
<td>117</td>
<td>136</td>
</tr>
<tr>
<td>TOTAL % OF PATIENTS CURRENTLY TREATED WITH RITUXIMAB (any regimen)</td>
<td>77%</td>
<td>68%</td>
<td>80%</td>
<td>78%</td>
<td>81%</td>
</tr>
<tr>
<td>Rituximab (BRANDED version)</td>
<td>70%</td>
<td>68%</td>
<td>66%</td>
<td>75%</td>
<td>76%</td>
</tr>
<tr>
<td>Rituximab (BIOSIMILAR version)</td>
<td>7%</td>
<td>0%</td>
<td>14%</td>
<td>3%</td>
<td>5%</td>
</tr>
</tbody>
</table>

n = all reported NHL patients receiving anti-cancer treatment, raw data

Alessandra Franceschetti
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HIGHER PRESCRIBING OF RITUXIMAB BIOSIMILARS POST FRONT LINE TREATMENTS

• In the UK and Germany, prescribing of rituximab biosimilars among patients recently initiated on their current line of anti-cancer drug therapy (i.e., within the 3 months prior to physician reporting) increases as the line of therapy progresses

<table>
<thead>
<tr>
<th>Regimens including rituximab BIOSIMILAR</th>
<th>% of patients</th>
<th>Regimens including rituximab BRANDED</th>
<th>% of patients</th>
<th>Other regimens not including rituximab</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>All NHL patients (n=174)</td>
<td>14%</td>
<td>73%</td>
<td>13%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st line (incl. Maint) N=110</td>
<td>11%*</td>
<td>81%</td>
<td>8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd line (incl. Maint) N=48</td>
<td>18%</td>
<td>65%</td>
<td>17%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd+ line N=16</td>
<td>30%*</td>
<td>44%</td>
<td>26%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Significantly different between 1st line and 3rd+ line at p<0.05

% of recently initiated patients (within 3 months) currently treated with regimens including / excluding rituximab biosimilar - Q3 2017 - UK and GERMANY

All NHL patients (n=174)
1st line (incl. Maint) N=110
2nd line (incl. Maint) N=48
3rd+ line N=16

n = all reported NHL patients receiving anti-cancer treatment, raw data
CLINICAL PROFILE OF PATIENTS TREATED WITH RITUXIMAB BRANDED VS. BIOSIMILAR (1 of 2)

- Compared to patients treated with a regimen including rituximab branded, those reported as being treated with a rituximab biosimilar are more likely to have ECOG 0-1 (93% vs. 82%) and not to have comorbidities affecting cancer drug treatment (52% vs. 31%).

Patient distribution by ECOG status - Q3 2017 - UK and DE

- **ECOG 2+**
  - Rituximab Branded (n=179): 82%
  - Rituximab Biosimilar (n=27): 93%
- **ECOG 0-1**
  - Rituximab Branded (n=179): 18%
  - Rituximab Biosimilar (n=27): 7%

Patient distribution by main comorbidities - Q3 2017 - UK and DE

- **NONE**
  - Rituximab Branded (n=179): 31%
  - Rituximab Biosimilar (n=27): 52%
- **Hypertension**
  - Rituximab Branded (n=179): 17%
  - Rituximab Biosimilar (n=27): 19%
- **CV disease**
  - Rituximab Branded (n=179): 15%
  - Rituximab Biosimilar (n=27): 19%
- **Pulmonary disorder**
  - Rituximab Branded (n=179): 13%
  - Rituximab Biosimilar (n=27): 0%
- **Thyroid disorder**
  - Rituximab Branded (n=179): 18%
  - Rituximab Biosimilar (n=27): 7%
- **Diabetes**
  - Rituximab Branded (n=179): 7%
  - Rituximab Biosimilar (n=27): 7%
- **Obesity**
  - Rituximab Branded (n=179): 7%
  - Rituximab Biosimilar (n=27): 0%

n = all reported NHL patients receiving anti-cancer treatment and with stated ECOG / comorbidities, raw data

* Significantly different between rituximab BRANDED vs. rituximab BIOSIMILAR at p<0.05
Compared to patients treated with a regimen including rituximab branded, those reported as being treated with a rituximab biosimilar are more likely to have indolent than aggressive NHL (70% vs. 52%) and to have Follicular Lymphoma as sub-type of NHL (56% vs. 35%).

<table>
<thead>
<tr>
<th></th>
<th>Rituximab BRANDED (n=177)</th>
<th>Rituximab BIOSIMILAR (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aggressive</td>
<td>52%*</td>
<td>30%*</td>
</tr>
<tr>
<td>Indolent</td>
<td>48%*</td>
<td>70%*</td>
</tr>
</tbody>
</table>

*Significantly different between rituximab BRANDED vs. rituximab BIOSIMILAR at p<0.05

- **Patient distribution by histology - Q3 2017 - UK and DE**

- **Patient distribution by NHL sub-type - Q3 2017 - UK and DE**

CONCLUSIONS
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Physicians responsible for the drug treatment of NHL patients in the EU5 have started to prescribe rituximab biosimilars.

Prescribing is higher in the UK and Germany, the two countries where, following EMA approval, commercialization has started first.

An analysis by treatment line shows prescribing of rituximab biosimilars in the UK and Germany is higher post front line treatments.

Patients in better overall health, with indolent histology and FL as subtype of NHL are more likely to be prescribed a rituximab biosimilar.
CONCLUSIONS

Physicians who start prescribing rituximab biosimilars seem to adopt a precautionary strategy, initiating the biosimilar in situations where potential side effects would be less debilitating, such as for patients in better overall health or requiring less intensive chemotherapy.

As level of experience increases over time, physicians might start prescribing biosimilars rather than the branded option more frequently; hence this analysis will be repeated in July/September 2018 and extended to additional indications where other mAb biosimilars have now been approved, but prescribing in the day-to-day clinical practice has not yet taken place.