Ublituximab versus Teriflunomide in Relapsing Multiple Sclerosis: Results of the Phase 3 ULTIMATE I and II Trials

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EAN Abstract #: A-21-00763
Ublituximab is a novel glycoengineered anti-CD20 mAb. It is a chimeric IgG1 antibody with a glycoengineered structure, whereas Rituximab and Ocrelizumab are chimeric and humanized IgG1 antibodies, respectively. Ofatumumab is a recombinant fully human IgG1 antibody.

**Regimen**
- **Ublituximab**: 150mg D1, 450mg D15, then 450mg every 24wk
- **Rituximab**: 1g D1 & D15, then 1g every 24wk
- **Ocrelizumab**: 300mg D1 & D15, then 600mg every 24wk
- **Ofatumumab**: 20mg every 4wk

**Route**
- Intravenous for all

**Infusion time**
- Ublituximab: 1 hr<br>***Initial infusion time over 4 hours***
- Rituximab: Not Approved for MS
- Ocrelizumab: 2 hrs<br>***Initial infusion time over 2.5 hours***
- Ofatumumab: Subcutaneous

**Primary MOA**
- **ADCC**
  - Ublituximab: ++++
  - Rituximab: ++
  - Ocrelizumab: +++
  - Ofatumumab: ++
- **CDC**
  - Ublituximab: +
  - Rituximab: ++
  - Ocrelizumab: ++
  - Ofatumumab: +++

Adapted from Ancau et al. 2019 and Sellebjerg et al. 2020. ADCC: antibody-dependent cellular cytotoxicity; ADCP: antibody-dependent cellular phagocytosis; CDC: complement-dependent cytotoxicity; D: day; MS: multiple sclerosis; wk: week.
ULTIMATE I & II: Study Design

Identical Phase 3, randomized, multi-center, double-blinded, active-controlled studies that were conducted in parallel

Screening

Population
- Age 18-55 years
- Diagnosis of MS per 2010 McDonald criteria
- Relapsing forms of MS: RRMS or SPMS with disease activity
- EDSS 0 – 5.5
- Neurologic stability ≥30 days prior to screening

Patients required to have:
- ≥ 2 documented relapses within the 2 years prior
- Or ≥1 relapse in the year prior
- And/or ≥ 1 Gd-enhancing lesion in the year prior to screening

Treatment Period

Teriflunomide
- 14 mg PO QD until last day of W95
- Infusion placebo on same schedule as below

Ublituximab
- 150 mg IV on D1, and 450 mg IV on D15, W24, W48, W72
- Oral placebo QD from D1 until last day of W95

Follow-up*

*After completing Week 96, patients entered into a 20-week safety follow-up and were eligible to enroll into an open-label extension study.

SPMS: Secondary Progressive Multiple Sclerosis; RRMS: Relapsing Remitting Multiple Sclerosis
**Objective:** To evaluate the efficacy and safety of ublituximab compared with teriflunomide in patients with relapsing multiple sclerosis

### By individual study

| Primary endpoint | Annualized relapse rate at 96 weeks  
(number of confirmed multiple sclerosis relapses in a year) |
|------------------|--------------------------------------------------------------------------------------------------|
| Key secondary endpoints | - Total number of Gd-enhancing T1 lesions by Week 96  
- Total number of new or enlarging T2 hyperintense lesions by Week 96  
- Proportion of subjects with NEDA from Week 24 to Week 96 |

### Pre-specified pooled analysis

<table>
<thead>
<tr>
<th>Key secondary endpoints</th>
<th>Time to CDP for at least 12 weeks</th>
</tr>
</thead>
</table>
| Tertiary analyses      | Time to CDP for at least 24 weeks  
Time to CDI for at least 12 weeks  
Time to CDI for at least 24 weeks |

ARR: annualized relapse rate; CDP: confirmed disability progression; CDI: confirmed disability improvement; Gd: gadolinium; NEDA: no evidence of disease activity.
**ULTIMATE I & II: Independent Global Studies**

- First patient first infusion: 22 September 2017
- Last patient first infusion: 04 October 2018
- 1094 patients were randomized across 106 sites in 10 countries

<table>
<thead>
<tr>
<th>Country</th>
<th>ULTIMATE I n (%)</th>
<th>ULTIMATE II n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belarus</td>
<td>64 (11.7)</td>
<td>64 (11.7)</td>
</tr>
<tr>
<td>Croatia</td>
<td>-</td>
<td>49 (9.0)</td>
</tr>
<tr>
<td>Georgia</td>
<td>83 (15.1)</td>
<td>-</td>
</tr>
<tr>
<td>Poland</td>
<td>41 (7.5)</td>
<td>77 (14.1)</td>
</tr>
<tr>
<td>Russia</td>
<td>133 (24.2)</td>
<td>163 (29.9)</td>
</tr>
<tr>
<td>Serbia</td>
<td>64 (11.7)</td>
<td>-</td>
</tr>
<tr>
<td>Spain</td>
<td>5 (0.9)</td>
<td>8 (1.5)</td>
</tr>
<tr>
<td>UK</td>
<td>4 (0.7)</td>
<td>5 (0.9)</td>
</tr>
<tr>
<td>Ukraine</td>
<td>107 (19.5)</td>
<td>143 (26.2)</td>
</tr>
<tr>
<td>USA</td>
<td>48 (8.7)</td>
<td>36 (6.6)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>549</strong></td>
<td><strong>545</strong></td>
</tr>
</tbody>
</table>

UK: United Kingdom; USA: United States of America
## Patient Disposition & Analysis Population

### ULTIMATE I

<table>
<thead>
<tr>
<th>Discontinued Treatment</th>
<th>Teriflunomide N = 275</th>
<th>*</th>
<th>Ublituximab N = 274</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td>1 (0.4)</td>
<td></td>
<td>17 (6.2)</td>
</tr>
<tr>
<td>Withdrawal of consent</td>
<td>15 (5.5)</td>
<td></td>
<td>6 (2.2)</td>
</tr>
<tr>
<td>Investigator decision</td>
<td>2 (0.7)</td>
<td></td>
<td>4 (1.5)</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>-</td>
<td></td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>2 (0.7)</td>
<td></td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Lack of efficacy</td>
<td>2 (0.7)</td>
<td></td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Others*</td>
<td>1 (0.4)</td>
<td></td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

### ULTIMATE II

<table>
<thead>
<tr>
<th>Discontinued Treatment</th>
<th>Teriflunomide N = 273</th>
<th>*</th>
<th>Ublituximab N = 272</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse event</td>
<td>1 (0.4)</td>
<td></td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Withdrawal of consent</td>
<td>23 (8.4)</td>
<td></td>
<td>23 (8.4)</td>
</tr>
<tr>
<td>Investigator decision</td>
<td>2 (0.7)</td>
<td></td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>-</td>
<td></td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>2 (0.7)</td>
<td></td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Lack of efficacy</td>
<td>2 (0.7)</td>
<td></td>
<td>4 (1.5)</td>
</tr>
<tr>
<td>Others*</td>
<td>1 (0.4)</td>
<td></td>
<td>3 (1.1)</td>
</tr>
</tbody>
</table>

### Completed Treatment

<table>
<thead>
<tr>
<th>Teriflunomide N = 275</th>
<th>Ublituximab N = 274</th>
</tr>
</thead>
<tbody>
<tr>
<td>252 (91.6)</td>
<td>240 (87.6)</td>
</tr>
<tr>
<td>239 (87.5)</td>
<td>254 (93.4)</td>
</tr>
</tbody>
</table>

*Data represented as n (%). *Others include: alternative treatment and COVID-19.*
## Patient Demographics & Baseline Characteristics

**ULTIMATE I & II populations are consistent and poolable**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Teriflunomide N = 274</th>
<th>Ublituximab N = 271</th>
<th>Teriflunomide N = 272</th>
<th>Ublituximab N = 272</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± standard deviation or n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>37.0 ± 9.63</td>
<td>36.2 ± 8.24</td>
<td>36.2 ± 8.96</td>
<td>34.5 ± 8.76</td>
</tr>
<tr>
<td>Sex, Female, n (%)</td>
<td>179 (65.3)</td>
<td>166 (61.3)</td>
<td>176 (64.7)</td>
<td>178 (65.4)</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>266 (97.1)</td>
<td>264 (97.4)</td>
<td>268 (98.5)</td>
<td>269 (98.9)</td>
</tr>
<tr>
<td>African American</td>
<td>6 (2.2)</td>
<td>6 (2.2)</td>
<td>3 (1.1)</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>Type of MS, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapsing Remitting</td>
<td>270 (98.5)</td>
<td>264 (97.4)</td>
<td>267 (98.2)</td>
<td>268 (98.5)</td>
</tr>
<tr>
<td>Secondary Progressive</td>
<td>4 (1.5)</td>
<td>7 (2.6)</td>
<td>5 (1.8)</td>
<td>4 (1.5)</td>
</tr>
<tr>
<td>Duration of MS since first symptoms, years</td>
<td>6.81 ± 5.89</td>
<td>7.52 ± 6.48</td>
<td>7.39 ± 6.26</td>
<td>7.31 ± 6.52</td>
</tr>
<tr>
<td>Previously untreated*, n (%)</td>
<td>162 (59.1)</td>
<td>162 (59.8)</td>
<td>155 (57.0)</td>
<td>138 (50.7)</td>
</tr>
<tr>
<td>Number of relapses in last 12 months</td>
<td>1.4 ± 0.67</td>
<td>1.3 ± 0.65</td>
<td>1.2 ± 0.65</td>
<td>1.3 ± 0.65</td>
</tr>
<tr>
<td>Number of relapses in last 24 months</td>
<td>2.0 ± 1.11</td>
<td>1.8 ± 0.96</td>
<td>1.8 ± 0.92</td>
<td>1.8 ± 0.94</td>
</tr>
<tr>
<td>EDSS at screening</td>
<td>2.89 ± 1.17</td>
<td>2.96 ± 1.21</td>
<td>2.96 ± 1.20</td>
<td>2.80 ± 1.31</td>
</tr>
<tr>
<td>T2 lesion volume, cm³</td>
<td>14.9 ± 15.8</td>
<td>15.9 ± 16.0</td>
<td>15.7 ± 17.5</td>
<td>14.7 ± 13.5</td>
</tr>
<tr>
<td>Number of T2 lesions</td>
<td>60.4 ± 37.01</td>
<td>64.1 ± 38.59</td>
<td>64.0 ± 41.23</td>
<td>65.3 ± 41.23</td>
</tr>
<tr>
<td>Patients free of Gd+ T1 lesions, n (%)</td>
<td>156 (57.4)</td>
<td>153 (56.7)</td>
<td>135 (50.0)</td>
<td>131 (48.2)</td>
</tr>
<tr>
<td>Number of Gd+ T1 lesions at baseline</td>
<td>1.6 ± 3.67</td>
<td>2.3 ± 5.47</td>
<td>2.5 ± 5.47</td>
<td>2.6 ± 5.77</td>
</tr>
</tbody>
</table>

Modified Intent-to-Treat population: All patients in the ITT population who received at least one dose of study drug and had at least one baseline and post-baseline efficacy assessment. *Untreated with disease-modifying therapy in 5 years prior to study entry. DMT: disease-modifying therapy; EDSS: expanded disability status scale; Gd+: gadolinium-enhancing; MS: multiple sclerosis.
Primary Endpoint: Annualized Relapse Rate (ARR)

ULTIMATE I

ARR ratio (95% CI): 0.406 (0.268, 0.615)

- Teriflunomide: N = 274
- Ublituximab: N = 271

Relative reduction: 60%
p < 0.0001

ULTIMATE II

ARR ratio (95% CI): 0.509 (0.330, 0.784)

- Teriflunomide: N = 272
- Ublituximab: N = 272

Relative reduction: 49%
p = 0.0022

The modified Intention-to-Treat (mITT) population consists of all subjects in the ITT population who received at least one dose of study medication and had at least one baseline and post-baseline efficacy assessment. Based on negative binomial model (GEE) for the relapse count per subject with logarithmic link function, treatment, region, and baseline EDSS strata as covariates and log (years of treatment) as offset. CI: confidence interval.
MRI: Total Number of Gd + T1 Lesions

**ULTIMATE I**

- **Teriflunomide**
  - N = 270
  - Number of Gd+ T1 lesions: 0.491
- **Ublituximab**
  - N = 265
  - Number of Gd+ T1 lesions: 0.016

**97% Relative reduction**  
**p < 0.0001**

**Rate ratio (95% CI): 0.033 (0.019, 0.058)**

**ULTIMATE II**

- **Teriflunomide**
  - N = 267
  - Number of Gd+ T1 lesions: 0.250
- **Ublituximab**
  - N = 272
  - Number of Gd+ T1 lesions: 0.009

**96% Relative reduction**  
**p < 0.0001**

**Rate ratio (95% CI): 0.035 (0.019, 0.064)**

The modified Intention-to-Treat MRI (mITT-MRI) population consists of all subjects in the ITT population who received at least one dose of study medication, had at least one baseline and post-baseline efficacy assessment, and had at least one baseline and post-baseline MRI efficacy assessment. Based on negative binomial model (GEE) with logarithmic link function, covariates treatment, region, baseline EDSS strata, baseline number of lesions (0/>=1) and an offset based on the log-transformed number of post-baseline MRI scans. MRI assessed by Independent Review.
MRI: Number of New or Enlarging T2 Lesions

The modified Intention-to-Treat MRI (mITT-MRI) population consists of all subjects in the ITT population who received at least one dose of study medication, had at least one baseline and post-baseline efficacy assessment, and had at least one baseline and post-baseline MRI efficacy assessment. Based on negative binomial model (GEE) with logarithmic link function, covariates treatment, region, baseline EDSS strata, baseline number of lesions (0/>=1) and an offset based on the log-transformed number of post-baseline MRI scans. MRI assessed by Independent Review.
Confirmed Disability Progression (CDP)

Pre-specified pooled analysis

12-week CDP

Hazard ratio (95% CI): 0.843 (0.504, 1.407); \( p = 0.5099 \)

24-week CDP

Hazard ratio (95% CI): 0.657 (0.358, 1.205); \( p = 0.1716 \)

The modified Intention-to-Treat (mITT) population consists of all subjects in the ITT population who received at least one dose of study medication and had at least one baseline and post-baseline efficacy assessment. Hazard ratio is estimated using Cox regression model with treatment group as covariate stratified by region, baseline EDSS and study. \( P \)-value is from stratified log-rank test. UTX: ublituximab; Teri: teriflunomide.
Confirmed Disability Improvement (CDI)
Pre-specified pooled tertiary analysis

12-week CDI

- **116%**
  - Increased chance vs teriflunomide
  - p = 0.0003
  - Hazard ratio (95% CI): 2.158 (1.406, 3.313)

24-week CDI

- **103%**
  - Increased chance vs teriflunomide
  - p = 0.0026
  - Hazard ratio (95% CI): 2.031 (1.269, 3.248)

The modified Intention-to-Treat (mITT) population consists of all subjects in the ITT population who received at least one dose of study medication and had at least one baseline and post-baseline efficacy assessment. Hazard ratio is estimated using Cox regression model with treatment group as covariate stratified by region, baseline EDSS and study. P-value is from stratified log-rank test. UTX: ublituximab; Teri: teriflunomide

Percent increased chance based on hazard ratio
No Evidence of Disease Activity (NEDA)

**ULTIMATE I**

- **Teriflunomide**
  - N = 274
  - 15.0% Improvement vs teriflunomide
  - p < 0.0001
- **Ublituximab**
  - N = 271
  - 44.6% Improvement vs teriflunomide
  - p < 0.0001

**ULTIMATE II**

- **Teriflunomide**
  - N = 272
  - 11.4% Improvement vs teriflunomide
  - p < 0.0001
- **Ublituximab**
  - N = 272
  - 43.0% Improvement vs teriflunomide
  - p < 0.0001

Odds ratio (95% CI): 5.442 (3.536, 8.375)

The modified Intention-to-Treat (mITT) population consists of all subjects in the ITT population who received at least one dose of study medication and had at least one baseline and post-baseline efficacy assessment. Logistic regression model with covariates treatment, region, baseline EDSS strata and log transformed baseline MRI counts (T1 unenhancing, T2, Gd enhancing).
## Adverse Events

### Most common AEs, n (%) ≥5% in any treatment group

<table>
<thead>
<tr>
<th></th>
<th>Teriflunomide</th>
<th>Ublituximab</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=548</td>
<td>N=545</td>
</tr>
<tr>
<td>Any AE</td>
<td>486 (88.7)</td>
<td>483 (88.6)</td>
</tr>
<tr>
<td>IRR</td>
<td>67 (12.2)</td>
<td>260 (47.7)</td>
</tr>
<tr>
<td>Headache</td>
<td>138 (25.2)</td>
<td>165 (30.3)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>96 (17.5)</td>
<td>97 (17.8)</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>5 (0.9)</td>
<td>51 (9.4)</td>
</tr>
<tr>
<td>Back pain</td>
<td>53 (9.7)</td>
<td>48 (8.8)</td>
</tr>
<tr>
<td>Respiratory tract infection viral</td>
<td>31 (5.7)</td>
<td>41 (7.5)</td>
</tr>
<tr>
<td>Respiratory tract infection</td>
<td>38 (6.9)</td>
<td>40 (7.3)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>33 (6.0)</td>
<td>39 (7.2)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>53 (9.7)</td>
<td>36 (6.6)</td>
</tr>
<tr>
<td>Lymphocyte count decreased</td>
<td>9 (1.6)</td>
<td>34 (6.2)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>17 (3.1)</td>
<td>32 (5.9)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>11 (2.0)</td>
<td>31 (5.7)</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>23 (4.2)</td>
<td>30 (5.5)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>16 (2.9)</td>
<td>28 (5.1)</td>
</tr>
<tr>
<td>Nausea</td>
<td>26 (4.7)</td>
<td>28 (5.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>35 (6.4)</td>
<td>19 (3.5)</td>
</tr>
<tr>
<td>Alopecia</td>
<td>84 (15.3)</td>
<td>18 (3.3)</td>
</tr>
</tbody>
</table>

AE: adverse event. IRR: Infusion-related reaction. IRR includes AEs designated as IRR in the CRF. AEs included within IRR are not included in individual preferred terms.
Serious Adverse Events

### SAEs, n (%)

<table>
<thead>
<tr>
<th></th>
<th>Teriflunomide N = 548</th>
<th>Ublituximab N = 545</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any serious AEs</td>
<td>34 (6.2)</td>
<td>52 (9.5)</td>
</tr>
</tbody>
</table>

### Most common SAEs by SOC

- **Infections and infestations**: 14 (2.6) vs. 22 (4.0)
- **Nervous system disorders**: 7 (1.3) vs. 5 (0.9)

- Three total malignancies were reported
  - 2 ublituximab (endometrial, uterine) versus teriflunomide 1 (tongue)

- Three total deaths occurred
  - Ublituximab: pneumonia, encephalitis (post-measles), salpingitis
  - 1 death was deemed possibly related to treatment (pneumonia)

- No cases of progressive multifocal leukoencephalopathy (PML)

SAE: serious adverse event; SOC: system organ class
Infusion Related Reactions by Dose & Severity

- IRRs were most frequent on the 1st dose: 43% in the ublituximab group and 9.7% in the teriflunomide group (placebo infusion) reported an IRR on Day 1.
- Most IRRs were mild to moderate and decreased in frequency with subsequent dosing.
- Three subjects (0.6%) discontinued ublituximab due to an IRR following the first dose, which included a myocardial ischemia deemed unrelated to treatment.

**Patients with IRR (%)**

- **Teriflunomide**
  - Grade 4
  - Grade 3
  - Grade 2
  - Grade 1

- **Ublituximab**

**N at risk**

- **Week**
  - Teri: 548, 545, 529, 512, 503
  - UTX: 545, 540, 531, 520, 508

IRR: infusion related reaction; Teri: teriflunomide; UTX: ublituximab.
Proportion of Patients With Ig Levels <LLN

**IgM**
- Baseline: 2.4%
- Week 48: 12.8%
- Week 96: 20.9%

**IgG**
- Baseline: 5.9%
- Week 48: 6.3%
- Week 96: 6.4%

**IgA**
- Baseline: 4.9%
- Week 48: 6.5%
- Week 96: 1.1%

**LLN Threshold**
- Age < 20: 0.61 g/L
- Age ≥ 20: 0.7 g/L

**Baseline**
- Teriflunomide: 4.6 g/L
- Ublituximab: 4.9 g/L

**Week 48**
- Teriflunomide: 5.9 g/L
- Ublituximab: 6.3 g/L

**Week 96**
- Teriflunomide: 6.4 g/L
- Ublituximab: 5.3 g/L

**LLN Threshold**
- Age < 20: 5.49 g/L
- Age ≥ 20: 7.0 g/L

**LLN Threshold**
- Age < 20: 0.23 g/L
- Age ≥ 20: 0.4 g/L

LLN: Lower Limit of Normal
Conclusions

- In the Phase III ULTIMATE I & II studies, ublituximab significantly reduced ARR and MRI parameters compared with teriflunomide
- A very low rate of disability progression was observed with ublituximab, with >94% of patients showing no 12-week CDP, and >96% of patients showing no 24-week CDP, although neither was statistically different from teriflunomide
- In a pre-specified pooled tertiary analysis, ublituximab increased the proportion of patients with 12-week CDI and 24-week CDI
- A significantly higher percentage of patients treated with ublituximab compared with teriflunomide achieved NEDA
- Ublituximab exhibited a favorable safety and tolerability profile with no unexpected safety signals
- These data are being prepared for a Biological License Application

In ULTIMATE I & ULTIMATE II, ublituximab, a one-hour infusion, demonstrated robust efficacy and a favorable safety profile that benefited RMS patients