Kesimpta® US Approval Investor Call
August 21, 2020
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Victor Bulto, Head of Novartis Pharma US

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Q&A
Samir Shah, Global Head Investor Relations
Overview and MS portfolio

Marie-France Tschudin
President of Novartis Pharmaceuticals
Novartis has proven innovation, infrastructure and deep understanding of customer needs in MS

Proven innovation track record

1. Mayzent® is now approved in 37 countries, launched in 5 countries including US, Germany & Canada.
2. Approved in US.

Gilenya®
First high efficacy oral DMT & first approved in pediatrics

Mayzent®
First oral DMT studied and proven in active SPMS

Kesimpta®
First choice DMT combining B-cell efficacy with favorable safety profile and the flexibility of self administration

1. Mayzent® is now approved in 37 countries, launched in 5 countries including US, Germany & Canada.
2. Approved in US.
Over 700k people living with RMS in major markets; frequent switching among classes and brands

MS patient population (2019)

US

- 415k MS diagnosed
- 312k RMS diagnosed (75%)
- 235k RMS treated (76%)

EU5

- 566k MS diagnosed
- 420k RMS diagnosed (76%)
- 320k RMS treated (74%)

Sources: Calculated based on actual IQVIA SU data validated through DRG Epi database and secondary research. RMS includes CIS, RRMS, aSPMS.
BRACE and first-line orals commonly used in early stages, reserving high efficacy DMTs* for later...

Use of disease-modifying treatments in MS¹

<table>
<thead>
<tr>
<th>1st line</th>
<th>2nd line</th>
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</thead>
<tbody>
<tr>
<td>US</td>
<td>EU</td>
<td>US</td>
</tr>
<tr>
<td>mAbs</td>
<td>High-efficacy orals</td>
<td>BRACE &amp; First-line orals</td>
</tr>
<tr>
<td>13%</td>
<td>7%</td>
<td>16%</td>
</tr>
<tr>
<td>77%</td>
<td>78%</td>
<td>16%</td>
</tr>
<tr>
<td>16%</td>
<td>33%</td>
<td>29%</td>
</tr>
<tr>
<td>10%</td>
<td>10%</td>
<td>11%</td>
</tr>
</tbody>
</table>

WW market volume by delivery type²

- **Infusions**: 21%
- **Orals**: 44%
- **BRACE/ injectables**: 35%

**MAbs**: Ocrevus®, Lemtrada®, Tysabri®; **High-efficacy orals**: Gilenya®, Mayzent®, Mavenclad®; **BRACE & First-line orals**: Interferons, Copaxone®, GA Gx, Tecfidera®, Aubagio®; *High efficacy DMTs may include orals and MAbs*

1. Symphony APLD (Sep 2018-Aug 2019). EU5 IPSOS Monitor 2019. 2. MS Market = BRACE + Orals + MAbs; Volume = Standard Units converted to days of therapy (DOT); DOT normalizes dosing schedules to be comparable for different therapies. Source: IQVIA PADDS, MAT Feb 2020.
...despite data showing high-efficacy treatments, started early, result in better outcomes...

Cumulative hazard of CDP in patients with RRMS treated from disease onset versus late with high-efficacy treatment

Benefits of early use of high-efficacy treatment

- Lower risk of progressing to EDSS ≥6
- Slower EDSS progression
- Lower risk of progression to SPMS
- Higher work attendance & productivity

1. He A et al. Lancet Neurol. 2020;19(4):307–316. Retrospective analysis, measured from disease onset. Bold lines are cumulative hazard estimates and shaded areas are 95% CIs. CDP, confirmed disability progression; CI, confidence interval; HR, hazard ratio; RMS, relapsing multiple sclerosis.
...thus need for high efficacy treatment that balances safety, convenience and has easier access

Even with all DMTs available to patients today, 44% of people with MS aren’t satisfied with today’s treatments¹,²,³

Due to:

Lack of efficacy
Side-effects/ tolerability issues
Treatment burden
Direct costs of treatments and testing
Indirect costs of time commitments

44% not satisfied

Resulting in frequent switching (2019)¹,⁴

<table>
<thead>
<tr>
<th></th>
<th>US</th>
<th>EU5</th>
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</thead>
<tbody>
<tr>
<td>Stable / continuing</td>
<td>72%</td>
<td>56%</td>
</tr>
<tr>
<td>Dynamic (includes naive &amp; switch patients)</td>
<td>28%</td>
<td>44%</td>
</tr>
</tbody>
</table>

1. EU5 IPSOS Monitor Q4 2019 (Patients dissatisfied with current Oral, Injectables, and IV medications).  
3. MS Patient Journey research 2019.  
4. US Symphony APLD data 2019
Kesimpta® has the potential to become 1st choice, high efficacy DMT for patients, physicians and payers

For patients who want
High efficacy without treatment burden impacting their lives
Flexibility of at-home self-administration

For physicians who want
High efficacy that balances safety
An easily administered, subcutaneous solution requiring no premedication
To avoid reliance on infusion infrastructure

For payers who want
High efficacy at a price that enables broad access
An at-home treatment with no added medical costs
Launches are on track in major markets across the globe

Selected Kesimpta® submissions

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
<th>Approval Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>MAA validated</td>
<td>FDA approval August 2020</td>
</tr>
<tr>
<td>EU</td>
<td>CHMP opinion expected H1 2021/ Approval expected H1 2021</td>
<td>Parallel submission for joint review (ACSS* consortium)</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Swissmedic approval expected H1 2021</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>TGA approval expected H1 2021</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>Health Canada approval expected H1 2021</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>PMDA approval expected H1 2021</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>China FDA approval expected H2 2021</td>
<td></td>
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</tbody>
</table>

Kesimpta®
data and label

Norman Putzki
Head of Global Drug Development Neuroscience
Kesimpta® was designed to address the needs of people living with MS

Unique mode of binding and s.c. dosing delivering high efficacy

Precise B-cell depletion in the lymph nodes, sparing the spleen, helps maintain immune function

Flexibility of once-monthly, at-home self-administration delivered through a Sensoready® pen
Monthly dosing regimen results in rapid and sustained depletion of B-cells in all body weights

Regardless of body weight, the median B-cell counts reduced rapidly with ofatumumab and were sustained at 0 cells / μL up to Week 96.

Median B-cell counts over 96 weeks in subgroups by quartiles of baseline body weight

Source: Modified from Hauser et al., AAN 2020, B-cell Depletion and Efficacy Outcomes with Ofatumumab: Subgroup Analysis from the Pooled Phase 3 ASCLEPIOS I and II Trials; P7.1-013.
Kesimpta® demonstrated up to nearly 60% reduction in relapses (ARR) vs teriflunomide

Full analysis set. Primary endpoint. *Negative binomial regression model. N, Total number of patients included in the analysis. ARR, annualised relapse rate; CI, confidence interval

Source: Kappos et al., AAN 2020, Versus Teriflunomide in Patients with Relapsing Multiple Sclerosis: Phase 3 ASCLEPIOS I and II Trials
Kesimpta® significantly reduced acute focal MRI activity and burden of T2 lesions vs. teriflunomide

Number of Gd+ T1 lesions per scan

<table>
<thead>
<tr>
<th>ASCLEPIOS I</th>
<th>0.452</th>
<th>0.0115</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teriflunomide (N=422)</td>
<td>Ofatumumab (N=432)</td>
<td></td>
</tr>
<tr>
<td>97.5% relative reduction, p&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASCLEPIOS II</th>
<th>0.514</th>
<th>0.032</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teriflunomide (N=434)</td>
<td>Ofatumumab (N=439)</td>
<td></td>
</tr>
<tr>
<td>93.8% relative reduction, p&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of new / enlarging T2 lesions per year

<table>
<thead>
<tr>
<th>ASCLEPIOS I</th>
<th>4.00</th>
<th>0.72</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teriflunomide (N=431)</td>
<td>Ofatumumab (N=440)</td>
<td></td>
</tr>
<tr>
<td>82.0% relative reduction, p&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASCLEPIOS II</th>
<th>4.15</th>
<th>0.64</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teriflunomide (N=443)</td>
<td>Ofatumumab (N=448)</td>
<td></td>
</tr>
<tr>
<td>84.5% relative reduction, p&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Kappos et al., AAN 2020, Versus Teriflunomide in Patients with Relapsing Multiple Sclerosis: Phase 3 ASCLEPIOS I and II Trials
Kesimpta® showed 37% and 46% reductions in 12 and 24-week CDW¹ vs teriflunomide

1. CDW = Confirmed Disability Worsening.  2. Post-hoc analysis with revised definition, adapted from the OPERA trials, Hauser et al. 2017. A disability “progression” was defined as an increase from the baseline EDSS score of at least 1.0 point (or 0.5 points if the baseline EDSS score was >5.5) that was sustained for at least 12 (24) weeks.

12-week CDW²

<table>
<thead>
<tr>
<th>Risk reduction</th>
<th>Hazard ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>36.6%</td>
<td>0.634 (0.472; 0.851)</td>
</tr>
</tbody>
</table>

24-week CDW²

<table>
<thead>
<tr>
<th>Risk reduction</th>
<th>Hazard ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>45.9%</td>
<td>0.541 (0.381; 0.768)</td>
</tr>
</tbody>
</table>

Risk reduction

12-week CDW²: 13.3% 9.6%

24-week CDW²: 10.5% 5.6%

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9/10 patients had no evidence of disease activity (NEDA-3) in the second year in a post hoc analysis

OR (95% CI): 3.64 (2.87; 4.61); p<0.001
OR (95% CI): 3.36 (2.67; 4.21); p<0.001
OR (95% CI): 8.09 (6.26; 10.45); p<0.001

CI, confidence interval; M, Month; N', number of patients in each group; NEDA-3, no evidence of disease activity.
## Favorable overall safety profile

### ASCLEPIOS I

<table>
<thead>
<tr>
<th>Variable</th>
<th>Ofatumumab (N = 465)</th>
<th>Teriflunomide (N = 462)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All events†*, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any adverse event</td>
<td>382 (82.2)</td>
<td>380 (82.3)</td>
</tr>
<tr>
<td>Adverse events leading to treatment discontinuation</td>
<td>27 (5.8)</td>
<td>24 (5.2)</td>
</tr>
<tr>
<td>Infections</td>
<td>229 (49.2)</td>
<td>238 (51.5)</td>
</tr>
<tr>
<td>Injection-related reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection-related systemic reactions‡</td>
<td>75 (16.1)</td>
<td>76 (16.5)</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>48 (10.3)</td>
<td>38 (8.2)</td>
</tr>
<tr>
<td>Serious infections</td>
<td>12 (2.6)</td>
<td>7 (1.5)</td>
</tr>
<tr>
<td>Serious injection-related reactions</td>
<td>2 (0.4)</td>
<td>0</td>
</tr>
<tr>
<td>Malignancies</td>
<td>3 (0.6)</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### ASCLEPIOS II

<table>
<thead>
<tr>
<th>Variable</th>
<th>Ofatumumab (N = 481)</th>
<th>Teriflunomide (N = 474)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All events†*, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any adverse event</td>
<td>409 (85.0)</td>
<td>408 (86.1)</td>
</tr>
<tr>
<td>Adverse events leading to treatment discontinuation</td>
<td>27 (5.6)</td>
<td>25 (5.3)</td>
</tr>
<tr>
<td>Infections</td>
<td>259 (53.8)</td>
<td>255 (53.8)</td>
</tr>
<tr>
<td>Injection-related reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection-related systemic reactions‡</td>
<td>116 (24.1)</td>
<td>64 (13.5)</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>38 (7.9)</td>
<td>36 (7.6)</td>
</tr>
<tr>
<td>Serious infections</td>
<td>12 (2.5)</td>
<td>10 (2.1)</td>
</tr>
<tr>
<td>Serious injection-related reactions</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Malignancies</td>
<td>2 (0.4)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>1 (0.2)</td>
</tr>
</tbody>
</table>

* Adverse events were coded according to the preferred terms in the Medical Dictionary for Regulatory Activities, version 20.0.  
† Excluding multiple sclerosis relapses that were reported as adverse events.  
‡ Only reactions/symptoms occurring within 24 hours after injection are included (i.e. time to onset of reaction ≤24 hours).
No increase in overall infections supported by preserved IgG levels at 96 weeks

Proportion of patients (%) with immunoglobulin levels below LLN at Week 96

A notable low IgM level was defined as a level that is 10% below LLN. A notable low IgG level was defined as a level that is 20% below LLN. LLN, lower limit of normal.

No impact on IgG levels after 96 weeks: could lead to fewer treatment interruptions

Low impact on IgM: few patients achieving notably low levels of IgM

Source: de Seze et al., EAN 2020, Effect of Ofatumumab on Serum Immunoglobulin Levels and Infection Risk in Relapsing Multiple Sclerosis Patients from the Phase 3 ASCLEPIOS I and II Trials; LB82.
**FDA approved Kesimpta® with a broad RMS label**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Kesimpta® is for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults</th>
</tr>
</thead>
</table>
| Posology   | - 20 mg/0.4 mL solution in a single-dose pre-filled Sensoready® pen  
- Initial dose: 20 mg administered at Week 0, 1, and 2  
- Subsequent doses: 20 mg administered monthly starting at Week 4 |
| Clinical   | All results compared to teriflunomide 14mg once daily  
- Significant reduction in the annualized relapse rate of 50.5% and 58.5%  
- Significantly reduced the risk of 3-month CDP (-34.4%)*  
- Significantly reduced the number of Gd-enhancing T1 lesions and rate of new or enlarging T2 lesions  
- Significant and consistent reduction in serum NFL levels from first assessment at month 3 |
| Safety     | - The proportion of patients with infections was similar in both treatment groups  
- Systemic injection-related reactions occurred predominantly within 24 hours of the first injection.  
- Injection-site reaction (local) symptoms were low in frequency and severity for all injections. |
| Treatment initiation | - The first injection of Kesimpta® should be performed under the guidance of an HCP  
- Prior to initiating Kesimpta®, perform Hepatitis B virus (HBV) screening and testing for quantitative serum immunoglobulins  
- Monitoring and use of premedication is not required |

*Pre-specified analysis part of the ASCLEPIOS studies. Different from slide 18 which is a post-hoc analysis based on criteria used in the OPERA studies to enable comparison to ocrelizumab.
US market and launch readiness

Victor Bulto
Head of Novartis Pharma US
Kesimpta® has the potential to become 1st choice for RMS patients and treating physicians

**Powerful efficacy**
- Patients treated with Kesimpta® experienced on average only 1 relapse every 10 patient-years¹
- 9/10 patients had no evidence of disease activity (NEDA-3) in year 2 in post hoc analysis²

**Targeted & precise regimen**
Favorable safety and convenience

- Rapid and sustained B-cell depletion in lymph nodes sparing the spleen

**Flexibility**

- Improved convenience – at home self-administration unlocks potential 1L use with a more readily available b-cell treatment
- Improved productivity – eliminates need for appointments, travel and time away from home or work associated with infusions

**Favorable economics & budget predictability**

- Kesimpta® is one of the lowest cost* branded DMTs in the US
- No added real-world costs and mark-ups associated with infusions

High efficacy therapies increasing market share in US, opportunity for further penetration remains

US MS market value¹
USD billion, %

<table>
<thead>
<tr>
<th>Year</th>
<th>High-efficacy therapies</th>
<th>Other therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>~12</td>
<td>18%</td>
</tr>
<tr>
<td>2015</td>
<td>~13.3</td>
<td>21%</td>
</tr>
<tr>
<td>2016</td>
<td>~14.5</td>
<td>21%</td>
</tr>
<tr>
<td>2017</td>
<td>~15.2</td>
<td>26%</td>
</tr>
<tr>
<td>2018</td>
<td>~14.7</td>
<td>35%</td>
</tr>
<tr>
<td>2019</td>
<td>~14.6</td>
<td>42%</td>
</tr>
</tbody>
</table>

The US MS market has grown to USD 15bn
Shifting from lower to higher efficacy therapies
Compromise of safety, convenience and access has held back greater adoption
B-Cell therapies expected to drive further expansion of high-efficacy share

¹. Evaluate Pharma, net sales. High efficacy therapies include Gilenya®, Mayzent®, Mavenclad®/Lemtrada®, Ocrevus®, Tysabri®, Zeposia®. Other therapies include: Interferons, Copaxone®, Gx GA, Aubagio®, Tecfidera®, Vumerity®.
Potential to improve outcomes for patients on lower efficacy therapy, particularly in 1st line or 1st switch

US MS patient share

<table>
<thead>
<tr>
<th>Line</th>
<th>Patients</th>
<th>MAbs</th>
<th>High-efficacy orals</th>
<th>BRACE &amp; First-line orals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st line</td>
<td>13%</td>
<td>10%</td>
<td>77%</td>
<td></td>
</tr>
<tr>
<td>2nd line</td>
<td>16%</td>
<td>10%</td>
<td>74%</td>
<td></td>
</tr>
<tr>
<td>3rd line</td>
<td>29%</td>
<td>11%</td>
<td>60%</td>
<td></td>
</tr>
</tbody>
</table>

Early high efficacy approach can lead to better outcomes but limited today by

- Safety concerns
- Type of administration
- Infrastructure requirements for infusions

3/4 first line patients & first switch patients are treated with lower efficacy approaches

MAbs: Ocrevus®, Lemtrada®, Tysabri®; High-efficacy orals: Gilenya®, Mayzent®, Mavenclad®; BRACE & First-line orals: Interferons, Copaxone®, GA Gx, Tecfidera®, Aubagio®

**Kesimpta® addresses patient’s preferences delivering high efficacy with fast and simple initiation**

### Patient preference

- Increasing awareness of benefits of high-efficacy therapy to reduce progression
- Preference for at-home administration and maximum independence

### Fast and simple initiation

- Simple blood test recommended prior to initiation
- No pre-medication required
- Like other SC therapies, 1st administration under HCP guidance
- Ship to patient home

### Flexible at home self-administration

- Once-monthly at home self-administration
- Takes 3-4 seconds
- Same auto-injector as Cosentyx®

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1. IPSOS, Multiple Sclerosis Syndicated Patient Community: Treatment discussions, 2019.  
Flexibility, predictability and speed are important attributes for customers in patient’s journey

**Flexibility**
- Give practices and patients choice
  - Fully electronic initiation
  - Broad SP or Hub patient initiation
  - Ship to patient’s home

**Predictability**
- Transparency and consistency at each step
  - Visibility to first-initiation steps and payer approval status
  - Purposeful touchpoints with choice of modalities (website, text, phone call)

**Speed**
- Keep it simple
  - Streamlined and parallel pathed first-initiation steps
  - Bridge program for commercially insured patients
  - In-office samples
Kesimpta® is one of the lowest cost branded DMTs available in the US, for people with RMS

Kesimpta® is competitively priced to reflect its unique value and ensure broad access

<table>
<thead>
<tr>
<th>Branded DMTs self-administered annual maintenance WAC price range ($USD)</th>
<th>Branded DMTs administered through infusions annual maintenance WAC price range ($USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>114,000</td>
<td>93,000</td>
</tr>
<tr>
<td>83,000</td>
<td>Kesimpta®</td>
</tr>
<tr>
<td>77,000</td>
<td>65,000</td>
</tr>
</tbody>
</table>

• Kesimpta® delivers high efficacy
  – Patients treated with Kesimpta® experienced on average only 1 relapse every 10 patient-years³
  – Annual total cost of care is significantly higher when compared to the patients without relapse¹*

• Kesimpta® has no added real-world costs and mark-ups associated with infusions²

Ready to launch, pioneering an adaptive, hybrid approach

**HCPs**
F2F engagement may be limited

- **Adaptive digital and field force engagement**
  - Amplified non personal promotion via novel social media platforms
  - AI* engine enables rapid adaptation of content and promotional mix by HCP

**Patients**
seek tailored education

- **Dynamic and customized content**
  - Advanced analytics to identify patients at key decision making windows
  - Educational content tailored to their personal point in the MS journey

**Patient Support Service**
addressing heterogeneous needs

- **Seamless, predictable and swift patient starts**
  - Flexible first-initiation to address varying office preferences, including fully electronic initiation
  - Portal with transparent view along the patient journey

*Artificial intelligence*
Concluding remarks

Marie-France Tschudin
President of Novartis Pharmaceuticals
Kesimpta® has the potential to become 1st choice for RMS patients, physicians and payers

- **Powerful efficacy**
  - Patients treated with Kesimpta® experienced on average only 1 relapse every 10 patient-years
  - 9/10 patients had no evidence of disease activity (NEDA-3) in year 2 in post hoc analysis

- **FDA broad label**
  - Confirming high efficacy with favorable safety/ tolerability, infection rates similar to teriflunomide with rapid/sustained B-cell depletion in lymph nodes sparing the spleen
  - At-home self-administration with a Sensoready® pen
  - Enabling the launch despite the ongoing pandemic

- **Broad access**
  - For patients with flexible and once-monthly at-home self-administration
  - For physicians unlocking 1L use with more readily available b-cell treatment
  - For payers with no added real-world costs* and mark-ups associated with infusions

- **Ready to launch**
  - Ready to launch, pioneering an adaptive, hybrid approach

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1Assumes EDSS-confirmed relapses, based on ASCLEPIOS I & II studies

*maintenance cost
Q&A

Samir Shah
Global Head Investor Relations
Thank you