

## MEDIA UPDATE

### **Novartis receives EU approval for Kesimpta® (ofatumumab), the first and only self-administered, targeted B-cell therapy for adult patients with relapsing multiple sclerosis**

- *There are more than 1 million people living with multiple sclerosis (MS) in Europe<sup>1</sup>, Kesimpta® (ofatumumab) addresses the current unmet need for a high-efficacy disease-modifying therapy (DMT) that combines powerful efficacy and favorable safety profile with the flexibility of self-administration at home via the Sensoready® autoinjector pen<sup>2,3</sup>*
- *Approval based on two Phase III ASCLEPIOS studies that met primary endpoints where Kesimpta showed a reduction of annual relapses by over 50% versus teriflunomide, a first-line treatment in MS, and achieved more than 30% relative risk reduction of 3-month confirmed disability progression<sup>2</sup>*
- *Kesimpta may halt new disease activity in relapsing forms of MS (RMS) patients, as shown in post hoc analysis, where nearly nine out of 10 patients treated with Kesimpta achieved no evidence of disease activity (NEDA-3) in their second year of treatment<sup>4</sup>*
- *EU approval follows recent approvals for Kesimpta including the US, Canada, Switzerland, Singapore, Australia and Japan*

**Basel, March 30, 2021** — Novartis announced today that the European Commission has approved Kesimpta® (ofatumumab) for the treatment of relapsing forms of multiple sclerosis (RMS) in adults with active disease defined by clinical or imaging features. Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that has shown superior efficacy with a similar safety profile compared with teriflunomide, a first-line treatment in MS<sup>2</sup>. Kesimpta is the first B-cell therapy that can be self-administered once-monthly at home via the Sensoready® autoinjector pen and can be a first-choice treatment option for patients with RMS<sup>3</sup>.

“With more than 1 million people living with MS – an incurable condition so far - in Europe, it is encouraging to see that research continues to develop more treatments. We welcome the approval from the European Medicines Agency that gives another treatment option for people living with RMS”, said Pedro Carrascal, President of the European Multiple Sclerosis Platform (EMSP).

“Slowing the worsening of disability is one of the main goals when managing RMS and evidence shows that early initiation of a high-efficacy treatment can improve long-term outcomes. Additionally, as RMS progresses, it can substantially increase overall healthcare costs as a result of increased disability,” said Haseeb Ahmad, Global Head of Value &

Access, Novartis Pharmaceuticals. “Kesimpta’s powerful efficacy and favorable safety profile has the potential to become a first-choice treatment to help improve the quality of life of people living with MS, as well as having broader value in potentially reducing medical costs associated with infusion therapies. Kesimpta is a testament to our commitment to reimagine medicine and we remain dedicated to helping to improve the lives of people living with this disease.”

### **About Kesimpta® (ofatumumab)**

Kesimpta is a targeted, precisely dosed and delivered B-cell therapy that provides the flexibility of self-administration for adults with relapsing forms of multiple sclerosis (RMS). It is an anti-CD20 monoclonal antibody (mAb) self-administered by a once-monthly injection, delivered subcutaneously<sup>2,3</sup>. Initial doses of Kesimpta are at Weeks 0, 1 and 2, with the first injection performed under the guidance of a healthcare professional. As shown in preclinical studies, Kesimpta is thought to work by binding to a distinct epitope on the CD20 molecule inducing potent B-cell lysis and depletion<sup>5</sup>. The selective mechanism of action and subcutaneous administration of Kesimpta allows precise delivery to the lymph nodes, where B-cell depletion in MS is needed, and preclinical studies have shown that it may preserve the B-cells in the spleen<sup>6</sup>. Once-monthly dosing of Kesimpta differs from other anti-CD20 therapies as it allows faster repletion of B-cells, offering more flexibility in MS management<sup>7</sup>. Ofatumumab was originally developed by Genmab and licensed to GlaxoSmithKline. Novartis obtained rights for ofatumumab from GlaxoSmithKline in all indications, including RMS, in December 2015<sup>8</sup>.

Novartis is working closely with all stakeholders to ensure that eligible European patients can start benefitting from this treatment as quickly as possible. In August 2020, the US Food and Drug Administration approved Kesimpta as an injection for subcutaneous use for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in adults. Additionally, Kesimpta has been approved for the treatment of relapsing forms of multiple sclerosis in Canada, Switzerland, Singapore, Australia, Japan, Argentina, United Arab Emirates, Albania, and India.

### **Novartis in Neuroscience**

Novartis has a long heritage and strong ongoing commitment to neuroscience and to bringing innovative treatments to patients suffering from neurological and neuropsychiatric conditions where there is a high unmet need. We are committed to supporting patients and physicians with our ambition to pioneer, develop and deliver treatments across four pillars: multiple sclerosis, pediatric neurology, neurodegeneration and neuropsychiatry.

### **Disclaimer**

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### **About Novartis**

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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