



Genmab Announces European Marketing Authorization for Kesimpta® (ofatumumab) in Relapsing Multiple Sclerosis

March 30, 2021

Company Announcement

- **Novartis receives European approval for Kesimpta® (ofatumumab) for the treatment of relapsing forms of multiple sclerosis in adults**
- **Approval follows positive opinion by European Committee for Medicinal Products for Human Use (CHMP) in January 2021**
- **Approval based on Phase 3 ASCLEPIOS I and II studies**
- **First and only self-administered, targeted B-cell therapy for adult patients with relapsing multiple sclerosis approved in Europe**

Copenhagen, Denmark; March 30, 2021 – Genmab A/S (Nasdaq: GMAB) announced today that the European Commission (EC) has granted Novartis marketing authorization for the use of Kesimpta® (ofatumumab) in the treatment of relapsing forms of multiple sclerosis (RMS) in adults with active disease defined by clinical or imaging features. The EC approval follows a positive opinion issued for subcutaneous ofatumumab in RMS by the CHMP of the European Medicines Agency (EMA) in January 2021. Kesimpta, which is developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG, is the first B-cell therapy that can be self-administered once-monthly at home via the Sensoready® autoinjector pen.

"We are extremely pleased that Kesimpta is now approved in both Europe and in the U.S., providing RMS patients with a convenient, efficacious and safe treatment option as demonstrated in the study findings from the ASCLEPIOS trials. We are looking forward to the launch of Kesimpta in the various European markets," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The approval was based on data from the Phase 3 ASCLEPIOS I and II trials, which investigated the efficacy and safety of monthly subcutaneous ofatumumab 20mg versus once daily oral teriflunomide 14mg in adults with RMS. The results from the ASCLEPIOS studies were published in the August 6, 2020 issue of *The New England Journal of Medicine*.

About ASCLEPIOS

The ASCLEPIOS I and II studies (NCT02792218 and NCT02792231) are twin, identical design, flexible duration (up to 30 months), double-blind, randomized, multi-center Phase 3 studies evaluating the safety and efficacy of ofatumumab 20mg monthly subcutaneous injections versus teriflunomide 14mg oral tablets taken once daily in adults with a confirmed diagnosis of RMS^{1,2}. The studies enrolled 1,882 patients with RMS, between the ages of 18 and 55 years, with an Expanded Disability Status Scale (EDSS) score between 0 and 5.5^{1,2}. The studies were conducted in over 350 sites in 37 countries.

The primary endpoint of both studies was to demonstrate that ofatumumab is superior to teriflunomide in reducing the frequency of confirmed relapses as evaluated by the annualized relapse rate (ARR) in patients treated up to 30 months^{1,2}. Secondary endpoints included time to disability progression confirmed at three and six months respectively, confirmed disability improvement at six months, gadolinium enhancing T1 lesions, number of new or enlarging T2 lesions, serum levels of neurofilament light chain (NfL), and rate of brain volume loss^{1,2}. Safety and the pharmacokinetic properties of ofatumumab were also all measured throughout the treatment period^{1,2}.

About Kesimpta® (ofatumumab)

Ofatumumab is a fully human CD20 monoclonal antibody. It is self-administered by a once-monthly injection, delivered subcutaneously. Initial doses of Kesimpta are given at Weeks 0, 1 and 2, with the first injection performed under the guidance of a healthcare provider. It is approved in the U.S. for the treatment of RMS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults. In Europe Kesimpta is approved for the treatment of RMS in adults with active disease defined by clinical or imaging features. Kesimpta is the first B-cell therapy that can be self-administered at home by patients using a Sensoready® pen. Ofatumumab works by binding to the CD20 molecule on the B-cell surface and inducing potent B-cell lysis and depletion³. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system characterized by myelin destruction and axonal damage of the brain, optic nerves and spinal cord⁴. MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss⁵. MS affects approximately 2.8 million people worldwide⁶. Prevalence of MS is higher in the European and Americas regions, with a prevalence of 133 out of 10,000 people in Europe living with MS⁶. It is often characterized into the following forms: primary progressive MS (PPMS) and relapsing forms of MS (RMS), which includes relapsing-remitting MS (RRMS) and secondary progressive MS (SPMS)⁷. Approximately 85% of patients initially present with RMS⁸.

About Genmab

Genmab is an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the

creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates, including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company is headquartered in Copenhagen, Denmark with locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan. For more information, please visit Genmab.com.

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¹ ClinicalTrials.gov. Efficacy and Safety of Ofatumumab Compared to Teriflunomide in Patients With Relapsing Multiple Sclerosis (ASCLEPIOS I). <https://clinicaltrials.gov/ct2/show/NCT02792218>. Accessed January 2020.

² ClinicalTrials.gov. Efficacy and Safety of Ofatumumab Compared to Teriflunomide in Patients With Relapsing Multiple Sclerosis.(ASCLEPIOS II). <https://clinicaltrials.gov/ct2/show/NCT02792231>. Accessed January 2020.

³ Smith P, Kakarieka A, Wallstroem E. Ofatumumab is a fully human anti-CD20 antibody achieving potent B-cell depletion through binding a distinct epitope. Poster presentation at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Congress; September 14-17; 2016; London, UK.

⁴ Guthrie E. Multiple sclerosis: a primer and update. Adv Studies Pharm. 2007;4(11):313-317

⁵ John Hopkins Medicine. Multiple sclerosis (MS). https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/multiple_sclerosis/conditions/index.html. Accessed August 2019.

⁶ Multiple Sclerosis International Federation. Atlas of MS 2020-Mapping multiple sclerosis around the world. Available from: <https://www.msif.org/wp-content/uploads/2020/10/Atlas-3rd-Edition-Epidemiology-report-EN-updated-30-9-20.pdf> (Last accessed: January 2021).

⁷ Multiple sclerosis international federation. Types of MS. <https://www.msif.org/about-ms/types-of-ms/>. Accessed August 2019

⁸ Datamonitor. Multiple Sclerosis Treatment. Published August 2016.

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Attachment

- [300321 CA24 Kesimpta EU Approval](#)