

CHMP Issues Positive Opinion Recommending Ofatumumab in Relapsing Multiple Sclerosis

Company Announcement

- Novartis receives positive CHMP opinion for subcutaneous ofatumumab for adult patients with relapsing forms of multiple sclerosis
- Opinion based on Phase 3 ASCLEPIOS I and II studies

Copenhagen, Denmark; January 28, 2021 – Genmab A/S (Nasdaq: GMAB) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion and recommended granting marketing authorization of subcutaneous ofatumumab for the treatment of relapsing forms of multiple sclerosis (RMS) in adults with active disease defined by clinical or imaging features. Novartis submitted the Marketing Authorization Application for ofatumumab in this indication in January 2020. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

“The positive CHMP opinion for subcutaneous ofatumumab in relapsing multiple sclerosis is an important step in potentially bringing this product to patients in Europe who will benefit from the efficacy and ease of dosing that ofatumumab will provide. We look forward to the European Commission’s final decision on this application,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The opinion 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 presented at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in September 2019 and 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 two 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 Ofatumumab

Ofatumumab is a fully human CD20 monoclonal antibody (mAb) self-administered by a once-monthly subcutaneous injection in development for relapsing forms of multiple sclerosis (RMS). It was approved in the U.S., as Kesimpta[®], for the treatment of RMS in adults, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and is the first B-cell therapy that can be self-administered at home by patients using a Sensoready[®] pen. Initial loading doses of Kesimpta are given on Days 1, 7 and 14, with the first injection performed under the guidance of a healthcare provider. Ofatumumab works by binding to the CD20 molecule on the B-cell surface and inducing potent

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B-cell lysis and depletion. 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 cord³. MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss⁴. MS, which affects approximately 2.5 million people worldwide⁵, 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)⁶. Approximately 85% of patients initially present with RMS⁷.

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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This Company Announcement contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with pre-clinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products or technologies obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on www.genmab.com and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

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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.

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

⁴ John Hopkins Medicine. Multiple sclerosis (MS).

https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/multiple_sclerosis/conditions/index.html. Accessed August 2019.

⁵ GlobalData. EpiCast Report: Multiple Sclerosis - Epidemiology Forecast to 2026. Published November 2017.

⁶ Multiple sclerosis international federation. Types of MS. <https://www.msif.org/about-ms/types-of-ms/>. Accessed August 2019

⁷ Datamonitor. Multiple Sclerosis Treatment. Published August 2016.