
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF MARCH 2021

COMMISSION FILE NUMBER 001-38976

Genmab A/S

(Exact name of Registrant as specified in its charter)

**Kalvebod Brygge 43
1560 Copenhagen V
Denmark
+45 70 20 27 28**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1)

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7)

Yes No

This report on Form 6-K shall be deemed to be incorporated by reference in Genmab A/S's registration statements on Form S-8 (File No. 333-232693) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENMAB A/S

BY: /s/ Anthony Pagano

Name: Anthony Pagano

Title: Executive Vice President & Chief Financial
Officer

DATE: March 30, 2021

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	Company Announcement Dated March 30, 2021: Genmab Announces European Marketing Authorization for Kesimpta® (ofatumumab) in Relapsing Multiple Sclerosis



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

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

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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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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.

Genmab A/S and/or its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; DuoBody in combination with the DuoBody logo®; HexaBody®; HexaBody in combination with the HexaBody logo®; DuoHexaBody®; HexElect®; and UniBody®. Kesimpta® and Sensoready® are trademarks of Novartis AG or its affiliates.

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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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