

U.S. FDA Filing Acceptance and Priority Review for sBLA, Submitted by Novartis, for Ofatumumab in Relapsing Multiple Sclerosis

Media Release

Copenhagen, Denmark, February 24, 2020

- U.S. FDA has accepted, with priority review, the sBLA submitted by Novartis for subcutaneous ofatumumab in RMS
- Novartis anticipates potential regulatory approval in the U.S. in June 2020
- Marketing Authorization Application for ofatumumab in RMS also accepted for review by EMA with potential regulatory approval anticipated by Novartis by the second quarter of 2021

Genmab A/S (Nasdaq: GMAB) announced today that the U.S. Food and Drug Administration (U.S. FDA) has accepted, with priority review, the supplemental Biologics License Application (sBLA) submitted by Novartis for subcutaneous ofatumumab for the treatment of relapsing forms of multiple sclerosis (RMS) in adults. Novartis anticipates potential regulatory approval in the U.S. in June 2020. In addition to the sBLA in the U.S., Novartis submitted a Marketing Authorization Application for approval of subcutaneous ofatumumab in RMS to the European Medicines Agency (EMA), which was also recently accepted for review, with potential approval expected by the second quarter of 2021. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

The regulatory submissions were based on data from the Phase III 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 these studies were presented at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in September 2019.

“We are very pleased that subcutaneous ofatumumab has moved closer to potential approval for patients with relapsing multiple sclerosis in both the U.S. and in Europe. We hope that the priority review will mean that patients in the U.S. will have access to this treatment option earlier in 2020,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

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 III 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 relapsing MS, 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 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}.

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About Ofatumumab

Ofatumumab (OMB157) is a fully human CD20 monoclonal antibody (mAb) self-administered by a once-monthly subcutaneous injection that is in development for relapsing MS. Ofatumumab works by binding to the CD20 molecule on the B-cell surface and inducing potent B-cell lysis and depletion. Positive Phase IIb results in MS patients were presented in 2014 and showed a marked significant reduction in the number of new brain lesions in the first 24 weeks after ofatumumab administration³. Novartis initiated a Phase III program for ofatumumab in RMS in August 2016. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

About Multiple Sclerosis

MS disrupts the normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss⁴. MS, which affects approximately 2.3 million people worldwide⁵, is often characterized into the following forms: primary progressive MS (PPMS) and relapsing MS, which includes relapsing-remitting MS (RRMS) and secondary progressive MS (SPMS)⁶. Approximately 85% of patients initially present with relapsing forms of MS⁵.

About Genmab

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer. Founded in 1999, the company is the creator of three approved antibodies: DARZALEX[®] (daratumumab, under agreement with Janssen Biotech, Inc.) for the treatment of certain multiple myeloma indications in territories including the U.S., Europe and Japan, Arzerra[®] (ofatumumab, under agreement with Novartis AG), for the treatment of certain chronic lymphocytic leukemia indications in the U.S., Japan and certain other territories and TEPEZZA[™] (teprotumumab, under agreement with Roche granting sublicense to Horizon Therapeutics plc) for the treatment of thyroid eye disease in the U.S. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. A subcutaneous formulation of ofatumumab is in development by Novartis for the treatment of relapsing multiple sclerosis. Genmab also has a broad clinical and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody[®] platform for generation of bispecific antibodies, the HexaBody[®] platform, which creates effector function enhanced antibodies, the HexElect[®] platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody[®] platform, which enhances the potential potency of bispecific antibodies through hexamerization. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab has alliances with top tier pharmaceutical and biotechnology companies. Genmab is headquartered in Copenhagen, Denmark with sites in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan.

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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 final prospectus for our U.S. public offering and listing 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 Media Release 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.

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 Bar-Or A, et al. Subcutaneous ofatumumab in patients with relapsing-remitting multiple sclerosis: The MIRROR study. *Neurology*. 2018; 90(20):e1805–1814.

⁴ John Hopkins Medicine. Multiple sclerosis (MS).

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

⁵ Multiple Sclerosis International Federation. Atlas of MS 2013. <http://www.msif.org/wp-content/uploads/2014/09/Atlas-of-MS.pdf>. Accessed August 2019.

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