



Genmab's Partner for Ofatumumab, Novartis, Reports that Ofatumumab Demonstrates Superiority Versus Teriflunomide in Two Head-to-Head Phase III Multiple Sclerosis Studies

August 30, 2019

Company Announcement

- **In ASCLEPIOS I and II, ofatumumab (OMB157) met primary endpoints to reduce the annualized relapse rate (ARR) over teriflunomide in patients with relapsing forms of multiple sclerosis (RMS)**
- **Key secondary endpoints of delaying time to confirmed disability progression were also met**
- **Ofatumumab delivered sustained efficacy with a safety profile in line with observations from prior Phase II results**
- **Novartis plans to initiate submissions to health authorities by end of 2019**

Copenhagen, Denmark; August 30, 2019 – Genmab A/S (Nasdaq: GMAB) announced today that its partner for ofatumumab, Novartis, reported positive results for ofatumumab (OMB157) from the Phase III ASCLEPIOS I and II studies. The ASCLEPIOS studies, which investigated the efficacy and safety of monthly subcutaneous ofatumumab 20mg versus once daily oral teriflunomide 14mg in adults with relapsing forms of multiple sclerosis (RMS), met the primary endpoints where ofatumumab showed a highly significant and clinically meaningful reduction in the number of confirmed relapses, evaluated as the annualized relapse rate (ARR). Key secondary endpoints of delaying the time to confirmed disability progression were also met. According to Novartis, ofatumumab delivered sustained efficacy and the safety profile of ofatumumab as seen in the ASCLEPIOS studies is in line with the observations from prior Phase II results.

"This data signifies a possible turning point for ofatumumab and provides support for our belief that it has the potential, if approved, to become the first subcutaneous B-cell therapy for relapsing MS that can be self-administered by patients at home. We look forward to feedback from regulatory authorities and to this exciting next phase in ofatumumab's development," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Based on the ASCLEPIOS data, Novartis, which has the rights to develop and commercialize ofatumumab under a license from Genmab, plans to initiate submissions to health authorities by end of 2019.

Results of the Phase III ASCLEPIOS studies will be presented as a late-breaker presentation on September 13 at the prestigious 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), taking place September 11–13, 2019, in Stockholm, Sweden.

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}.

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. Novartis obtained rights for ofatumumab from Genmab in all indications, including MS, in December 2015.

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 three forms: relapsing-remitting MS (RRMS), which includes RMS, secondary progressive MS (SPMS – often defined as cognitive and physical changes, and an overall accumulation of disability⁶) and primary progressive MS (PPMS)⁷. 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 has two approved antibodies, DARZALEX[®] (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra[®] (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications, other blood cancers and amyloidosis. A subcutaneous formulation of ofatumumab is in development for 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 core sites in Utrecht, the Netherlands and Princeton, New Jersey, U.S.

Contact:

Marisol Peron, Corporate Vice President, Communications & Investor Relations

T: +1 609 524 0065; E: mmp@genmab.com

For Investor Relations:

Andrew Carlsen, Senior Director, Investor Relations

T: +45 3377 9558; E: acn@genmab.com

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 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 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[®]. Arzerra[®] is a trademark of Novartis AG or its affiliates. DARZALEX[®] is a trademark of Janssen Pharmaceutica NV.

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 August 2019.

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 August 2019.

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 National Multiple Sclerosis Society. Secondary Progressive MS (SPMS). <https://www.nationalmssociety.org/What-is-MS/Types-of-MS/Secondary-progressive-MS>. Accessed August 2019.

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

Company Announcement no. 43
CVR no. 2102 3884
LEI Code 529900MTJPDPE4MHJ122

Genmab A/S
Kalvebod Brygge 43
1560 Copenhagen V
Denmark

Attachment

- [190830_CA43_Ofatumumab RMS Data](#)