

## Detailed Results from the Phase III ASCLEPIOS I & II Studies of Ofatumumab in Patients with Relapsing Multiple Sclerosis Presented at ECTRIMS

### Company Announcement

- Details from the ASCLEPIOS I & II studies of subcutaneous ofatumumab (OMB157) versus teriflunomide in patients with relapsing multiple sclerosis (RMS) were presented at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

**Copenhagen, Denmark; September 13, 2019 – Genmab A/S (Nasdaq: GMAB) announced that its partner for ofatumumab, Novartis, presented positive results from the Phase III ASCLEPIOS I and II studies at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), in Stockholm, Sweden.** The head-to-head ASCLEPIOS studies 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) with the primary endpoints of reduction in the number of confirmed relapses, evaluated as the annualized relapse rate (ARR). Both ASCLEPIOS I and II studies met their primary endpoints. Patients with RMS on ofatumumab had a reduction in ARR by 50.5% (0.11 vs. 0.22) and 58.5% (0.10 vs 0.25) compared to teriflunomide (both studies  $p < 0.001$ ) in ASCLEPIOS I and II studies respectively. Regarding secondary endpoints of the trials, ofatumumab showed highly significant suppression of gadolinium (Gd) T1 lesions when compared to teriflunomide demonstrating a profound suppression of new inflammatory activity. Ofatumumab showed a relative risk reduction of 34.4% in 3-month confirmed disability progression (CDP) ( $p = 0.002$ ) and 32.5% in 6-month CDP ( $p = 0.012$ ) versus teriflunomide in pre-specified pooled analyses. The safety profile of ofatumumab as seen in the ASCLEPIOS studies was in line with the observations from prior Phase II results. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement with Novartis Pharma AG. Novartis plans to initiate submissions to health authorities by end of 2019.

“We are extremely pleased with the very positive data presented at the prestigious ECTRIMS Congress, as these further support our firm belief in the potential of subcutaneous ofatumumab to provide an excellent and very convenient option to profoundly improve the lives of patients living with relapsing multiple sclerosis,” 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<sup>1,2</sup>. 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<sup>1,2</sup>. 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<sup>1,2</sup>. 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<sup>1,2</sup>. Safety and the pharmacokinetic properties of ofatumumab were also all measured throughout the treatment period<sup>1,2</sup>.

### 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

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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 administration<sup>3</sup>. 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 with Novartis Pharma AG. 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 loss<sup>4</sup>. MS, which affects approximately 2.3 million people worldwide<sup>5</sup>, 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)<sup>6</sup>. Approximately 85% of patients initially present with relapsing forms of MS<sup>5</sup>.

### 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<sup>®</sup> (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra<sup>®</sup> (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<sup>®</sup> platform for generation of bispecific antibodies, the HexaBody<sup>®</sup> platform, which creates effector function enhanced antibodies, the HexElect<sup>®</sup> platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody<sup>®</sup> 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.

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Bar-Or A, et al. Subcutaneous ofatumumab in patients with relapsing-remitting multiple sclerosis: The MIRROR study. *Neurology*. 2018; 90(20):e1805–1814.

<sup>4</sup> John Hopkins Medicine. Multiple sclerosis (MS).

[https://www.hopkinsmedicine.org/neurology\\_neurosurgery/centers\\_clinics/multiple\\_sclerosis/conditions/index.html](https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/multiple_sclerosis/conditions/index.html). Accessed August 2019.

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

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