Genmab A/S (Nasdaq: GMAB) announced that its partner for ofatumumab, Novartis, often characterized into the following forms: primary progressive MS (PPMS) and relapsing MS, which includes 5. The studies were conducted platform, which creates effector function enhanced antibodies, the HexElect 1,2,4. Secondary endpoints included time to disability progression confirmed at three and six 5(ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in platform, which combines two co-dependently acting 1,2. The studies enrolled 1,882 patients with relapsing 1,2. Safety and the pharmacokinetic properties of ofatumumab were also all 1,2. MS, which affects approximately 2.3 million people worldwide, 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 multiple sclerosis,; said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

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 administration5. 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 plans to initiate submissions to health authorities by end of 2019.

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) 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 RMS1,2. 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 5.51,2. 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 months1,2. 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 loss1,2. Safety and the pharmacokinetic properties of ofatumumab were also all measured throughout the treatment period1,2.

About MS
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.
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.

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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 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®; HexaElec®; and UniBody®. Arzerra® is a trademark of Novartis AG or its affiliates. DARZALEX® is a trademark of Janssen Pharmaceutica NV.


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Attachment

- 190913_CA44_Ofatumumab Data at ECTRIMS