U.S. FDA Extends Review of sBLA, Submitted by Novartis, for Ofatumumab in Relapsing Multiple Sclerosis

Media Release

Copenhagen, Denmark, June 2, 2020

- **The U.S. FDA has notified Novartis that the agency has extended its review of the sBLA for subcutaneous ofatumumab in RMS**
- **Regulatory action in the U.S. now anticipated in September 2020**

Genmab A/S (Nasdaq: GMAB) announced today that the U.S. Food and Drug Administration (U.S. FDA) has notified Novartis that the agency has extended its review of the supplemental Biologics License Application (sBLA) for subcutaneous ofatumumab for the treatment of relapsing forms of multiple sclerosis (RMS) in adults. Regulatory action in the U.S. is now anticipated in September 2020. Ofatumumab is being developed and marketed worldwide by Novartis under a license agreement between Genmab and Novartis Pharma AG.

“As our partner Novartis works with the U.S. FDA to continue the review for subcutaneous ofatumumab in relapsing multiple sclerosis, we continue to look forward to its potential approval in the U.S., as well as in other territories where regulatory filings are underway,” 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 administration. 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 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. A subcutaneous formulation of daratumumab, DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj), has been approved in the U.S. for the treatment of adult patients with certain multiple myeloma indications. 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,

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Princeton, New Jersey, U.S. and Tokyo, Japan.

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