Genmab Announces U.S. FDA Approval of Subcutaneous Formulation of Daratumumab, DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj), for the Treatment of Patients with Multiple Myeloma

Company Announcement

- **Subcutaneous formulation of daratumumab, DARZALEX *FASPRO*™, approved by the U.S. FDA for the treatment of patients with multiple myeloma**
- **Approval based on data from Phase III COLUMBA and Phase II PLEIADES studies**
- **In the studies, the fixed-dose subcutaneous formulation reduced treatment time from hours to minutes and demonstrated similar efficacy and safety with significantly fewer infusion-related reactions compared with the intravenous formulation**

Copenhagen, Denmark; May 01, 2020 – Genmab A/S (Nasdaq: GMAB) announced today that the U.S. Food and Drug Administration (U.S. FDA) has approved the use of the subcutaneous formulation of daratumumab, DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj). The Biologics License Application (BLA) for this formulation was submitted by Genmab's licensing partner, Janssen Biotech, Inc. (Janssen) in July 2019. DARZALEX *FASPRO* is approved for the treatment of adult patients with multiple myeloma: in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant (ASCT); in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for ASCT and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy; in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. DARZALEX *FASPRO* is a fixed-dose formulation that can be administered over approximately three to five minutes, significantly less time than intravenous DARZALEX®, which is given over several hours. In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

The approval was based on data from two studies: the Phase III non-inferiority COLUMBA (MMY3012) study, which compared the subcutaneous formulation of daratumumab to the intravenous formulation in patients with relapsed or refractory multiple myeloma and data from the Phase II PLEIADES (MMY2040) study, which is evaluating subcutaneous daratumumab in combination with different standard multiple myeloma treatment regimens. The topline results from the COLUMBA study were announced in February 2019 and subsequently presented in oral sessions at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting and the 24th European Hematology Association (EHA) Annual Congress. An update of the COLUMBA data as well as data from the PLEIADES study were presented during poster sessions at the 61st American Society of Hematology (ASH) Annual Meeting in December 2019.

"The approval of the subcutaneous formulation of daratumumab, DARZALEX *FASPRO*, is a landmark event in the development of daratumumab. Not only is it now the first and only subcutaneous CD38 antibody approved for the treatment of multiple myeloma, the subcutaneous administration of DARZALEX *FASPRO* considerably reduces treatment burden, as the fixed-dose injection is administered in approximately three to five minutes, offering patients a more convenient treatment experience. As seen in the pivotal study supporting the approval, this reduction in infusion time from hours to minutes led to higher satisfaction levels for patients and in addition, infusion-related reactions were both mild and significantly reduced with this formulation of daratumumab. We are very much looking forward to the launch of DARZALEX *FASPRO* in the U.S. and the potential for positive impact it will have on the lives of the patients receiving the drug," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

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About the COLUMBA (MMY3012) study
The Phase III trial (NCT03277105) is a randomized, open-label, parallel assignment study that included 522 adults diagnosed with relapsed and refractory multiple myeloma. Patients were randomized to receive either: subcutaneous (SC) daratumumab, as 1,800 mg daratumumab with rHuPH20 2,000 U/mL once weekly in Cycle 1 and 2, every two weeks in Cycles 3 to 6, every 4 weeks in Cycle 7 and thereafter until disease progression, unacceptable toxicity or the end of study; or 16 mg/kg IV daratumumab once weekly in Cycle 1 and 2, every two weeks in Cycles 3 to 6, every 4 weeks in Cycle 7 and thereafter until disease progression, unacceptable toxicity or the end of study. The co-primary endpoints of the study are overall response rate and Maximum trough concentration of daratumumab (C_{trough}; defined as the serum pre-dose concentration of daratumumab on Cycle 3 Day 1).

About the PLEIADES (MMY2040) study
The Phase II trial (NCT03412565) is a non-randomized, open-label, parallel assignment study that includes 265 adults either newly diagnosed or with relapsed or refractory multiple myeloma. Patients with newly diagnosed multiple myeloma are being treated with 1,800 mg SC daratumumab in combination with either bortezomib, lenalidomide and dexamethasone (D-VRd) or bortezomib, melphalan and prednisone (D-VMP). Patients with relapsed or refractory multiple myeloma are being treated with 1,800 mg SC daratumumab plus lenalidomide and dexamethasone (D-Rd). An additional cohort of patients with relapsed and refractory multiple myeloma treated with daratumumab plus carfilzomib and dexamethasone (D-Kd) was subsequently added to the study. The primary endpoint for the D-VMP, D-Kd and D-Rd cohorts is overall response rate. The primary endpoint for the D-VRd cohort is very good partial response or better rate.

About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant (ASCT); in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT; in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy; in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI); and as a monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.[1] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in Europe: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for ASCT; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT; in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for ASCT; for use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy; and as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy[2]. The option to split the first infusion of DARZALEX over two consecutive days has been approved in both Europe and the U.S. In Japan, DARZALEX intravenous infusion is approved for the treatment of adult patients: in combination with lenalidomide and

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dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT; in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market in the United States, Europe and Japan. For more information, visit www.DARZALEX.com.

DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, is approved in the United States for the treatment of adult patients with multiple myeloma: in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for ASCT; in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for ASCT and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy; in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and as monotherapy, in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. DARZALEX *FASPRO* is the first subcutaneous CD38-directed antibody approved in the U.S. for the treatment of multiple myeloma.

Daratumumab is a human IgG1k monoclonal antibody (mAb) that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells. Daratumumab triggers a person's own immune system to attack the cancer cells, resul cvfting in rapid tumor cell death through multiple immune-mediated mechanisms of action and through immunomodulatory effects, in addition to direct tumor cell death, via apoptosis (programmed cell death).[1,2,3,4,5,6]

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. A comprehensive clinical development program for daratumumab is ongoing, including multiple Phase III studies in smoldering, relapsed and refractory and frontline multiple myeloma settings. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases in which CD38 is expressed, such as amyloidosis and T-cell acute lymphocytic leukemia (ALL). Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA for certain indications of multiple myeloma, including as a monotherapy for heavily pretreated multiple myeloma and in combination with certain other therapies for second-line treatment of multiple myeloma.

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

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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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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 most recent Annual Report on Form 20-F 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.

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