Genmab Announces that Janssen has Submitted a Type II Variation Application to the European Medicines Agency for use of Subcutaneous DARZALEX® (daratumumab) in Patients with Light-chain (AL) amyloidosis

Media Release

Copenhagen, Denmark, November 5, 2020

- **Janssen submitted a Type II variation application to the European Medicines Agency for subcutaneous formulation of daratumumab in combination with bortezomib, cyclophosphamide and dexamethasone in light-chain (AL) amyloidosis**
- **Submission is based on data from the Phase 3 ANDROMEDA (AMY3001) study**

Genmab A/S (Nasdaq: GMAB) announced today that Janssen Pharmaceutica NV (Janssen) has submitted a Type II variation application to the European Medicines Agency (EMA) for the subcutaneous (SC) formulation of daratumumab (daratumumab and hyaluronidase-fihj) in combination with bortezomib, cyclophosphamide, and dexamethasone (VCd) for the treatment of adult patients with light-chain (AL) amyloidosis. In August 2012, Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize daratumumab. The submission of this Type II variation application study triggers a USD 5 million milestone payment to Genmab.

"We are extremely pleased about the submission for subcutaneous DARZALEX in patients with AL amyloidosis to the European Health Authorities based on the Phase 3 ANDROMEDA (AMY3001) study. We are hopeful that this will lead to the first approved treatment option for patients with this devastating disease which would also be the first approved indication for DARZALEX in Europe outside of multiple myeloma," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The submission is based on the Phase 3 ANDROMEDA study of daratumumab and hyaluronidase-fihj in combination with VCd as treatment for patients with newly diagnosed AL amyloidosis. The data were presented as a late-breaking abstract at the 25th European Hematology Association Annual Congress in June 2020.

The milestone associated with this submission does not impact Genmab's 2020 guidance.

About the ANDROMEDA (AMY3001) study
The Phase 3 study (NCT03201965) included 388 patients newly diagnosed with AL amyloidosis. Patients were randomized to receive treatment with either daratumumab and hyaluronidase-fihj in combination with bortezomib (a proteasome inhibitor), cyclophosphamide (a chemotherapy), and dexamethasone (a corticosteroid) (VCd) or treatment with VCd alone. The primary endpoint of the study was the percentage of patients who achieve hematologic complete response.

About Light-chain (AL) Amyloidosis
Amyloidosis is a disease that occurs when amyloid proteins, which are abnormal proteins, accumulate in tissues and organs. When the amyloid proteins cluster together, they form deposits that damage the tissues and organs. AL amyloidosis most frequently affects the heart, kidneys, liver, nervous system and digestive tract. There is currently no cure or existing approved therapies for AL amyloidosis though it can be treated with chemotherapy, dexamethasone, stem cell transplants and supportive therapies.[1] It is estimated that in 2019 there were 4,388 diagnosed incident cases of AL amyloidosis in the five major European markets[2]

Genmab Announces that Janssen has Submitted a Type II Variation Application to the European Medicines Agency for use of Subcutaneous DARZALEX® (daratumumab) in Patients with Light-chain (AL) amyloidosis

About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) has become a backbone therapy in the treatment of multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with carfilzomib and dexamethasone for the treatment of patients with relapsed/refractory

multiple myeloma who have received one to three previous lines of therapy; in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; 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.[3] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma.

DARZALEX is indicated for the treatment of adult patients in Europe via intravenous infusion or subcutaneous administration: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; 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[4]. Daratumumab is the first subcutaneous CD38 antibody approved in Europe for the treatment of multiple myeloma. 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 dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; 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.[5] DARZALEX *FASPRO* is the first subcutaneous CD38 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, resulting 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).[3,6,7,8,9]

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 the following 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, Kesimpta® (subcutaneous ofatumumab, under agreement with Novartis AG), for the treatment of adults with relapsing forms of multiple sclerosis in the U.S. 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, known as DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) in the U.S., has been approved in the U.S. and Europe for the treatment of adult patients with certain multiple myeloma indications. The first approved Genmab created therapy, Arzerra® (ofatumumab, under agreement with Novartis AG), approved for the treatment of certain chronic lymphocytic leukemia indications, is available in Japan and is also available in other territories via compassionate use or oncology access programs. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. 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, Princeton, New Jersey, U.S. and Tokyo, Japan.

Contact:

Marisol Peron, Corporate Vice President, Communications & Investor Relations
T: +1 609 524 0065; E: mmp@genmab.com

Genmab Announces that Janssen has Submitted a Type II Variation Application to the European Medicines Agency for use of Subcutaneous DARZALEX® (daratumumab) in Patients with Light-chain (AL) amyloidosis

For Investor Relations:
Andrew Carlsen, Senior Director, Investor Relations
T: +45 3377 9558; E: acn@genmab.com

This Media Release 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 Media Release 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.

[1] Mayo Clinic website: www.mayoclinic.com/health/amyloidosis/DS00431
[2] Global Data, "Amyloidosis: Epidemiology Forecast to 2029," June 2020
[3] DARZALEX Prescribing information, August 2020 https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761036s029lbl.pdf Last accessed August 2020
[4] DARZALEX Summary of Product Characteristics, available at https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex Last accessed June 2020
[5] DARZALEX *FASPRO* Prescribing information, May 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761145s000lbl.pdf Last accessed May 2020
[6] De Weers, M et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors. The Journal of Immunology. 2011; 186: 1840-1848.
[7] Overdijk, MB, et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. MAbs. 2015; 7: 311-21.
[8] Krejcik, MD et al. Daratumumab Depletes CD38+ Immune-regulatory Cells, Promotes T-cell Expansion, and Skews T-cell Repertoire in Multiple Myeloma. Blood. 2016; 128: 384-94.
[9] Jansen, JH et al. Daratumumab, a human CD38 antibody induces apoptosis of myeloma tumor cells via Fc receptor-mediated crosslinking. Blood. 2012; 120(21): abstract 2974