Genmab Announces Positive Topline Results in Phase III COLUMBA Study of Subcutaneous Daratumumab

Company Announcement

- **Phase III COLUMBA study comparing the subcutaneous formulation of daratumumab to the intravenous formulation in patients with relapsed or refractory multiple myeloma met both co-primary endpoints**
- **Results show that daratumumab administered subcutaneously was non-inferior in efficacy and pharmacokinetics as compared to daratumumab administered intravenously**
- **Data will be discussed with health authorities to prepare for regulatory filings in support of bringing convenience of subcutaneous daratumumab option to patients**

Copenhagen, Denmark; February 25, 2019 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today topline results from the Phase III COLUMBA study (MMY3012) of subcutaneous (SC) versus intravenous (IV) daratumumab for patients with relapsed or refractory multiple myeloma. The results showed that SC administration of daratumumab co-formulated with recombinant human hyaluronidase PH20 is non-inferior to IV administration of daratumumab with regard to the co-primary end points of overall response rate (ORR) and Maximum Trough concentration (C_{trough}) of daratumumab on day 1 of the third treatment cycle.

The ORR for patients treated with SC daratumumab was 41.1% (n=263) versus 37.1% in patients treated with IV daratumumab (n= 259). The lower limit of the 95% Confidence Interval (CI) for the ratio of the two met the specified non-inferiority criterion for this co-primary endpoint. The geometric mean of C_{trough} for patients treated with SC daratumumab was 499 μg/mL (n=149) versus 463 μg/mL in patients treated with IV daratumumab (n= 146). The lower limit of the 95% CI for the ratio of the two met the specified non-inferiority criterion for this co-primary endpoint.

No new safety signals were detected and Janssen Biotech, Inc., which licensed daratumumab from Genmab in 2012, will discuss the potential for a regulatory submission for this formulation with health authorities, and plans to submit the data to an upcoming medical conference and for publication in a peer-reviewed journal.

“With the data from each of the key clinical studies we learn more about the difference that daratumumab potentially can make to the lives of patients suffering with multiple myeloma. I am particularly excited about the results from this study as it may support a much quicker and far more convenient administration of daratumumab, which would provide an important benefit for many patients and their families,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the COLUMBA (MMY3012) study
The Phase III trial (NCT03277105) is a randomized, open-label, parallel assignment study that includes 522 adults diagnosed with relapsed and refractory multiple myeloma. Patients were randomized to receive either: SC daratumumab, as 1800 mg daratumumab with rHuPH20 2000 U/mL once weekly in Cycle 1 and 2, every two weeks in Cycle 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 Cycle 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 ORR and Maximum trough of daratumumab (C_{trough}; defined as the serum pre dose concentration of daratumumab on Cycle 3 Day 1).

About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) injection for intravenous infusion is indicated in the United States 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.[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 is indicated in Europe 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. 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 is approved in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adults with relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market in the United Stated, Europe and Japan. For more information, visit www.DARZALEX.com.

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).[1,2,3,4,5]

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 frontline multiple myeloma settings and in amyloidosis. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases, such as NKT-cell lymphoma, B and T-ALL. Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA, for multiple myeloma, as both a monotherapy and in combination with other therapies.

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® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications and other blood cancers. 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® platform for generation of bispecific antibodies, the HexaBody® platform, which creates effector function enhanced antibodies and the HexElect™ platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency. 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. For more information visit www.genmab.com.

Contact:

Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communications

Genmab A/S
Kalvebod Brygge 43
1560 Copenhagen V, Denmark

Tel: +45 7020 2728
www.genmab.com

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T: +45 33 44 77 20; E: rcg@genmab.com

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 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. 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.

[1] DARZALEX Prescribing information, February 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761036s016lbl.pdf Last accessed February 2019
[2] 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.
[3] 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.
[4]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.
[5]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.