Genmab Announces Daratumumab Data to be Presented at 2016 ASCO Annual Meeting

Company Announcement

- **Oral plenary session presentation on daratumumab Phase III Castor study data**
- **Trial in progress poster presentation from Phase I study of subcutaneous daratumumab**

Copenhagen, Denmark; April 20, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that two daratumumab abstracts have been accepted for presentation at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 3 – 7. The titles of the abstracts are available on the ASCO website at www.asco.org via ASCO's iPlanner. With the exception of the daratumumab Phase III Castor study data, which has been designated as a late breaking abstract by ASCO, the full abstracts are scheduled to be published on the ASCO website on May 18 at 5:00PM EDT.

Daratumumab Phase III Castor Study Data
Safety and efficacy data from the Phase III study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma will be presented in the Plenary Session at the ASCO meeting on June 5. A total of 498 patients with relapsed or refractory multiple myeloma were enrolled in the study. The study met the primary endpoint of improving progression free survival (PFS); Hazard Ratio (HR) = 0.39, p<0.0001. The median PFS for patients treated with daratumumab has not been reached, compared to median PFS of 7.2 months for patients who did not receive daratumumab.

Daratumumab showed a manageable safety profile in the study consistent with the reported safety profile of monotherapy and background bortezomib/dexamethasone therapy.

As announced on March 30, 2016 an Independent Data Monitoring Committee recommended stopping the study as the primary endpoint had been reached at the time of the pre-specified interim analysis. Patients originally assigned to the bortezomib plus dexamethasone treatment group will be offered the option of receiving daratumumab following confirmed disease progression. Patients continue to be monitored for safety and overall survival.

Abstract details: Phase 3 randomized controlled study of daratumumab, bortezomib and dexamethasone (DVd) vs bortezomib and dexamethasone (Vd) in patients (pts) with relapsed or refractory multiple myeloma (RRMM): CASTOR study– Abstract # LBA4, Oral presentation, Sunday, June 5 at 3:10PM-3:25PM CDT
This abstract has been designated a late breaking abstract and the embargo will be lifted on Sunday, June 5 at 6:30AM CDT.

"ASCO is one of the premier medical conferences of the year and we are very pleased that highly impressive data with one of our key programs, daratumumab, will be presented again this year," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

List of Further Abstracts to Be Presented
Daratumumab
An open-label, dose-escalation Phase 1b study of subcutaneous daratumumab with recombinant human hyaluronidase in patients with relapsed or refractory multiple myeloma (PAVO) – Abstract # 333b, Trials in progress poster presentation, Monday, June 6 at 8:00AM -11.30AM CDT
The study described in this abstract is ongoing.

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About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) injection for intravenous infusion is indicated in the United States for the treatment of patients with multiple myeloma 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.[1] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (FDA) approval to treat multiple myeloma. 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. It is believed to induce rapid tumor cell death through programmed cell death, or apoptosis,[1,2] and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,[1,2] antibody-dependent cellular phagocytosis[3,4] and antibody-dependent cellular cytotoxicity.[1,2] In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and subsets of regulatory T cells (Tregs) and B cells (Bregs), all of which express CD38. These reductions in MDSCs, Tregs and Bregs were accompanied by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.[1]

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. Five Phase III clinical studies with daratumumab in relapsed and frontline settings are currently ongoing, and additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma, non-Hodgkin's lymphoma and a solid tumor indication.

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, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and DARZALEX® (daratumumab) for the treatment of heavily pretreated or double refractory multiple myeloma. Daratumumab is in clinical development for additional multiple myeloma indications and for non-Hodgkin's lymphoma. 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, and the HexaBody® platform which creates effector function enhanced antibodies. 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.

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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 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 in relation to actual results, unless required by law.

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[1] DARZALEX Prescribing Information, November 2015.
[2] De Weers 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 et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. MAbs. 2015; 7: 311-321.
[4] Khagi and Mark. Potential role of daratumumab in the treatment of multiple myeloma. Onco Targets Ther. 2014; 7: 1095–1100.