Genmab Announces Positive Topline Result in Phase III POLLUX Study of Daratumumab in Relapsed or Refractory Multiple Myeloma

Company Announcement

- **Phase III POLLUX study of daratumumab in combination with lenalidomide and dexamethasone in patients with relapsed or refractory multiple myeloma met the primary endpoint at a pre-planned interim analysis**
- **Independent Data Monitoring Committee recommends unblinding the data**
- **Data will be discussed with health authorities to prepare for regulatory filings**

Copenhagen, Denmark; May 18, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the Phase III POLLUX study (MMY3003) of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with relapsed or refractory multiple myeloma met the primary endpoint of improving progression free survival (PFS) at a pre-planned interim analysis (Hazard Ratio (HR) = 0.37 (95% CI 0.27-0.52), p < 0.0001). Patients who received treatment with daratumumab in combination with lenalidomide and dexamethasone had a 63% reduction in risk of their disease progressing, compared to those who did not receive daratumumab. The median PFS for patients treated with daratumumab in combination with lenalidomide and dexamethasone has not been reached, compared to an estimated median PFS of 18.4 months for patients who received lenalidomide and dexamethasone alone.

Overall, the safety profile of daratumumab in combination with lenalidomide and dexamethasone was manageable and consistent with the known safety profile of the lenalidomide and dexamethasone combination, with the ongoing Phase II study, GEN503, which evaluated safety and efficacy of daratumumab in combination with lenalidomide and dexamethasone as well as daratumumab monotherapy.

Based on the results at the pre-planned interim analysis conducted by an Independent Data Monitoring Committee (IDMC), it was recommended that the data be unblinded. Patients originally assigned to the lenalidomide plus dexamethasone alone treatment group will be offered the option of receiving daratumumab monotherapy following confirmed disease progression. All patients will continue to be monitored for safety and overall survival. Further analysis of the safety and efficacy data is underway and will be shared with the health authorities. Janssen Biotech, Inc., which licensed daratumumab from Genmab in 2012, will engage in a dialogue with health authorities about the potential for a regulatory submission for this indication. The trial results are also aimed to be presented at the 21st Congress of the European Hematology Association (EHA) as well as submitted for publication in a peer-reviewed journal.

“The POLLUX study is the second key Phase III study of daratumumab to meet the primary endpoint at a pre-planned interim analysis and demonstrates a favorable benefit-risk ratio. We have now seen that daratumumab can potentially be used to effectively treat relapsed or refractory multiple myeloma in combination with either lenalidomide or bortezomib, two standard of care multiple myeloma treatments,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the study
The Phase III POLLUX study enrolled 569 patients who had relapsed or refractory multiple myeloma. Patients were randomized to receive either daratumumab combined with lenalidomide (an immunomodulatory drug) and dexamethasone (a corticosteroid), or lenalidomide and dexamethasone alone. The primary endpoint of the study is progression free survival (PFS).

About multiple myeloma
Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.[1] Multiple myeloma is the third most common blood cancer in the U.S., after leukemia and lymphoma.[2] Approximately 26,850 new patients were estimated to be diagnosed

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with multiple myeloma and approximately 11,240 people would die from the disease in the U.S. in 2015.[3] Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would die from the disease in 2015.[4] While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms which can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[5] Patients who relapse after treatment with standard therapies, including proteasome inhibitors or immunomodulatory agents, have poor prognoses and few treatment options.[6]

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.[7] 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,[7,8] and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,[7,8] antibody-dependent cellular phagocytosis[9,10] and antibody-dependent cellular cytotoxicity.[7,8] 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)[7], 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.[7]

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.

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

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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.

References

[1] American Cancer Society. "Multiple Myeloma Overview." Available at http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed February 2016.
[2] National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed February 2016.
[3] American Cancer Society. "What are the key statistics about multiple myeloma?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics. Accessed September 2015.
[4] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of New Cancers in 2015. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=0&window=1&submit=%C2%A0Execute. Accessed September 2015.
[5] American Cancer Society. "How is Multiple Myeloma Diagnosed?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed February 2016.
[6] Kumar, SK et al. Risk of progression and survival in multiple myeloma relapsing after last therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. Leukemia. 2012; 26:149-57.
[7] DARZALEX Prescribing Information, November 2015.
[8] 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.
[9] 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: 311-321.
[10] Khagi, Y and Mark, TM. Potential role of daratumumab in the treatment of multiple myeloma. Onco Targets Ther. 2014; 7: 1095–1100.