Genmab Announces Submission of Regulatory Application for Daratumumab in Relapsed/Refractory Multiple Myeloma in Japan and Updates Financial Guidance

Company Announcement

- **Regulatory application submitted in Japan for daratumumab for relapsed or refractory multiple myeloma**
- **Submission based on data from SIRIUS, CASTOR and POLLUX studies**
- **Genmab to receive USD 10 million in milestone payments from Janssen – financial guidance updated**

Copenhagen, Denmark; December 20, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that Janssen Pharmaceutical K.K. has submitted a New Drug Application to the Ministry of Health, Labor and Welfare (MHLW) in Japan for the use of daratumumab (DARZALEX®) for the treatment of adults with relapsed or refractory multiple myeloma. The submission of the application triggers milestone payments totaling USD 10 million to Genmab from Janssen. Genmab is updating its financial guidance for 2016 to include the milestones. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"We are pleased that the first regulatory application for daratumumab in the Asia Pacific region has been submitted and look forward to the decision of the Japanese regulatory authorities," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We continue to be excited by the potential of daratumumab to make a positive impact on the lives of patients with multiple myeloma and their families."

The submission is built around three pivotal studies: the Phase II SIRIUS study (MMY2002), published in *The Lancet* in April 2016; the Phase III CASTOR study (MMY3004), published in *The New England Journal of Medicine* in August 2016; the Phase III POLLUX study (MMY3003), published in *The New England Journal of Medicine* in October 2016; and supported by several other studies.

OUTLOOK

MDKK	Revised Guidance	Previous Guidance
Revenue	1,720 – 1,770	1,650 – 1,700
Operating expenses	(800) – (850)	(800) – (850)
Operating income	895 – 945	825 – 875
Cash position at end of year*	3,650 – 3,750	3,650 – 3,750
**Cash, cash equivalents, and marketable securities*		

Genmab is improving its 2016 financial guidance published on November 21, 2016 due to the inclusion of daratumumab milestones totaling USD 10 million associated with the submission of the regulatory application for daratumumab in relapsed or refractory multiple myeloma in Japan.

Operating Result

We expect our 2016 revenue to be in the range of DKK 1,720 – 1,770 million, an increase of DKK 70 million compared to the previous guidance. We have increased our projected daratumumab milestones to DKK 1,090 million (previously DKK 1,020 million) due to inclusion of USD 10 million in milestone payments triggered by the submission of the regulatory application for daratumumab in relapsed or refractory multiple myeloma in Japan. We expect DARZALEX royalties to remain in the range of DKK 400 – 450 million, which are based on an estimated USD 500 – 550 million of DARZALEX sales in 2016.

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The remainder of the revenue mainly consists of Arzerra® royalties, DuoBody® milestones, and non-cash amortization of deferred revenue.

We anticipate that our 2016 operating expenses will remain in the range of DKK 800 – 850 million.

As a result of the increased revenue, we now expect the operating income for 2016 to be approximately DKK 895 - 945 million, compared to DKK 825 - 875 million in the previous guidance.

Cash Position

There is no change to the cash position at the end of 2016 of DKK 3,650 - 3,750 million as we expect to receive payment for the additional milestones shortly after year-end.

Outlook: Risks and Assumptions

In addition to factors already mentioned, the estimates above are subject to change due to numerous reasons, including but not limited to the achievement of certain milestones associated with our collaboration agreements; the timing and variation of development activities (including activities carried out by our collaboration partners) and related income and costs; DARZALEX and Arzerra sales and corresponding royalties to Genmab; fluctuations in the value of our marketable securities; and currency exchange rates. The financial guidance does not include any potential proceeds from future warrant exercises and also assumes that no significant agreements are entered into during 2016 that could materially affect the results.

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 30,330 new patients are expected to be diagnosed with multiple myeloma and approximately 12,650 people are expected to die from the disease in the U.S. in 2016.[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 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 and as a monotherapy 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. DARZALEX is indicated in Europe for use 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. 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).[7,8,9,10,11]

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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 multiple myeloma 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, NKT-cell lymphoma, amyloidosis, and solid tumors. 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, non-Hodgkin's lymphoma and solid tumors. 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, 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.

[1] American Cancer Society. "Multiple Myeloma Overview." Available at http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma.Accessed June 2016.
[2] National Cancer Institute. "A Snapshot of Myeloma." Available at www.cancer.gov/research/progress/snapshots/myeloma. Accessed June 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 June 2016.
[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 June 2016.
[5] American Cancer Society. "How is Multiple Myeloma Diagnosed?" http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed June 2016.

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[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] FDA 2015. Daratumumab Prescribing information. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/761036Orig1s000lbledt.pdf. Last accessed December 2016.
[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] Jansen JH, Bross P, Overdijk MB, et al. Daratumumab, a human CD38 antibody induces apoptosis of myeloma tumor cells via Fc receptor-mediated crosslinking. Blood. 2012;120(21):abstract 2974.
[10] 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.
[11] 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.