Genmab Announces U.S. FDA Approval of DARZALEX® (daratumumab) for Relapsed Multiple Myeloma and Updates Financial Guidance

Company Announcement

- **DARZALEX (daratumumab) approved by U.S. FDA in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for relapsed or refractory multiple myeloma**
- **Financial guidance updated to include milestone payments totaling USD 65 million**

Copenhagen, Denmark; November 21, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today the U.S. Food and Drug Administration (FDA) has approved the use of DARZALEX® (daratumumab) 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 July 2016, daratumumab was granted a Breakthrough Therapy Designation (BTD) in this patient population. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize DARZALEX.

Genmab will receive milestone payments totaling USD 65 million from Janssen associated with the first commercial sale of the daratumumab in combination with lenalidomide and dexamethasone and in combination with bortezomib and dexamethasone in the United States. As this will occur quickly after this approval, Genmab is improving its financial guidance for the year. See the Outlook section of this announcement for more information.

“This is an exciting day for patients with multiple myeloma in the U.S., who will now have the opportunity to receive DARZALEX at an earlier point in treatment of their disease,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “We believe daratumumab has the potential to become a backbone therapy for multiple myeloma.”

The approval was based on data from two Phase III studies: the CASTOR study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone alone in patients with relapsed or refractory multiple myeloma, and the POLLUX study of daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone in patients with relapsed or refractory multiple myeloma.

Data from the Phase I study of daratumumab in combination with pomalidomide and dexamethasone in relapsed or refractory multiple myeloma was also submitted as part of the supplemental Biologics License Application (sBLA) for daratumumab in the newly approved indications in August 2016. The FDA granted a Standard Review for the use of daratumumab in combination with pomalidomide and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target date of June 17, 2017 for the combination of daratumumab with pomalidomide and dexamethasone.

DARZALEX was initially approved by the FDA in November 2015 for the monotherapy 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 immunomodulatory agent.

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OUTLOOK

MDKK	Revised Guidance	Previous Guidance
Revenue	1,650 – 1,700	1,200 – 1,250
Operating expenses	(800) – (850)	(800) – (850)
Operating income	825 – 875	375 – 425
Cash position at end of year*	3,650 – 3,750	3,650 – 3,750
**Cash, cash equivalents, and marketable securities*		

Genmab is improving the 2016 financial guidance it published on November 2, 2016, due to the inclusion of daratumumab milestones totaling USD 65 million. The milestones are associated with the first commercial sale of DARZALEX in combination with lenalidomide and dexamethasone, and bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy in the U.S. following FDA approval in this indication.

Operating Result

We expect our 2016 revenue to be in the range of DKK 1,650 – 1,700 million, an increase of DKK 450 million compared to the previous guidance. We have increased our projected daratumumab milestones to DKK 1,020 million (previously DKK 570 million) due to inclusion of USD 65 million in milestone payments triggered by the first commercial sale of DARZALEX in combination with lenalidomide and dexamethasone, and bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. We expect DARZALEX royalties to remain in the range of DKK 400 – 450 million, based on an estimated USD 500 – 550 million of DARZALEX sales in 2016. 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 825 – 875 million, compared to DKK 375 – 425 million in the previous guidance.

Cash Position

There is no change to the projected 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 assumes that no significant agreements are entered into during 2016 that could materially affect the results.

About the CASTOR study

The Phase III CASTOR study included 498 patients who had relapsed or refractory multiple myeloma. Patients were randomized to receive either daratumumab combined with subcutaneous bortezomib (a type of chemotherapy, called a proteasome inhibitor) and dexamethasone (a corticosteroid), or

bortezomib and dexamethasone alone. The study met the primary endpoint of improving progression free survival (PFS); Hazard Ratio (HR) = 0.39, 95% CI 0.28-0.53, 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 also significantly increased the overall response rate (ORR) (79% vs. 60%, p<0.0001), including doubling rates of complete response (CR) or better (18% vs. 9%) and rates of very good partial response (VGPR) or better (57% vs. 28%). The most common grade 3 or 4 adverse events in patients treated with daratumumab in combination with bortezomib and dexamethasone compared to those who only received bortezomib and dexamethasone were thrombocytopenia (47% vs 35%), anemia (13% vs 14%) and neutropenia (15% vs 5%). Daratumumab-associated infusion-related reactions were reported in 45% of patients, were mostly grade 1/2, and occurred predominantly during the first infusion. This is consistent with the reported safety profile of daratumumab monotherapy and background bortezomib/dexamethasone therapy.

About the POLLUX 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 study met the primary endpoint of improving progression-free survival (PFS) (Hazard Ratio (HR) = 0.37; 95% CI 0.27-0.52; p<0.0001) for patients treated with daratumumab versus patients who did not receive daratumumab. 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. Additionally, daratumumab significantly increased ORR (91% vs. 75%, p<0.0001, including doubling rates of CR or better (42% vs. 19%), as well as rates of VGPR or better (75% vs. 43%). The most common grade 3 or 4 adverse events in patients treated with daratumumab in combination with lenalidomide and dexamethasone versus those who received only lenalidomide and dexamethasone were neutropenia (53% vs 40%), thrombocytopenia (13% vs 15%), and anemia (13% vs 19%). Daratumumab-associated infusion-related reactions occurred in 48% of patients, were mostly grade 1/2, and occurred predominantly during the first infusion. Overall, the safety profile was consistent with known toxicities of daratumumab monotherapy and combination therapy of lenalidomide and dexamethasone.

Both the CASTOR study and the POLLUX study were published in *The New England Journal of Medicine* in August 2016 and October 2016 respectively.

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 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.

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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. 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), 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.[7,11]

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 solid tumors.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS - None

WARNINGS AND PRECAUTIONS
Infusion Reactions – DARZALEX® can cause severe infusion reactions. Approximately half of all patients experienced a reaction, most during the first infusion. Infusion reactions can also occur with subsequent infusions. Nearly all reactions occurred during infusion or within 4 hours of completing an infusion. Prior to the introduction of post-infusion medication in clinical trials, infusion reactions occurred up to 48 hours after infusion. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt infusion for reactions of any severity and institute medical management as needed. Permanently discontinue therapy for life-threatening (Grade 4) reactions. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion reactions, administer oral corticosteroids to all patients following DARZALEX infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

Interference with Serological Testing - Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted. Notify blood transfusion

centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX. Type and screen patients prior to starting DARZALEX.

Neutropenia - DARZALEX may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. DARZALEX dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX is recommended. Consider supportive care with growth factors.

Thrombocytopenia - DARZALEX may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. DARZALEX dose delay may be required to allow recovery of platelets. No dose reduction of DARZALEX is recommended. Consider supportive care with transfusions.

Interference with Determination of Complete Response - Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both, the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Adverse Reactions – In patients who received DARZALEX in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (92%), thrombocytopenia (73%), upper respiratory tract infection (65%), infusion reactions (48%), diarrhea (43%), fatigue (35%), cough (30%), muscle spasms (26%), nausea (24%), dyspnea (21%) and pyrexia (20%). The overall incidence of serious adverse events was 49%. Serious adverse reactions were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%) and pyrexia (3%).

In patients who received DARZALEX in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: thrombocytopenia (90%), neutropenia (58%), peripheral sensory neuropathy (47%), infusion reactions (45%), upper respiratory tract infection (44%), diarrhea (32%), cough (27%), peripheral edema (22%), and dyspnea (21%). The overall incidence of serious adverse events was 42%. Serious adverse reactions were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%).

In patients who received DARZALEX as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (60%), thrombocytopenia (48%), infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). Serious adverse reactions were reported in 51 (33%) patients. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%).

DRUG INTERACTIONS

Effect of Other Drugs on daratumumab: The coadministration of lenalidomide or bortezomib with DARZALEX did not affect the pharmacokinetics of daratumumab.

Effect of Daratumumab on Other Drugs: The coadministration of DARZALEX with bortezomib did not affect the pharmacokinetics of bortezomib.

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. A subcutaneous formulation of ofatumumab is in development for relapsing multiple sclerosis. 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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