Genmab Announces U.S. FDA Approval of DARZALEX® (daratumumab) in Combination with Pomalidomide and Dexamethasone for Relapsed or Refractory Multiple Myeloma

Company Announcement

- **DARZALEX (daratumumab) approved by U.S. FDA in combination with pomalidomide and dexamethasone for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor**
- **Genmab to receive milestone payments totaling USD 25 million**

Copenhagen, Denmark; June 16, 2017 – 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 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. DARZALEX is being developed under an August 2012 agreement in which Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop, manufacture and commercialize the product. Genmab will receive milestone payments totaling USD 25 million from Janssen in connection with the approval and first commercial sale of DARZALEX under the newly expanded label. The sale is expected to occur quickly after the approval. The approval and related milestones do not impact the financial guidance issued by Genmab on May 10, 2017.

"We are very pleased to receive the FDA's decision to approve DARZALEX in combination with pomalidomide and dexamethasone. This offers another alternative to patients with multiple myeloma who haven't seen lasting effects from other types of treatment," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The approval was based on data from the Phase I (MMY1001, EQUULEUS) study of daratumumab in combination with pomalidomide and dexamethasone in relapsed or refractory multiple myeloma.

About the EQUULEUS study
The Phase I EQUULEUS open-label study, Pom-D arm, included 103 patients with multiple myeloma who had received prior treatment with a proteasome inhibitor (PI) and an immunomodulatory agent. Patients in the study received 16 mg/kg daratumumab in combination with pomalidomide and dexamethasone. The overall response rate in the study was 59% (95% CI: 49.1%, 68.8%), with very good partial response (VGPR) achieved in 28% of patients. Complete response (CR) was achieved in 6% of patients and stringent CR (sCR) was achieved in 8% of patients. The median time to response was 1 month (range: 0.9 to 2.8 months). The median duration of response was 13.6 months (range: 0.9+ to 14.6+ months). The most frequent adverse reactions (>20%) in the study were: infusion reactions (50%), diarrhea (38%), nausea (30%), vomiting (21%), fatigue (50%), pyrexia (25%), upper respiratory tract infection (50%), muscle spasms (26%), cough (43%) and dyspnea (33%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions (Grade 3/4) reported in ≥5% patients included pneumonia (7%). The most common treatment-emergent hematology laboratory abnormalities were lymphopenia (94%), neutropenia (95%), thrombocytopenia (75%) and anemia (57%). The most common Grade 3/4 treatment-emergent hematology laboratory abnormalities were neutropenia (82%), lymphopenia (71%), anemia (30%) and thrombocytopenia (20%).

The median age of patients in the study was 64 years with 8% of patients older than 75. Patients in the study had received a median of four prior lines of therapy, and 74% of patients had received prior autologous stem cell transplant (ASCT). Eighty-nine percent of patients were refractory to lenalidomide and 71% were refractory to bortezomib; 64% of patients were refractory to bortezomib and lenalidomide.

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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 were expected to be diagnosed with multiple myeloma and approximately 12,650 people were 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; in combination with pomalidomide and dexamethasone for the treatment of 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.[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 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. DARZALEX is the first human CD38 monoclonal antibody approved in Europe. 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]

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, NKT-cell lymphoma, amyloidosis, myelodysplastic syndromes 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.

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%).

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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 in combination with pomalidomide and dexamethasone, the most frequently reported adverse reactions (incidence >20%) were: infusion reactions (50%), diarrhea (38%), nausea (30%), vomiting (21%), fatigue (50%), pyrexia (25%), upper respiratory tract infection (50%), muscle spasms (26%), cough (43%) and dyspnea (33%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions (Grade 3/4) reported in ≥5% patients included pneumonia (7%). The most common treatment-emergent hematology laboratory abnormalities were lymphopenia (94%), neutropenia (95%), thrombocytopenia (75%) and anemia (57%). The most common Grade 3/4 treatment-emergent hematology laboratory abnormalities were neutropenia (82%), lymphopenia (71%), anemia (30%) and thrombocytopenia (20%).

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, pomalidomide 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, 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, other blood cancers, 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

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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.

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