

## Genmab Announces Studies of Daratumumab (DARZALEX®) in Combination with Nivolumab in Solid Tumors and Multiple Myeloma

### Media Release

- Phase Ib/II studies of daratumumab in combination with Bristol-Myers Squibb's (BMS) immune checkpoint inhibitor nivolumab in solid tumors and multiple myeloma to start in 2017
- Studies conducted under a clinical trial collaboration agreement between Janssen and BMS

**Copenhagen, Denmark; January 5, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today daratumumab will be investigated in Phase Ib/II clinical studies in combination with nivolumab (a PD-1 checkpoint inhibitor) in several solid tumor types and in multiple myeloma.**

The studies will be conducted under a clinical trial collaboration agreement between Genmab's licensing partner for daratumumab, Janssen Biotech, Inc., and Bristol-Myers Squibb (BMS). The studies will be sponsored by BMS.

The solid tumor studies will evaluate the safety, tolerability and clinical benefit of daratumumab in combination with nivolumab in patients with advanced or metastatic tumors including non-small cell lung, head and neck, pancreatic, colorectal and triple negative breast cancers. Additional tumor types may also be evaluated. The multiple myeloma study will evaluate the safety and tolerability of daratumumab in combination with nivolumab with or without pomalidomide and dexamethasone in relapsed-refractory multiple myeloma. Studies are expected to start in 2017. In 2016, daratumumab was added to an existing BMS Phase I study investigating daratumumab in combination with nivolumab in multiple myeloma; this study is ongoing.

"The development program for daratumumab continues to rapidly expand and we look forward to the start of these new studies in combination with nivolumab, and in particular, to seeing what impact the combination of these two immunomodulatory antibodies have in treating multiple myeloma and various solid tumors," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

### 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.<sup>1</sup> Multiple myeloma is the third most common blood cancer in the U.S., after leukemia and lymphoma.<sup>2</sup> 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.<sup>3</sup> Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would die from the disease in 2015.<sup>4</sup> 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.<sup>5</sup> Patients who relapse after treatment with standard therapies, including proteasome inhibitors or immunomodulatory agents, have poor prognoses and few treatment options.<sup>6</sup>

### 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.<sup>7</sup> 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

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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](http://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).<sup>7,8,9,10,11</sup>

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, lung cancer and other 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](http://www.genmab.com).

### Contact:

Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communication  
T: +45 33 44 77 20; M: +45 25 12 62 60; E: [r.gravesen@genmab.com](mailto:r.gravesen@genmab.com)

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<sup>1</sup> American Cancer Society. "Multiple Myeloma Overview." Available at <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed June 2016.

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<sup>2</sup> National Cancer Institute. "A Snapshot of Myeloma." Available at [www.cancer.gov/research/progress/snapshots/myeloma](http://www.cancer.gov/research/progress/snapshots/myeloma). Accessed June 2016.

<sup>3</sup> 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.

<sup>4</sup> 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](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.

<sup>5</sup> American Cancer Society. "How is Multiple Myeloma Diagnosed?" <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis>. Accessed June 2016.

<sup>6</sup> 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.

<sup>7</sup> FDA 2015. Daratumumab Prescribing information. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/761036Orig1s000bledt.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/761036Orig1s000bledt.pdf). Last accessed December 2016.

<sup>8</sup> 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.

<sup>9</sup> Jansen, JH et al. Daratumumab, a human CD38 antibody induces apoptosis of myeloma tumor cells via Fc receptor-mediated crosslinking. *Blood*. 2012;120(21):abstract 2974.

<sup>10</sup> 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.

<sup>11</sup> 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.