

## **Genmab Announces Approval of DARZALEX® (daratumumab) for Relapsed or Refractory Multiple Myeloma in Japan**

### **Company Announcement**

- **DARZALEX approved for relapsed or refractory multiple myeloma in Japan**
- **Genmab to receive USD 25 million in milestone payments upon first commercial sale in Japan**

**Copenhagen, Denmark; September 27, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that the Ministry of Health, Labor and Welfare (MHLW) in Japan has approved the use of DARZALEX® (daratumumab) in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma.** 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 earn milestone payments of USD 25 million from Janssen upon the first commercial sale of DARZALEX in Japan in the coming months. As the first commercial sale could take place in either late 2017 or early 2018, Genmab is not updating its financial guidance for 2017. If the first commercial sale is achieved prior to year end, Genmab expects to update its financial guidance at that time.

“Multiple myeloma is one of the most common forms of blood cancer in Japan and we are very pleased that DARZALEX will soon also become available for Japanese multiple myeloma patients who have failed other treatments,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The approval is based on two pivotal studies: 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, including two safety studies (MMY1002 and MMY1005) in Japanese patients with relapsed or refractory multiple myeloma.

### **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 Japan, after leukemia and lymphoma.<sup>2</sup> Approximately 8,700 new patients were expected to be diagnosed with multiple myeloma and approximately 4,200 people were expected to die from the disease in Japan in 2016.<sup>2</sup> Globally, it was estimated that 124,225 people would be diagnosed and 87,084 would die from the disease in 2015.<sup>3</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>4</sup> Patients who relapse after treatment with standard therapies, including proteasome inhibitors or immunomodulatory agents, have poor prognoses and few treatment options.<sup>5</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; 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 (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.<sup>6</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 in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the

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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. In Japan, DARZALEX is approved in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for treatment of adults with relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market. 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>6,7,8,9,10</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, 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.

### 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](http://www.genmab.com).

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## Genmab Announces Approval of DARZALEX® (daratumumab) for Relapsed or Refractory Multiple Myeloma in Japan

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### References

- <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.
- <sup>2</sup> Cancer Information Service. "Projected Cancer Statistics 2016." Available at [http://ganjoho.jp/en/public/statistics/short\\_pred.html](http://ganjoho.jp/en/public/statistics/short_pred.html). Accessed September 2017.
- <sup>3</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>4</sup> American Cancer Society. "How is Multiple Myeloma Diagnosed?" <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis>. Accessed June 2016.
- <sup>5</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>6</sup> DARZALEX Prescribing information, June 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/761036s005lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761036s005lbl.pdf). Last accessed June 2017.
- <sup>7</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>8</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>9</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.
- <sup>10</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.