

# Patent Infringement Lawsuit Filed Against Genmab and Janssen in the United States Regarding DARZALEX®

## **Company Announcement**

- Morphosys AG files patent infringement complaint against Genmab and Janssen Biotech, Inc. with the US District Court of Delaware
- Complaint is under US patent no. 8,263,746

Copenhagen, Denmark; April 4, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that Morphosys apparently has filed a complaint at the US District Court of Delaware against Genmab and Genmab's collaboration partner Janssen Biotech, Inc. for patent infringement under US patent no. 8,263,746 based on activities relating to manufacture, use and sale of DARZALEX (daratumumab) in the United States. The US patent relates to CD38 antibodies defined by functional features.

DARZALEX is approved in the US 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 and a marketing application has been submitted in the EU for daratumumab for use in patients with relapsed and refractory multiple myeloma by Janssen.

Janssen will in consultation with Genmab determine the appropriate action in response to the complaint.

## **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.¹ DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (FDA) approval to treat multiple myeloma. 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, <sup>1,2</sup> and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity, <sup>1,2</sup> antibody-dependent cellular phagocytosis<sup>3,4</sup> and antibody-dependent cellular cytotoxicity. <sup>1,2</sup> In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and subsets of regulatory T cells (Tregs) both of which express CD38. These reductions in MDSCs and Tregs were paralleled by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow. <sup>1</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 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 and non-Hodgkin's lymphoma.

### **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. Daratumumab is in clinical development for additional

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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 <a href="https://www.genmab.com">www.genmab.com</a>.

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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 <a href="www.genmab.com">www.genmab.com</a>. 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.

Genmab A/S and its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo™; the DuoBody logo®; the HexaBody logo™; HuMax®; HuMax-CD20®; DuoBody®; HexaBody® and UniBody®. Arzerra® is a trademark of Novartis AG or its affiliates. DARZALEX® is a trademark of Janssen Biotech, Inc.

#### References

- <sup>1</sup> DARZALEX Prescribing Information, November 2015.
- <sup>2</sup> De Weers et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors. The Journal of Immunology. 2011. Vol. 186, No. 3 1840-1848.
- <sup>3</sup> Overdijk et al. Phagocytosis Is A Mechanism of Action for daratumumab. Available at https://ash.confex.com/ash/2012/webprogram/Paper51257.html. Accessed September 2015.

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<sup>4</sup> Khagi and Mark. Potential role of daratumumab in the treatment of multiple myeloma. Onco Targets Ther. 2014; 7: 1095–1100.