

# Genmab Announces New Phase III Study of Daratumumab in Front Line Multiple Myeloma

## **Company Announcement**

- Second Phase III study of daratumumab in front line multiple myeloma
- Study expected to start in the first half of 2015

Copenhagen, Denmark; August 11, 2014 – Genmab A/S (OMX: GEN) announced today that its collaboration partner, Janssen Biotech, Inc. ("Janssen") plans to start a new Phase III study of daratumumab in multiple myeloma. The study (MMY3008) will compare daratumumab in combination with lenalidomide and dexamethasone to lenalidomide and dexamethasone alone as front line treatment for patients who are not considered candidates for stem cell transplantation (SCT). The study is planned to start in the first half of 2015. The first Phase III study in front line multiple myeloma was announced in July and is expected to start towards the end of this year. Today's news is the fourth daratumumab Phase III study to be announced.

"This new study of daratumumab in front line multiple myeloma is part of the extensive development plan created under our collaboration with Janssen Biotech for our CD38 antibody daratumumab," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

### About the MMY3008 study

This Phase III study is a randomized, open-label, multicenter study and will include approximately 700 newly diagnosed, chemotherapy naïve multiple myeloma patients ineligible for stem cell transplantation (SCT). Patients will be randomized to receive either daratumumab combined with lenalidomide (an immunomodulatory agent) and dexamethasone (a corticosteroid) or lenalidomide and dexamethasone alone. The primary endpoint of the study is progression free survival (PFS).

#### **About daratumumab**

Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

#### About Genmab A/S

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company currently has one marketed antibody, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications, a clinical pipeline with both late and early stage programs, and an innovative pre-clinical 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. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab's strategy and the company 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"



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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.

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