

Daratumumab and Ofatumumab Data to Be Presented at 21st Congress of EHA

Media Release

- **Daratumumab interim data from Phase III POLLUX study to be presented at EHA**
- **Daratumumab Phase III CASTOR data to be presented**
- **Two additional daratumumab abstracts to be presented**
- **Total of 8 ofatumumab abstracts to be presented**

Copenhagen, Denmark; May 19, 2016 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that data on daratumumab and ofatumumab will be presented at the 21st Congress of the European Hematology Association (EHA) in Copenhagen, June 9-12. The abstracts have been published at the EHA website at www.ehaweb.org, with the exception of the daratumumab Phase III CASTOR abstract, which is under embargo.

“At this year’s EHA congress, physicians will have the opportunity to learn more about both the daratumumab and ofatumumab programs. We are particularly excited that the highly positive interim data from the Phase III POLLUX study combining daratumumab with lenalidomide and dexamethasone for the treatment of relapsed or refractory multiple myeloma will be presented at this important hematology meeting in Europe,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Daratumumab abstracts submitted by Janssen

An open-label, randomised, Phase 3 study of daratumumab, lenalidomide, and dexamethasone (DRd) versus lenalidomide and dexamethasone (Rd) in relapsed or refractory multiple myeloma (RRMM): POLLUX – Oral presentation, Sunday, June 12, 12:30PM - 12:45PM CEST
These data have been selected for inclusion in the EHA press briefing on June 10.

Phase III randomized controlled study of daratumumab, bortezomib, and dexamethasone (DVd) versus bortezomib and dexamethasone (Vd) in patients (pts) with relapsed or refractory multiple myeloma (RRMM): CASTOR study – Oral presentation, Sunday, June 12, 12:00PM - 12:15PM CEST

Daratumumab monotherapy compared with real-world historical control data in heavily pretreated patients with highly refractory multiple myeloma: an adjusted treatment comparison – E-Poster, Thursday, June 9

Pharmacodynamic relationship between natural killer cells and daratumumab exposure in relapsed/refractory multiple myeloma – Poster presentation, Friday, June 10, 5:15PM – 6:45PM CEST

Ofatumumab abstracts submitted by Novartis

A phase III study of ofatumumab vs rituximab in indolent B-cell non-Hodgkin lymphoma relapsed after rituximab-containing therapy (HOMER): results of the interim analysis – Poster presentation, Friday, June 10, 5:15PM – 6:45PM CEST

Estimating cost effectiveness based on a single-arm clinical trial: ofatumumab for double-refractory chronic lymphocytic leukaemia - Poster presentation, Friday, June 10, 5:15PM – 6:45PM CEST

Ofatumumab and Idelalisib abstracts submitted by Gilead

Updated results of a phase 3 randomized, controlled study of idelalisib in combination with ofatumumab for previously treated chronic lymphocytic leukemia (CLL) – Poster presentation, Friday, June 10, 5:15PM - 6:45PM CEST

Management of transaminase elevations associated with idelalisib – Poster presentation, Friday, June 10, 5:15PM – 6:45PM CEST

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An evaluation of the CLL-IPI score and comprehensive prognostic factor analysis in patients with r/r CLL in idelalisib phase 3 randomized studies – Poster presentation, Friday, June 10, 5:15PM – 6:45PM CEST

Discontinuation of idelalisib treatment due to disease progression in patients with relapsed and refractory CLL: an evaluation of outcomes – Poster presentation, Friday, June 10, 5:15PM – 6:45PM CEST

Idelalisib plus an anti-CD20 antibody in patients with chronic lymphocytic leukemia (CLL) who are HBV core antibody positive: similar patterns of liver test abnormalities –E-Poster, Thursday, June 9

Patterns of idelalisib treatment-emergent lymphocytosis in patients with CLL or SLL– E-Poster, Thursday, June 9

The above studies represent investigational uses for which the safety and efficacy of Arzerra (ofatumumab) have not been demonstrated. Arzerra may not become commercially available for these indications.

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,^{1,2} and multiple immune-mediated mechanisms, including complement-dependent cytotoxicity,^{1,2} antibody-dependent cellular phagocytosis^{3,4} and antibody-dependent cellular cytotoxicity.^{1,2} In addition, daratumumab therapy results in a reduction of immune-suppressive myeloid derived suppressor cells (MDSCs) and subsets of regulatory T cells (Tregs) and B cells (Bregs), all of which express CD38. These reductions in MDSCs, Tregs and Bregs were accompanied by increases in CD4+ and CD8+ T cell numbers in both the peripheral blood and bone marrow.¹

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, non-Hodgkin's lymphoma and a solid tumor.

About Ofatumumab (Arzerra®)

Ofatumumab is a human monoclonal antibody that is designed to target the CD20 molecule found on the surface of chronic lymphocytic leukemia (CLL) cells and normal B lymphocytes.

In the United States, Arzerra is approved for use in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate. Arzerra is also approved as extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL in the U.S. In the European Union, Arzerra is approved for use in combination with chlorambucil or bendamustine for the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy. In more than 50 countries worldwide, Arzerra is also indicated as monotherapy for the treatment of patients with CLL who are refractory after prior treatment with fludarabine and alemtuzumab.

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Arzerra is not approved anywhere in the world for treatment of indolent B-cell non-Hodgkin lymphoma.

[Please see full Prescribing Information, including Boxed WARNING for Arzerra \(ofatumumab\).](#)

Arzerra is marketed under a collaboration agreement between Genmab and Novartis. Novartis also has rights to develop ofatumumab in autoimmune indications, including multiple sclerosis.

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 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 www.genmab.com.

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¹ DARZALEX Prescribing Information, November 2015.

² 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.

³ 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: 311-321.

⁴ Khagi, Y and Mark, TM. Potential role of daratumumab in the treatment of multiple myeloma. *Onco Targets Ther*. 2014; 7: 1095-1100.