

Genmab Announces Daratumumab and Ofatumumab Data to Be Presented at American Society of Hematology Annual Meeting (ASH)

Media Release

- **19 abstracts on Genmab programs scheduled for presentation at ASH including 3 daratumumab oral presentations and 11 daratumumab poster presentations**
- **Daratumumab highlights: new data on lenalidomide and pomalidomide combination treatments, updates on monotherapy studies and novel data on immunomodulatory effects of daratumumab**
- **5 abstracts on ofatumumab data to be presented**

Copenhagen, Denmark; November 5, 2015 – Genmab A/S (OMX: GEN) announced today that 14 daratumumab and 5 ofatumumab abstracts have been accepted for presentation at the 57th American Society of Hematology (ASH) Annual Meeting and Exposition December 5-8 in Orlando, Florida. The abstracts are available on the ASH website at www.hematology.org.

“We are delighted that daratumumab will be featured in three oral presentations at the 2015 ASH Annual Meeting. We are particularly looking forward to the presentation of the updated data from the Phase I study of daratumumab in combination with pomalidomide and dexamethasone in relapsed or relapsed and refractory multiple myeloma and the poster presentation describing previously unknown immunomodulatory effects of daratumumab,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “Data from the Phase II study of daratumumab in patients with heavily pretreated relapsed or refractory multiple myeloma, the Phase I/II study of daratumumab in combination with lenalidomide and dexamethasone in patients with relapsed and refractory multiple myeloma will also be presented in oral sessions.”

Daratumumab

Highlights

Clinical Efficacy of Daratumumab Monotherapy in Patients with Heavily Pretreated Relapsed or Refractory Multiple Myeloma – Oral presentation, Saturday, December 5

Daratumumab in Combination With Lenalidomide and Dexamethasone in Patients With Relapsed or Relapsed and Refractory Multiple Myeloma: Updated Results from a Phase 1/2 Study (GEN503) – Oral presentation, Monday, December 7

Immunomodulatory Effects and Adaptive Immune Response to Daratumumab in Multiple Myeloma – Poster presentation, Sunday, December 6

Open-label, Multicenter Phase 1b Study of Daratumumab in Combination with Pomalidomide and Dexamethasone in Patients with ≥ 2 Lines of Prior Therapy and Relapsed or Relapsed and Refractory Multiple Myeloma (MM) – Oral presentation, Monday, December 7

Other abstracts

Serum Proteomic Analysis of Multiple Myeloma Subjects Treated with Daratumumab Monotherapy – Poster presentation, Saturday, December 5

Management of Infusion-related Reactions Following Daratumumab Monotherapy in Patients with ≥ 3 Lines of Prior Therapy or Double Refractory Multiple Myeloma (MM): 54767414MMY2002 (Sirius) – Poster presentation, Saturday, December 5

Outcomes and Management of Red Blood Cell Transfusions in Multiple Myeloma Patients Treated with Daratumumab – Poster presentation, Monday, December 7

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Understanding the Dose Regimen for Daratumumab in Patients with Relapsed or Refractory Multiple Myeloma after Prior Proteasome Inhibitors and Immunomodulatory Drugs: A Quantitative Pharmacologic Perspective – Poster presentation, Monday, December 7

Target-mediated Drug Disposition of Daratumumab Following Intravenous Infusion in Relapsed or Refractory Multiple Myeloma after Prior Proteasome Inhibitors and Immunomodulatory Drugs: A Population Pharmacokinetic Analysis – Poster presentation, Monday, December 7

Analyses of Real-World Data on Overall Survival in Multiple Myeloma Patients With ≥ 3 Prior Lines of Therapy Including a PI and an IMiD, or Double Refractory to a PI and an IMiD – Poster presentation, Monday, December 7

Treatment of Ex Vivo Expanded NK Cells with Daratumumab F(ab')₂ Fragments Protects Adoptively Transferred NK Cells from Daratumumab-mediated Killing and Augments Daratumumab-induced Antibody Dependent Cellular Toxicity (ADCC) of Myeloma – Poster presentation, Monday, December 7

Generation and characterization of microvesicles after Daratumumab interaction with myeloma cells – Poster presentation, Saturday, December 5

Expression Profile of CD38 And Related Ectoenzymes in Myeloma Bone Niche: A Rational Basis for the Use of Daratumumab to Inhibit Osteoclast Formation and Activity – Poster presentation, Sunday, December 6

International Validation of a Dithiothreitol (DTT)-based Method to Resolve the Daratumumab Interference with Blood Compatibility Testing – Poster presentation, Monday, December 7

Ofatumumab

Risk-adapted Induction and Maintenance with Ofatumumab in Previously Untreated Patients with CLL/SLL – Poster presentation, Saturday, December 5

A Phase II Study of Ofatumumab-High Dose Methyl-prednisolone Followed by Ofatumumab-Alemtuzumab in 17p Deleted or TP53 Mutated CLL – Poster presentation, Monday, December 7

A Phase II Study of Ofatumumab in Combination with a Pan-AKT Inhibitor (Afulresertib) in Previously Treated Patients with CLL – Poster presentation, Saturday, December 5

A Phase II Study of Alemtuzumab-Ofatumumab (A+O) Combination in Patients with Previously Untreated CLL – An Update – Poster presentation, Saturday, December 5

Sequential Therapy with Ofatumumab, High Dose Methyl-prednisolone and Lenalidomide Is a Safe and Effective Regimen for the Treatment of Previously Treated and Untreated CLL/SLL: The HiLO Trial – Poster presentation, Sunday, December 6

About daratumumab

Daratumumab is an investigational 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 induces rapid tumor cell death through multiple immune-mediated mechanisms¹, including complement-dependent cytotoxicity¹, antibody-dependent cellular phagocytosis² and antibody-dependent cellular cytotoxicity¹, as well as via induction of apoptosis³. Five Phase III clinical studies with daratumumab in relapsed and frontline settings are currently ongoing. Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as

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smoldering myeloma and non-Hodgkin 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, manufacture and commercialize daratumumab.

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. 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.

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

Arzerra is marketed under a collaboration agreement between Genmab and Novartis.

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 currently has one marketed antibody, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and daratumumab in clinical development for multiple myeloma and non-Hodgkin's lymphoma, in addition to other clinical 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. 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 Michel 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; 186, p.1840-1848.

² Yulian Khagi and Tomer M Mark. Potential role of daratumumab in the treatment of multiple myeloma. *Onco Targets Ther*. 2014; 7:p. 1095–1100.

³ Jing Yang and Qing Yi. Therapeutic monoclonal antibodies for multiple myeloma: an update and future perspectives. *Am J Blood Res*. 2011; 1;p. 22–33.