

## Genmab Announces Abstracts Evaluating Products in Pipeline, Portfolio to be Presented at American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) Congress

### Media Release

Copenhagen, Denmark, May 19, 2021

- **Poster presentations highlighting clinical data for investigational bispecific antibody epcoritamab (DuoBody®-CD3xCD20) at ASCO and EHA**
- **Phase 3 trial-in-progress presentations for epcoritamab and investigational antibody-drug conjugate (ADC) tisotumab vedotin at ASCO**
- **Multiple poster and oral presentations highlighting daratumumab data at both congresses**

Genmab A/S (Nasdaq: GMAB) announced today that multiple abstracts evaluating several products in the company's portfolio, or created using Genmab's innovation, will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, being held virtually June 4-8, and at the European Hematology Association (EHA) Congress, being held virtually June 9-17. The presentations will include clinical data evaluating the investigational bispecific antibody epcoritamab (DuoBody®-CD3xCD20) in patients with Non-Hodgkin Lymphoma (NHL), several studies evaluating Janssen Biotech, Inc. (Janssen)'s daratumumab and the subcutaneous formulation of daratumumab, and multiple abstracts evaluating Janssen's bispecific program, which leverages Genmab's DuoBody technology platform. In addition, trial-in-progress (TiPs) summaries of phase 3 trials evaluating epcoritamab and the investigational antibody-drug conjugate (ADC) tisotumab vedotin in patients with cervical cancer will be presented.

All the abstracts have been published on the ASCO and EHA websites and may be accessed online via the [ASCO Meeting Library](#) and the [EHA Open Access Library](#).

Epcoritamab is being co-developed by Genmab and AbbVie (NYSE: ABBV). Tisotumab vedotin is being co-developed by Genmab and Seagen Inc. (Nasdaq: SGEN), under an agreement in which the companies share all costs and profits for the product on a 50:50 basis. Daratumumab is being developed by Janssen under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab, and the companies have a collaboration to create and develop bispecific antibodies using Genmab's DuoBody technology platform.

"The breadth and depth of the data being presented at ASCO and EHA demonstrate Genmab's dedication to creating and developing a comprehensive portfolio of innovative and differentiated antibody medicines with the goal of improving the lives of people with cancer and their families," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We will continue to progress the investigational products in our pipeline, alone and together with our partners, to deliver new therapeutic options to patients in need."

Abstracts accepted for presentation at ASCO include:

#### **Epcoritamab (DuoBody-CD3xCD20):**

- **Subcutaneous Epcoritamab in Patients With Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma: Safety Profile and Anti-tumor Activity**
- **Phase 3 Trial (GCT3013-05) of Epcoritamab Versus Standard of Care in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)**

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### Tisotumab vedotin

- Tisotumab Vedotin vs Investigator's Choice Chemotherapy in Second- or Third-Line Recurrent or Metastatic Cervical Cancer (innovaTV 301/ENGOT-cx12/GOG 3057, Trial in Progress)

### Daratumumab:

- Subcutaneous Daratumumab + Bortezomib, Cyclophosphamide, and Dexamethasone (VCd) in Patients With Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results From the Phase 3 ANDROMEDA Study
- Daratumumab (DARA) Maintenance or Observation (OBS) After Treatment With Bortezomib, Thalidomide and Dexamethasone (VTd) With or Without DARA and Autologous Stem Cell Transplant (ASCT) in Patients (pts) With Newly Diagnosed Multiple Myeloma (NDMM): CASSIOPEIA Part 2

Abstracts accepted for presentation at EHA include:

### Epcoritamab (DuoBody-CD3xCD20):

- Subcutaneous Epcoritamab in Patients With Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma: Safety Profile and Anti-tumor Activity

### Daratumumab:

- Subcutaneous Daratumumab + Bortezomib, Cyclophosphamide, and Dexamethasone (VCd) in Patients With Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results From the Phase 3 ANDROMEDA Study
- Daratumumab (DARA) Maintenance or Observation (OBS) After Treatment With Bortezomib, Thalidomide and Dexamethasone (VTd) With or Without DARA and Autologous Stem Cell Transplant (ASCT) in Patients (pts) With Newly Diagnosed Multiple Myeloma (NDMM): CASSIOPEIA Part 2
- Phase 3 Study of Daratumumab, Bortezomib, Melphalan, and Prednisone (D-VMP) Versus Bortezomib, Melphalan, and Prednisone (VMP) in Asian Patients with Newly Diagnosed Multiple Myeloma (NDMM): OCTANS

### About Epcoritamab

Epcoritamab is an investigational IgG1-bispecific antibody created using Genmab's proprietary DuoBody technology. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to tumors to elicit an immune response towards malignant cells. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B cells and induces T cell mediated killing of lymphoma B cells.<sup>1</sup> CD20 is a clinically validated therapeutic target, and is expressed on many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.<sup>2,3</sup> Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' broad oncology collaboration.

### About Tisotumab Vedotin

Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) composed of Genmab's fully human monoclonal antibody specific for tissue factor and Seagen's ADC technology that utilizes a protease-cleavable linker that covalently attaches the microtubule-disrupting agent monomethyl auristatin E (MMAE) to the antibody and releases it upon internalization, inducing target cell death. In cancer biology, tissue factor is a cell-surface protein and associated with tumor growth, angiogenesis, metastasis and poor prognosis.<sup>4</sup> Based on its elevated expression in multiple solid tumors and its rapid internalization, tissue factor was selected as a target for an ADC approach. Tisotumab vedotin is being

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co-developed by Genmab and Seagen, under an agreement in which the companies share all costs and profits for the product on a 50:50 basis.

Tisotumab vedotin is being evaluated in a global phase 3, randomized clinical trial innovaTV 301, versus investigator's choice of chemotherapy in recurrent or metastatic cervical cancer. The primary endpoint is overall survival and secondary endpoints include progression-free survival, duration of response, objective response rate, safety and tolerability. Enrollment is ongoing and the study is intended to support global registrations. In addition, tisotumab vedotin is being evaluated in ongoing clinical trials as monotherapy in recurrent or metastatic cervical cancer, ovarian cancer, and other solid tumors and in combination with commonly used therapies in recurrent or metastatic cervical cancer. These trials are evaluating tisotumab vedotin on a weekly or every three-week dosing schedule. More information about the [innovaTV 301 clinical trial](#), including enrolling sites, as well as other ongoing clinical trials is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### About DARZALEX®(daratumumab)

DARZALEX® (daratumumab) has become a backbone therapy in the treatment of multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with carfilzomib and dexamethasone for the treatment of patients with relapsed/refractory multiple myeloma who have received one to three previous lines of therapy; in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; 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>5</sup> DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma.

DARZALEX is indicated for the treatment of adult patients in Europe via intravenous infusion or subcutaneous administration: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; for use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the 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.<sup>6</sup> Daratumumab is the first subcutaneous CD38 antibody approved in Europe for the treatment of multiple myeloma. The option to split the first infusion of DARZALEX over two consecutive days has been approved in both Europe and the U.S.

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In Japan, DARZALEX intravenous infusion is approved for the treatment of adult patients: in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market in the United States, Europe and Japan. For more information, visit [www.DARZALEX.com](http://www.DARZALEX.com).

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, is approved in the United States for the treatment of adult patients with newly diagnosed light-chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone. It is also approved in the U.S. for the treatment of adult patients with multiple myeloma: in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for ASCT; in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for ASCT; in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for ASCT and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy; in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and as monotherapy, in patients 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>7</sup> DARZALEX FASPRO is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. DARZALEX FASPRO is the first subcutaneous CD38 antibody approved in the U.S. for the treatment of multiple myeloma and the first and only approved treatment for patients with AL amyloidosis in the U.S.

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>5,8,9,10,11</sup>

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. A comprehensive clinical development program for daratumumab is ongoing, including multiple Phase III studies in smoldering, relapsed and refractory and frontline multiple myeloma settings. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases in which CD38 is expressed, such as amyloidosis and T-cell acute lymphocytic leukemia (ALL). Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA for certain indications of multiple myeloma, including as a monotherapy for heavily pretreated multiple myeloma and in combination with certain other therapies for second-line treatment of multiple myeloma.

### About Genmab

Genmab is an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates,

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including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company is headquartered in Copenhagen, Denmark with locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan. For more information, please visit [Genmab.com](http://Genmab.com).

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<sup>1</sup>Engelbert et al. “DuoBody-CD3xCD20 induces potent T-cell-mediated killing of malignant B cells in preclinical models and provides opportunities for subcutaneous dosing.” EBioMedicine. 2020 Feb;52: 102625. doi: 10.1016/j.ebiom.2019.102625. Epub 2020 Jan 23. PMID: 31981978; PMCID: PMC6992935.

<sup>2</sup>Rafiq, Sarwish, et al. “Comparative Assessment of Clinically Utilized CD20-Directed Antibodies in Chronic Lymphocytic Leukemia Cells Reveals Divergent NK Cell, Monocyte, and Macrophage Properties.” Journal of Immunology (Baltimore, Md. 1950), U.S. National Library of Medicine, 15 Mar. 2013, [www.ncbi.nlm.nih.gov/pmc/articles/PMC3631574/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3631574/).

<sup>3</sup>Singh, Vijay, et al. “Development of Novel Anti-Cd20 Monoclonal Antibodies and Modulation in Cd20 Levels on Cell Surface: Looking to Improve Immunotherapy Response.” Journal of Cancer Science & Therapy, U.S. National Library of Medicine, Nov. 2015, [www.ncbi.nlm.nih.gov/pmc/articles/PMC4939752/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4939752/).

<sup>4</sup>Rondon et al. Semin Thromb Hemost 2019; 45:396–412.

<sup>5</sup>DARZALEX Prescribing information, August 2020 [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/761036s029lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761036s029lbl.pdf)  
Last accessed August 2020

<sup>6</sup>DARZALEX Summary of Product Characteristics, available at <https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex>  
Last accessed June 2020

<sup>7</sup>DARZALEX FASPRO Prescribing information, January 2021. Available at:  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761145s002lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761145s002lbl.pdf) Last accessed January 2021

<sup>8</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>9</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>10</sup>Krejci, 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>11</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.