



Genmab Announces that Janssen has Received European Marketing Authorizations for DARZALEX® (daratumumab) Subcutaneous Formulation, Including for the Treatment of Patients with Newly Diagnosed Light-chain (AL) Amyloidosis

June 22, 2021

Company Announcement

- **Janssen received European approval for DARZALEX® SC (daratumumab and hyaluronidase-fihj) in combination with bortezomib, cyclophosphamide and dexamethasone for the treatment of adult patients with newly diagnosed systemic light-chain (AL) amyloidosis, based on data from the Phase 3 ANDROMEDA (AMY3001) study**
- **Janssen also received approval for DARZALEX® SC in combination with pomalidomide and dexamethasone for adult patients with relapsed or refractory multiple myeloma, based on the Phase 3 APOLLO (MMY3013) study**
- **Approvals follow positive opinions by European Committee for Medicinal Products for Human Use (CHMP) in May 2021**

Copenhagen, Denmark; June 22, 2021 – Genmab A/S (Nasdaq: GMAB) announced today that the European Commission (EC) has granted marketing authorization for the daratumumab subcutaneous (SC) formulation (daratumumab and hyaluronidase-fihj), known as DARZALEX® SC in the European Union, in combination with bortezomib, cyclophosphamide, and dexamethasone (VCd) for the treatment of adult patients with newly diagnosed systemic light-chain (AL) amyloidosis. The EC also approved DARZALEX SC in combination with pomalidomide and dexamethasone (Pd) for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor (PI) and lenalidomide and were lenalidomide refractory, or who have received at least two prior therapies that included lenalidomide and a PI and have demonstrated disease progression on or after the last therapy. The approvals follow Positive Opinions by the CHMP of the European Medicines Agency in May 2021. In August 2012, Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"AL amyloidosis is a potentially fatal blood disorder for which there is no cure, so we are extremely pleased that patients with AL amyloidosis in Europe may soon have a regimen including DARZALEX SC as a treatment option," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We are also pleased that, with the approval based on the APOLLO study, the combination of daratumumab with pomalidomide and dexamethasone will now be a treatment option for certain patients with relapsed or refractory multiple myeloma in Europe."

About the ANDROMEDA (AMY3001) study

The Phase 3 study (NCT03201965) included 416 patients newly diagnosed with AL amyloidosis. Patients were randomized to receive treatment with either daratumumab and hyaluronidase-fihj in combination with bortezomib (a proteasome inhibitor), cyclophosphamide (a chemotherapy), and dexamethasone (a corticosteroid) or treatment with VCd alone. The primary endpoint of the study was the percentage of patients who achieve hematologic complete response.

About the APOLLO (MMY3013) study

The Phase 3 (NCT03180736), randomized, open-label, multicenter study included 304 patients with multiple myeloma who have previously been treated with lenalidomide and a PI. Patients were randomized 1:1 to either receive daratumumab in combination with Pd or Pd alone. In the original design of the study, patients in the daratumumab plus Pd arm were treated with the intravenous (IV) formulation of daratumumab. As of Amendment 1 to the study protocol, all new subjects in the experimental arm were dosed with the SC formulation of daratumumab and patients who had already begun treatment with IV daratumumab had the option to switch to the SC formulation. The primary endpoint of the study was progression free survival (PFS). The study was conducted in Europe under an agreement between Janssen, the European Myeloma Network (EMN) and Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON).

About AL Amyloidosis

Amyloidosis is a disease that occurs when amyloid proteins, which are abnormal proteins, accumulate in tissues and organs. When the amyloid proteins cluster together, they form deposits that damage the tissues and organs. AL amyloidosis most frequently affects the heart, kidneys, liver, nervous system and digestive tract. There is currently no cure for AL amyloidosis or existing approved therapies for AL amyloidosis patients in Europe, though it can be treated with chemotherapy, dexamethasone, stem cell transplants and supportive therapies.¹ It is estimated that in 2019 there were 4,388 diagnosed incident cases of AL amyloidosis in the five major European markets.²

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.³ Approximately 18,114 new patients were diagnosed with multiple myeloma and approximately 11,063 people died from the disease in the Western Europe in 2020.⁴ Globally, it was estimated that 176,404 people were diagnosed and 117,077 died from the disease in 2020.⁵ While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms which can include bone problems, low blood counts, calcium elevation, kidney problems or infections.⁶

About DARZALEX[®] SC (daratumumab and hyaluronidase-fihj)

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. DARZALEX[®] SC (daratumumab and hyaluronidase-fihj) is the first subcutaneous CD38 antibody approved in the Europe for the treatment of both multiple myeloma and AL amyloidosis. 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). 7,8, 9, 10, 11

For the full EU Summary of Product Characteristics, please [click here](#).

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, 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](#).

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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 or technologies 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 www.genmab.com and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

Genmab A/S and/or its subsidiaries own the following trademarks: Genmab[®]; the Y-shaped Genmab logo[®]; Genmab in combination with the Y-shaped Genmab logo[®]; HuMax[®]; DuoBody[®]; DuoBody in combination with the DuoBody logo[®]; HexaBody[®]; HexaBody in combination with the HexaBody logo[®]; DuoHexaBody[®]; HexElect[®]; and UniBody[®]. DARZALEX[®] is a trademark of Johnson & Johnson.

¹ Mayo Clinic website: www.mayoclinic.com/health/amyloidosis/DS00431

² Global Data, "Amyloidosis: Epidemiology Forecast to 2029," June 2020

³ American Cancer Society. "What is Multiple Myeloma." Available at <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed May 2021.

⁴ Globocan 2020. Western Europe Fact Sheet. Available at <http://gco.iarc.fr/today/data/factsheets/populations/926-western-europe-fact-sheets.pdf> Accessed May 2021

⁵ Globocan 2018. World Fact Sheet. Available at <https://gco.iarc.fr/today/data/factsheets/cancers/35-Multiple-myeloma-fact-sheet.pdf> Accessed May 2021

⁶ American Cancer Society. "Signs and Symptoms of Multiple Myeloma" <https://www.cancer.org/cancer/multiple-myeloma/detection-diagnosis-staging/signs-symptoms.html>. Accessed May 2021

⁷ DARZALEX Prescribing information, March 2021 https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761036s033lbl.pdf Last accessed May 2021

⁸ 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.

⁹ 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.

¹⁰ Krejcik, 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.

¹¹ 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

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Attachment

- [220621_CA53_ANDROMEDA_APOLLO EU approval](#)