Genmab A/S (Nasdaq: GMAB) announced today that the European Myeloma Network (EMN) in collaboration with Janssen Research & Development, LLC (Janssen) reported positive results from the Phase 3 APOLLO (IMMY3013) study of subcutaneous (SC) daratumumab in combination with pomalidomide and dexamethasone (Pd) versus Pd alone as treatment for patients with relapsed or refractory multiple myeloma who have previously been treated with lenalidomide and a proteasome inhibitor (PI). The study met the primary endpoint of improving progression-free survival (PFS). Overall, the safety profile of daratumumab SC in combination with Pd was consistent with the safety profile for each therapy separately.

We are pleased with these positive results for daratumumab, administered as a subcutaneous formulation, in combination with pomalidomide and dexamethasone. The corresponding intravenous regimen was previously approved by the U.S. FDA based on the Phase1 single-arm EQUULEUS study,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Janssen Biotech, Inc., which obtained an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab in 2012, intends to discuss the data with health authorities in preparation for regulatory submissions and plans to submit the data for presentation at an upcoming medical conference.

The APOLLO study was designed to confirm the results from the Phase 1 EQUULEUS (IMMY1001) study, which investigated intravenous (IV) daratumumab plus Pd in the same indication. In June 2017, the U.S. Food and Drug Administration (U.S. FDA) approved the use of DARZALEX in combination with Pd for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a PI based on the results of the EQUULEUS study.

About the APOLLO (IMMY3013) study
This 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 IV formulation of daratumumab. As of Amendment 1, 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 PFS. The study was conducted in Europe under an agreement between Janssen, EMN and Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON).

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. Multiple myeloma is the third most common blood cancer in the U.S., after leukemia and lymphoma. Approximately 26,000 new patients were estimated diagnosed with multiple myeloma and approximately 13,650 people were expected to have died from the disease in the U.S. in 2018. Globally, it was estimated that 160,000 people were diagnosed and 106,000 died from the disease in 2018. 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.

About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) intravenous infusion is indicated for the treatment of adult patients in the United States: 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. 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
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).6,9,10,11,12

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 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 is the creator of three approved antibodies: DARZALEX® (daratumumab, under agreement with Janssen Biotech, Inc.) for the treatment of certain multiple myeloma indications in territories including the U.S., Europe and Japan, Arzerra® (ofatumumab, under agreement with Novartis AG), for the treatment of certain chronic lymphocytic leukemia indications in the U.S., Japan and certain other territories and TEPEZZA® (tepratumumab, under agreement with Roche granting sublicense to Horizon Therapeutics plc) for the treatment of thyroid eye disease in the U.S. A subcutaneous formulation of daratumumab, known as DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) in the U.S., has been approved in the U.S. and Europe for the treatment of adult patients with certain multiple myeloma indications. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. A subcutaneous formulation of ofatumumab is in development by Novartis for the treatment of relapsing multiple sclerosis. 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, the HexaBody® platform, which creates effector function enhanced antibodies, the HexElec® platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody® platform, which enhances the potential potency of bispecific antibodies through hexamORIZATION. 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. Genmab is headquartered in Copenhagen, Denmark with sites in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan.

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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.

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