Ofatumumab and Daratumumab Data to Be Presented at 20th Congress of EHA

Media Release

- **Phase III data from ofatumumab plus fludarabine and cyclophosphamide study in relapsed CLL to be presented**
- **4 ofatumumab abstracts and 3 daratumumab abstracts to be presented at EHA**

Copenhagen, Denmark; May 21, 2015 – Genmab A/S (OMX: GEN) announced today that data on ofatumumab and daratumumab will be presented at the 20th Congress of the European Hematology Association (EHA) in Vienna, June 11-14. The abstracts have been published at the EHA website at www.ehaweb.org.

Data from the Phase III COMPLEMENT 2 study of ofatumumab plus fludarabine and cyclophosphamide (OFC) versus fludarabine and cyclophosphamide (FC) in relapsed chronic lymphocytic leukemia (CLL) will be presented in a poster session at the conference. Top-line results reported in April showed that treatment with OFC met the primary endpoint of improved progression-free survival (PFS) in patients with relapsed CLL (p=0.0036, Hazard ratio (HR)=0.67) compared to those given FC alone. The PFS as assessed by an Independent Review Committee (IRC) was 28.9 months in the OFC arm compared to 18.8 months in the FC arm. The overall response rate (ORR) by IRC assessment was 84% for OFC and 68% for FC (p=0.0004). Median overall survival was 56.4 months in the OFC arm and 45.8 months in the FC arm (p=0.1404, HR=0.78) with a median follow-up of 34 months.

The safety profile observed in this study was consistent with other trials of ofatumumab and no new safety signals were observed. Infusion reactions were mostly mild to moderate in severity. Nine percent of patients in the OFC arm experienced grade ≥ 3 infusion reactions (FC 3%). Other grade ≥ 3 adverse events were comparable between the arms, including infections (OFC 19%, FC 14%). Grade ≥ 3 cytopenias were seen in both arms including neutropenia (OFC 53%; FC 39%), thrombocytopenia (OFC 14%; FC 25%), and anaemia (OFC 8%; FC 12%).

Abstract details:
Ofatumumab (O) in combination with fludarabine (F) and cyclophosphamide (C) (OFC) vs. FC in patients with relapsed chronic lymphocytic leukemia (CLL): Results of the Phase III study COMPLEMENT 2 – Poster session, Sunday, June 14 from 10:45AM CET

About COMPLEMENT 2
COMPLEMENT 2 (NCT00824265) is an open-label, two-arm, randomized, Phase III study, which included 365 patients in 18 countries with relapsed CLL. Patients in the study were randomized 1:1 to treatment with up to six cycles of ofatumumab in combination with fludarabine and cyclophosphamide or up to six cycles with fludarabine and cyclophosphamide alone.

The primary endpoint of the study was PFS, which was assessed by an Independent Review Committee (IRC) according to the International Workshop for Chronic Lymphocytic Leukaemia (iwCLL) updated 2008 National Cancer Institute-sponsored Working Group (NCIWG) guidelines. Secondary endpoints included overall response rate, overall survival, patient reported outcomes, time to response, duration of response, time to progression, time to next therapy, safety assessments and quality of life.

List of Further Abstracts to Be Presented
Ofatumumab
Health related quality of life and patient reported outcomes of ofatumumab plus chlorambucil versus chlorambucil monotherapy in the COMPLEMENT 1 trial – Poster session, Saturday, June 13, 5:15PM to 6:45PM CET

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Health related quality of life and patient reported outcomes in patients receiving ofatumumab maintenance versus observation in the PROLONG trial – Poster session, Friday, June 12, 5:15PM to 6:45PM CET

Telomere length and POT1 mutations in CLL: Incidence, associations and clinical impact in the COMPLEMENT 1 trial – Poster session, Saturday, June 13, 5:15PM to 6:45PM CET

Daratumumab
Expression levels of CD38 and complement inhibitory proteins CD55 and CD59 predict response to daratumumab in multiple myeloma – Oral presentation, Saturday, June 13, 11:45AM to 12:00PM CET

An open-label, multicenter, phase 1b study of daratumumab in combination with pomalidomide-dexamethasone and with backbone regimens in patients with multiple myeloma – Poster session, Friday, June 12, 5:15PM to 6:45PM CET

Phase 2 study of daratumumab monotherapy in patients with ≥ 3 lines of prior therapy or double refractory multiple myeloma: 54767414MMY2002 (Sirius) – Oral presentation, Saturday, June 13, 12:30PM to 12:45PM CET (the abstract is planned to be included in a press briefing by ASCO on Saturday, May 30 from 8:00AM to 9:00AM CDT)

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.

Arzerra is not approved anywhere in the world in combination with fludarabine and cyclophosphamide for the treatment of relapsed chronic lymphocytic leukemia.

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

Important Safety Information for Arzerra (ofatumumab)
Treatment with Arzerra may cause side effects, some of which are serious and life-threatening.

Treatment with Arzerra may cause a side effect called an infusion reaction, which may be serious. Before treatment with Arzerra, doctors will prescribe 3 types of medicine to their patients to help reduce the risk of an infusion reaction including, a steroid (to reduce swelling and other symptoms of inflammation), a pain reliever, and an antihistamine (to reduce allergic reactions). Even though patients receive these medicines, they may still have an infusion reaction. If an infusion reaction occurs, the doctor will stop their patient's treatment with Arzerra so the infusion reaction can be treated. Patients should tell their doctor or seek medical treatment right away if they have any of these symptoms while receiving Arzerra or within 24 hours after receiving Arzerra: fever, chills, rash, hives, chest pain, back pain, stomach pain, swelling, dizziness, blurred vision, drowsiness, headache, cough, wheezing, or trouble breathing.

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Treatment with Arzerra may cause hepatitis B virus (HBV) infection to reoccur, which may cause serious liver problems and death. Patients who are newly exposed to HBV during or following treatment with Arzerra may experience serious liver problems and death. Patients should tell their doctor if they have had HBV infection or are a carrier of HBV. Before starting Arzerra, doctors will do a blood test to check for HBV infection. In some patients, additional blood tests may be done during and several months after treatment. Patients should call their doctor right away if they feel more tired than usual or notice a yellowing of the skin or eyes. These may be symptoms of hepatitis.

Progressive multifocal leukoencephalopathy (PML) is a rare brain infection that can occur with treatment with Arzerra. PML causes severe disability and can lead to death. Patients should call their doctor right away if they notice new medical problems or problems that are getting worse, such as confusion, dizziness or loss of balance, difficulty talking or walking, or strength, vision or other problems that have lasted over several days.

Tumor lysis syndrome (TLS), including the need for a hospital stay, can occur with treatment with Arzerra. TLS is caused by the fast breakdown of cancer cells, which then release their contents into the blood. This may lead to serious problems, including kidney failure or an abnormal heartbeat. Doctors may do a blood test to check their patients for TLS and may give medicines before starting treatment with Arzerra to help prevent TLS.

Arzerra can cause low blood cell counts (white blood cells, platelets, and red blood cells). These low blood cell counts can be severe and, in some cases, lead to death. Low white blood cells counts (neutropenia), can happen during treatment. Neutropenia can occur 42 days or longer after the end of treatment with Arzerra and may also last between 24 and 42 days after the last treatment dose. Doctors should regularly check their patient's blood to see if they have low blood cell counts. Patients should call their doctor right away if they have any bleeding, bruising, red or purple spots on their skin, paleness, worsening weakness, tiredness, cough that will not go away, fever, chills, congestion, or any flu-like symptoms while receiving Arzerra.

After a patient receives Arzerra, they should not receive live vaccines until the doctor who prescribed Arzerra has told them that they may do so.

The most common side effects with Arzerra include infusion reactions, feeling tired, low white blood cell count, shortness of breath, pneumonia, rash, fever, nausea, cough, bronchitis, diarrhea, upper respiratory tract infection and low red blood cell count.

Treatment with Arzerra can increase patients' chances for getting infections. Some infections, such as pneumonia, bronchitis, and sepsis (a blood infection), can be serious, and in some cases, life-threatening. Patients should call their doctor right away if they have a cough that will not go away, fever, chills, congestion, or any flu-like symptoms while receiving Arzerra. These symptoms may be signs of a serious infection.

Please see full Prescribing Information, including Boxed WARNING, for Arzerra (ofatumumab).

About daratumumab
Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has

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been granted Breakthrough Therapy Designation from the US FDA. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

About Genmab
Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human 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. Genmab's deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab's strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

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