

Genmab Announces Phase III Study of Arzerra[®] Met Primary Endpoint of Improved Progression-Free Survival in Patients with Relapsed CLL

Company Announcement

- Positive top-line results seen with Arzerra plus fludarabine and cyclophosphamide in chronic lymphocytic leukemia (CLL) patients when prior treatment stopped working
- Study met primary endpoint of improved progression-free survival (PFS)
- Data to be further analyzed and shared with regulatory authorities

Copenhagen, Denmark; April 27, 2015 – Genmab A/S (OMX: GEN) announced today that the top-line results from the Phase III COMPLEMENT 2 study showed that treatment with Arzerra[®] (ofatumumab) plus fludarabine and cyclophosphamide met the primary endpoint of improved progression-free survival (PFS) in patients with relapsed CLL ($p = 0.0036$) compared to those given fludarabine and cyclophosphamide alone. The safety profile observed in this study was consistent with other trials of ofatumumab and no new safety signals were observed.

“We are pleased with the positive topline results in this pivotal study of ofatumumab in combination with fludarabine and cyclophosphamide in relapsed CLL. This outcome is good news for patients with CLL, a disease for which relapses are inevitable. We look forward to sharing additional data from the study at an upcoming medical conference and to discussions with the regulatory authorities in collaboration with Novartis,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About CLL

CLL, the most commonly diagnosed adult leukemia in Western countries, accounts for approximately 1 in 4 cases of leukemia^{1,2}. Most CLL patients experience disease progression despite initial response to therapy and may require additional treatment³.

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) guidelines⁴. 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.

Ofatumumab is not approved for this indication and Novartis will further analyze the data from the COMPLEMENT 2 study and plans to share the results with regulatory agencies to evaluate the potential for future regulatory filings.

About Arzerra

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. Arzerra is also approved for first-line use in Russia, Iceland, Norway, Luxembourg and Brazil.

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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 marketed under a co-development and collaboration agreement between Genmab and Novartis, as successor in interest to GSK.

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.

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.

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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 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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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 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. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements in relation to actual results, unless required by law.

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References

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4. Hallek M, Cheson BD, Catovsky D, et al. Guidelines for the diagnosis and treatment of chronic lymphocytic leukemia: a report from the International Workshop on Chronic Lymphocytic Leukemia updating the National Cancer Institute-Working Group 1996 guidelines. *Blood* 2008; 111: 5446-56.