

Genmab Announces Novartis' Intention to Transition Arzerra® (ofatumumab) from Commercial Availability to Limited Availability via Compassionate Use Programs for the Treatment of CLL in Non-US Markets

Company Announcement

- **Novartis intends to transition the commercial availability of Arzerra to limited availability via compassionate use programs for treatment of CLL in non-US markets. Novartis will continue to market for CLL in the US**
- **Novartis will work with regulatory authorities to establish compassionate use programs so that patients benefitting from Arzerra can remain on treatment**
- **Genmab receives USD 50 million from Novartis as payment for lost potential milestones and royalties**

Copenhagen, Denmark; January 22, 2018 – Genmab A/S (Nasdaq Copenhagen: GEN) announced today that Novartis (SIX Swiss Exchange: NOVN) intends to transition Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia (CLL) indications from commercial availability to limited availability via compassionate use programs in all markets around the world except the United States. Novartis will work with regulatory authorities to establish compassionate use programs for patients outside the US currently being treated with Arzerra as an ongoing treatment, to ensure continuity of treatment for all patients who benefit from Arzerra. As a consequence, Novartis will pay Genmab a lump sum of USD 50 million as payment for lost potential milestones and royalties. This amount will be included in Genmab's 2018 guidance which will be issued on February 21, 2018. Royalties will continue to be earned on net sales of Arzerra. Arzerra is marketed under a collaboration agreement between Genmab and Novartis.

“Novartis' intention to transition Arzerra to compassionate use programs in the non-US markets reflects the fact that many more drugs have become available for CLL over the last five years and that there is a low number of patients using Arzerra outside of the US market. The compassionate use programs will ensure that patients who benefit from Arzerra can remain on treatment. We welcome the continued commercial availability of Arzerra for US patients,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Patients accessing the compassionate use program will be offered continued treatment with Arzerra for as long as they benefit from it, free of charge.

Novartis intends to start the transition process as soon as a carefully structured plan has been agreed with the various regulatory authorities.

The two Phase III studies of ofatumumab currently ongoing in Relapsing Multiple Sclerosis and the study of Arzerra in indolent non-Hodgkin lymphoma will continue.

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, for use in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL, and for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. In the European Union, Arzerra is currently 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 and in combination with

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fludarabine and cyclophosphamide for adult patients with relapsed CLL. In more than 60 countries worldwide, including the United States and EU member countries, Arzerra is also currently indicated as monotherapy for the treatment of patients with CLL who are refractory after prior treatment with fludarabine and alemtuzumab.

Please consult the full [European Summary of Product Characteristics](#) and full [US Prescribing information](#), including Boxed Warning, for all the labeled safety information for Arzerra.

Under the collaboration with Novartis, a subcutaneous formulation of ofatumumab is also being investigated in two Phase III clinical studies in relapsing multiple sclerosis.

Novartis has rights to develop ofatumumab in autoimmune indications, including multiple sclerosis.

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 has two approved antibodies, DARZALEX® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications, other blood cancers, and solid tumors. A subcutaneous formulation of ofatumumab is in development for 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, and the HexaBody® platform which creates effector function enhanced antibodies. 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. For more information visit www.genmab.com.

Contact:

Rachel Curtis Gravesen, Senior Vice President, Investor Relations & Communications
T: +45 33 44 77 20; M: +45 25 12 62 60; E: rcg@genmab.com

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Genmab A/S and its subsidiaries own the following trademarks: Genmab®, the Y-shaped Genmab logo®, Genmab in combination with the Y-shaped Genmab logo™; the DuoBody logo®, the HexaBody logo™; HuMax®, HuMax-CD20®, DuoBody®, HexaBody® and UniBody®. Arzerra® is a trademark of Novartis AG or its affiliates. DARZALEX® is a trademark of Janssen Biotech, Inc.