

Genmab Announces that Janssen has Submitted a Biologics License Application to U.S. FDA for Amivantamab in Non-small Cell Lung Cancer

Media Release

Copenhagen, Denmark, December 3, 2020

- Janssen submitted a BLA to U.S. FDA for amivantamab for patients with non-small cell lung cancer with epidermal growth factor receptor Exon 20 insertion mutations
- First regulatory submission for a DuoBody® product candidate

Genmab A/S (Nasdaq: GMA) announced today that Janssen Biotech, Inc. (Janssen) submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (U.S. FDA) seeking approval of amivantamab for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. This is the first BLA submission for a product candidate that was created using Genmab's proprietary DuoBody technology platform. In July 2012, Genmab entered into a collaboration with Janssen to create and develop bispecific antibodies using Genmab's DuoBody technology platform.

"Today's milestone underscores the promise of our DuoBody technology platform to effectively create innovative and truly differentiated bispecific antibody therapeutics," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

For more information related to Janssen's amivantamab filing [click here](#).

About Non-small Cell Lung Cancer

Lung cancer is the most common cancer worldwide. Approximately 80 to 85 percent of lung cancers are classified as NSCLC and include subtypes adenocarcinoma, squamous cell carcinoma and large cell carcinoma^{1,2}. Mutations in the EGFR gene are common in patients with NSCLC, including 10 to 15 percent of NSCLC patients in Western countries.^{3,4} The five-year survival rate for all patients with metastatic NSCLC with EGFR mutations who are treated with EGFR tyrosine kinase inhibitors is less than 20 percent.^{5,6} In addition, the estimated median overall survival for patients with NSCLC and EGFR Exon 20 insertion mutations is shorter than in patients with common EGFR mutations.⁷

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 the following 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, Kesimpta® (subcutaneous ofatumumab, under agreement with Novartis AG), for the treatment of adults with relapsing forms of multiple sclerosis in the U.S. and TEPEZZA® (teprotumumab, 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. The first approved Genmab created therapy, Arzerra® (ofatumumab, under agreement with Novartis AG), approved for the treatment of certain chronic lymphocytic leukemia indications, is available in Japan and is also available in other territories via compassionate use or oncology access programs. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. 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®

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platform, which creates effector function enhanced antibodies, the HexElect[®] 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 hexamerization. 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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¹ The World Health Organization. Cancer. <https://www.who.int/news-room/fact-sheets/detail/cancer>.

² American Cancer Society. What is Lung Cancer? <https://www.cancer.org/content/cancer/en/cancer/lung-cancer/about/what-is.html>.

³ Van Assche, Katrijn, et al. "EGFR Mutation Positive Stage IV Non-Small-Cell Lung Cancer: Treatment Beyond Progression." *Frontiers in Oncology*, Frontiers Media S.A., 8 Dec. 2014, www.ncbi.nlm.nih.gov/pmc/articles/PMC4259002/.

⁴ Midha, Anita, et al. "EGFR Mutation Incidence in Non-Small-Cell Lung Cancer of Adenocarcinoma Histology: a Systematic Review and Global Map by Ethnicity (MutMapII)." *American Journal of Cancer Research*, e-Century Publishing Corporation, 15 Aug. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4633915/.

⁵ Howlader N, Noone AM, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). *SEER Cancer Statistics Review, 1975-2016*, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2016/, based on November 2018 SEER data submission, posted to the SEER web site

⁶ Lin JJ, Cardarella S, Lydon CA, Dahlberg SE, Jackman DM, Jänne PA, et al. Five-Year Survival in EGFR-Mutant Metastatic Lung Adenocarcinoma Treated with EGFR-TKIs. *J Thorac Oncol*. 2016 Apr;11(4):556-65.

⁷ Oxnard, JR et. al. Natural history and molecular characteristics of lung cancers harboring EGFR exon 20 insertions. *J Thorac Oncol*. 2013 Feb;8(2):179-84. doi: 10.1097/JTO.0b013e3182779d18.