

# Genmab Files IND for HuMax-TF-ADC

# **Company Announcement**

- IND for HuMax®-TF-ADC submitted to FDA
- Genmab's first IND submission for antibody-drug conjugate (ADC) product
- Patient enrolment in clinical trial expected to start in 2013

Copenhagen, Denmark; July 18, 2013 – Genmab A/S (OMX: GEN) announced today the filing of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) to start a Phase I dose escalation trial of HuMax-TF-ADC to treat multiple solid tumors. A maximum of 78 patients with cancer of the ovary, cervix, endometrium, bladder, prostate, head & neck, esophagus or lung that have failed or are not eligible for standard treatments will be enrolled in the study. The safety and tolerability of HuMax-TF-ADC will be established during a dose escalation part of the study. This will be followed by a cohort expansion part that will investigate longer-term safety and potential signs of antitumor activity.

"HuMax-TF-ADC has shown an impressive ability to induce tumor regression in multiple pre-clinical cancer models. We aim to start the clinical evaluation of HuMax-TF-ADC in the coming months, adding another antibody, with the potential to help cancer patients, to Genmab's clinical pipeline," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

#### **About HuMax-TF-ADC**

HuMax-TF-ADC is an antibody-drug conjugate (ADC) composed of a human antibody against tissue factor (TF) conjugated to the cytotoxic drug monomethyl auristatin E (MMAE). HuMax-TF-ADC is being developed for the treatment of solid cancers. TF is an attractive tumor target because of its high expression in a broad range of solid cancers. After binding to TF, HuMax-TF-ADC enters the tumor cells where the cytotoxic agent is specifically released, leading to cell death. HuMax-TF-ADC was demonstrated to have potent anti-tumor activity in *in vivo* studies in mouse models in which a diverse panel of patient-derived tumors was assessed. HuMax-TF-ADC was shown to have an acceptable safety profile in non-clinical safety studies.

Genmab is developing HuMax-TF-ADC using Seattle Genetics' ADC technology under an agreement between the companies. Seattle Genetics may elect to co-develop HuMax-TF-ADC with Genmab at the end of Phase I clinical development.

### About Genmab A/S

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's first marketed antibody, ofatumumab (Arzerra®), was approved to treat chronic lymphocytic leukemia in patients who are refractory to fludarabine and alemtuzumab after less than eight years in development. Genmab's validated and next generation antibody technologies are expected to provide a steady stream of future product candidates. Partnering of 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 <a href="https://www.genmab.com">www.genmab.com</a>.

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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,



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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 <a href="www.genmab.com">www.genmab.com</a>. 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.

Genmab A/S and its subsidiaries own the following trademarks: Genmab<sup>®</sup>; the Y-shaped Genmab logo<sup>®</sup>; the DuoBody<sup>™</sup> logo; HuMax<sup>®</sup>; HuMax-CD20<sup>®</sup>; DuoBody<sup>®</sup>, HexaBody<sup>™</sup> and UniBody<sup>®</sup>. Arzerra<sup>®</sup> is a registered trademark of GlaxoSmithKline.

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