Tisotumab Vedotin Marketing Authorization Application Validated by European Medicines Agency for Treatment of Recurrent or Metastatic Cervical Cancer

Media Release

COPENHAGEN, Denmark; February 2, 2024

- **Validation is supported by data from Phase 3 innovaTV 301 trial**

Genmab A/S (Nasdaq: GMAB) and Pfizer, Inc. (NYSE PFE) today announced that the European Medicines Agency (EMA) has validated for review the marketing authorization application (MAA) of tisotumab vedotin, an antibody-drug conjugate (ADC), developed for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy. If approved, tisotumab vedotin would be the first ADC granted European Union (EU) marketing authorization for people living with cervical cancer.

The MAA is based on data from the global, randomized, Phase 3 innovaTV 301 trial (NCT04697628), in which tisotumab vedotin demonstrated superior overall survival (OS), progression-free survival (PFS) and a confirmed objective response rate (ORR) in patients with previously treated recurrent or metastatic cervical cancer compared to chemotherapy. Data from the innovaTV 204 pivotal Phase 2 single-arm clinical trial evaluating TIVDAK as monotherapy in patients with previously treated recurrent or metastatic cervical cancer was also included in the MAA. The safety profile of tisotumab vedotin in innovaTV 301 was consistent with its known safety profile as presented in the U.S. prescribing information.

“The validation of our application is an important milestone supporting our commitment to bringing a new therapeutic option for recurring or metastatic cervical cancer to more patients,” said Jan van de Winkel, Ph.D., Chief Executive Officer, Genmab. “There continues to be a need for therapeutic options for these patients, and we’re dedicated to delivering potential improved outcomes to women diagnosed with this devastating disease.”

“Today’s milestone signifies our progress in exploring the availability of tisotumab vedotin for more patients with recurrent or metastatic cervical cancer,” said Roger Dansey, M.D., Chief Development Officer, Oncology, Pfizer. “We remain dedicated to collaborating closely with regulatory authorities, while we navigate the process to potentially deliver a new therapeutic option to people facing this debilitating disease.”

About Cervical Cancer
Cervical cancer remains a disease with high unmet need despite advances in effective vaccination and screening practices to prevent and diagnose pre-/early-stage cancers for curative treatment. It is the fourth leading cause of cancer death in women worldwide,[i,ii] with approximately 570,000 new cases diagnosed and 311,000 new deaths of women annually.[iii,iv] Recurrent and/or metastatic cervical cancer is a particularly devastating and mostly incurable disease; when diagnosed in later stages, less than 5 percent of these patients survive five years.[v] In the European Union specifically, cervical cancer ranks 11th among the most frequently occurring cancers in women and 12th among the most frequent causes of cancer death in them.[vi]

About the innovaTV 301 Trial
The innovaTV 301 trial (NCT04697628) is a global, randomized, open-label Phase 3 trial evaluating tisotumab vedotin versus investigator’s choice of chemotherapy alone (topotecan, vinorelbine, gemcitabine, irinotecan, or pemetrexed) in 502 patients with recurrent or metastatic cervical cancer who received no more than two prior systemic regimens in the recurrent or metastatic setting.

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Patients with recurrent or metastatic cervical cancer with squamous cell, adenocarcinoma, or adenosquamous histology, and disease progression during or after treatment with chemotherapy doublet +/- bevacizumab and an anti-PD-(L)1 agent (if eligible) are included. The primary endpoint is overall survival. The main secondary outcomes are progression-free survival, confirmed objective response rate, time to response, and duration of response, as assessed by the investigator, as well as safety and quality of life outcomes.

The study was conducted by Seagen, recently acquired by Pfizer, in collaboration with Genmab, European Network of Gynaecological Oncological Trial Groups (ENGOT, study number ENGOT cx-12) and the Gynecologic Oncology Group (GOG) Foundation (study number GOG 3057). For more information about the Phase 3 innovaTV 301 clinical trial and other clinical trials with tisotumab vedotin, please visit www.clinicaltrials.gov.

About Tisotumab Vedotin
Tisotumab vedotin is an antibody-drug conjugate (ADC) composed of Genmab's human monoclonal antibody directed to tissue factor (TF) and Pfizer's ADC technology that utilizes a protease-cleavable linker that covalently attaches the microtubule-disrupting agent monomethyl auristatin E (MMAE) to the antibody. Determination of TF expression is not required. Nonclinical data suggest that the anticancer activity of tisotumab vedotin is due to the binding of the ADC to TF-expressing cancer cells, followed by internalization of the ADC-TF complex, and release of MMAE via proteolytic cleavage. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death. In vitro, tisotumab vedotin also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity.

Tisotumab vedotin-tftv (Tivdak®) is approved in the U.S. under the accelerated approval program, and a supplemental Biologics License Application (sBLA) seeking to convert its accelerated approval to a full approval was granted Priority Review by the U.S. Food and Drug Administration (FDA). Use of tisotumab vedotin in recurrent or metastatic cervical cancer is not approved in the EU.

About Genmab
Genmab is an international biotechnology company with a core purpose guiding its unstoppable team to strive towards improving the lives of patients through innovative and differentiated antibody therapeutics. For more than 20 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational research and data sciences, which has resulted in a proprietary pipeline including bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. To help develop and deliver novel antibody therapies to patients, Genmab has formed 20+ strategic partnerships with biotechnology and pharmaceutical companies. By 2030, Genmab's vision is to transform the lives of people with cancer and other serious diseases with Knock-Your-Socks-Off (KYSO™) antibody medicines.

Established in 1999, Genmab is headquartered in Copenhagen, Denmark with locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan. For more information, please visit Genmab.com and follow us on Twitter.com/Genmab.

About Pfizer Oncology
At Pfizer Oncology, we are at the forefront of a new era in cancer care. Our industry-leading portfolio and extensive pipeline includes game-changing mechanisms of action to attack cancer from multiple angles, including antibody-drug conjugates (ADCs), small molecules, bispecifics and other immunotherapies. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, genitourinary cancer and hematologic malignancies, as well as melanoma,

gastrointestinal, gynecological and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to extend and improve patients' lives. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on X (Twitter) at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer

About the Pfizer and Genmab Collaboration

Tisotumab vedotin is being co-developed by Genmab and Pfizer, under an agreement in which the companies share costs and profits for the product on a 50:50 basis.

Genmab Forward Looking Statements

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 or technologies 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 and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

Pfizer Disclosure Notice

The information contained in this release is as of February 2, 2024. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer Oncology and TIVDAK® (tisotumab vedotin-tftv), including the MAA pending with the EMA for TIVDAK for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after first-line therapy, potential to convert the accelerated approval of TIVDAK in the U.S. to full approval and potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of TIVDAK; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in particular jurisdictions for TIVDAK; whether and when any applications that may be pending or filed for TIVDAK may be approved by regulatory authorities (including the sBLA seeking to convert the accelerated approval of TIVDAK to full approval in the U.S. and the MAA pending with the EMA, for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after first-line therapy), which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether TIVDAK will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of TIVDAK; whether the collaboration between Pfizer and Genmab will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the US Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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