TIVDAK® (tisotumab vedotin-tftv) Supplemental Biologics License Application Accepted for Priority Review by U.S. Food and Drug Administration for Patients with Recurrent or Metastatic Cervical Cancer

Media Release

COPENHAGEN, Denmark; January 9, 2024

- **TIVDAK sBLA accepted for priority review, FDA action date is May 9, 2024**
- **Submission based on positive results from global phase 3 innovaTV 301 trial demonstrating overall survival benefit of tisotumab vedotin-tftv over chemotherapy**

Genmab A/S (Nasdaq: GMAB) and Pfizer, Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) seeking to convert the accelerated approval of TIVDAK® (tisotumab vedotin-tftv) to full approval, for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after first-line therapy. The application has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of May 9, 2024.

The sBLA is supported by efficacy and safety data from the global, randomized Phase 3 innovaTV 301 trial (NCT04697628), in which tisotumab vedotin-tftv demonstrated superior overall survival (OS), progression-free survival (PFS) and confirmed objective response rate (ORR), as assessed by the investigator, in patients with recurrent or metastatic cervical cancer compared to chemotherapy. The safety profile of tisotumab vedotin-tftv in innovaTV 301 was consistent with its known safety profile as presented in the U.S. prescribing information. In October 2023, results from the innovaTV 301 study were presented during the Presidential Symposium at the European Society of Medical Oncology (ESMO) Congress.

“Therapeutic options for metastatic cervical cancer that not only demonstrate a survival advantage but also include a novel approach to treating this condition are needed,” said Jan van de Winkel, Ph.D., Chief Executive Officer, Genmab. “This milestone underscores our commitment to continuing to deliver TIVDAK as a treatment option to women in the U.S. diagnosed with cervical cancer whose disease has progressed after first-line treatment.”

“The Phase 3 innovaTV 301 trial demonstrated a favorable benefit/risk profile, including improvement in overall survival, and adds to the overall data supporting TIVDAK as a treatment option for people with recurrent and metastatic cervical cancer who have limited treatment options,” said Roger Dansey, M.D., Chief Development Officer, Oncology, Pfizer. “The FDA acceptance of our sBLA for review is important progress toward continuing to offer an option that can extend the lives of more adults with cervical cancer.”

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. Recurrent and/or metastatic cervical cancer is a particularly devastating and mostly incurable disease; up to 15 percent of adults with cervical cancer are diagnosed with metastatic disease at diagnosis[1,2] and, for adults diagnosed at earlier stages who receive treatment, up to 31.5 percent will experience disease recurrence.[3] It was estimated that, in 2023, more than 13,960 new cases of invasive cervical cancer were diagnosed in the U.S. and 4,310 adults would die from the disease.[4]

About the innovaTV 301 Trial
The innovaTV 301 trial (NCT04697628) is a global, randomized, open-label Phase 3 trial evaluating tisotumab vedotin-tftv 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.

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 TIVDAK (tisotumab vedotin-tftv)
TIVDAK (tisotumab vedotin-tftv) 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-tftv 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-tftv also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity.

TIVDAK was granted accelerated approval in the U.S. by the FDA in September 2021. The accelerated approval is based on tumor response and durability of response 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. The data from innovaTV 301 will support global regulatory submissions.

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 *January 9, 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 potential to convert the accelerated approval of TIVDAK to full approval, potential benefits and plans for data from innovaTV 301 to support global regulatory submissions,* 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, 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 U.S. Securities and Exchange Commission and available at *www.sec.gov and www.pfizer.com*.

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[2] McLachlan J, Boussios S, Okines A, et al. The impact of systemic therapy beyond first-line treatment for advanced cervical cancer. Clin Oncol (R Coll Radiol). 2017;29(3):153-60.
[3] de Foucher T, Bendifallah S, Ouldamer L, et al. Patterns of recurrence and prognosis in locally advanced FIGO stage IB2 to IIB cervical cancer: retrospective multicentre study from the FRANCOGYN Group. Eur J Surg Oncol. 2019;45:659–665. doi: 10.1016/j.ejso.2018.11.014.
[4] Key Statistics for Cervical Cancer. American Cancer Society. Atlanta, GA. 2023. https://www.cancer.org/cancer/types/cervical-cancer/about/key-statistics.html