# Genmab Announces Very Favorable Topline Results from Phase 2 Clinical Trial of Tisotumab Vedotin in Recurrent or Metastatic Cervical Cancer

June 29, 2020

**Company Announcement**

- **Genmab and Seattle Genetics plan to discuss the results with the U.S. Food and Drug Administration (U.S. FDA)**
- **Full data to be presented at an upcoming medical meeting**

**Copenhagen, Denmark; June 29, 2020 – Genmab A/S (Nasdaq: GMAB) today announced very favorable topline results from the Phase 2 single-arm clinical trial known as innovaTV 204 evaluating tisotumab vedotin administered every three weeks for the treatment of patients who have relapsed or progressed on or after prior treatment for recurrent or metastatic cervical cancer.** Results from the trial showed a 24 percent confirmed objective response rate (ORR) by independent central review (95% Confidence Interval: 15.9% - 33.3%) with a median duration of response (DOR) of 8.3 months. The most common treatment-related adverse events (greater than or equal to 20 percent) included alopecia, epistaxis (nose bleeds), nausea, conjunctivitis, fatigue and dry eye. The data will be submitted for presentation at an upcoming medical meeting.

Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) directed to tissue factor, which is expressed on cervical cancer and can promote tumor growth, angiogenesis and metastases.[1] Standard therapies for previously treated recurrent and/or metastatic cervical cancer generally result in limited objective response rates of typically less than 15 percent with median overall survival ranging from 6.0 to 9.4 months, in an all-comers population.[1-8] Tisotumab vedotin is being developed in collaboration with Seattle Genetics.

“After treatment with first-line chemotherapy regimens, there is a high unmet need for new effective and tolerable treatment options for women with advanced cervical cancer, regardless of biomarkers and histology,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “These promising topline data from innovaTV 204 will be the basis of further engagement with the U.S. FDA as we continue to progress and expand our tisotumab vedotin development program in solid tumors with our partner.”

Additional clinical trials of tisotumab vedotin are currently enrolling patients, including in combination with pembrolizumab, carboplatin or bevacizumab, and with a weekly dosing schedule in patients with locally advanced or metastatic cervical cancer. Tisotumab vedotin is also being evaluated in other tissue factor expressing tumor types, including ovarian and other solid tumors.

**About innovaTV 204 Trial**
The innovaTV 204 trial (also known as GCT1015-04 or innovaTV 204/GOG-3023/ENGOT-cx6) is an ongoing single-arm, global, multicenter study of tisotumab vedotin for patients with recurrent or metastatic cervical cancer who were previously treated with doublet chemotherapy with bevacizumab if eligible per local standards. Additionally, patients were eligible if they had received up to two prior lines of therapy in the metastatic setting. In the study operationalized by Genmab, 101 patients were treated with tisotumab vedotin at multiple centers in the U.S. and Europe. The primary endpoint of the trial was confirmed objective response rate per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by independent central review. Key secondary endpoints included duration of response, progression-free survival, overall survival, safety and tolerability.

The study was conducted by Genmab in collaboration with Seattle Genetics Inc., European Network of Gynaecological Oncological Trial Groups (ENGOT) and Gynecologic Oncology Group (GOG). For more information about the Phase 2 innovaTV 204 clinical trial and other clinical trials with tisotumab vedotin, please visit www.clinicaltrials.gov.

**About Cervical Cancer**
Cervical cancer originates in the cells lining the cervix. Over 13,500 women are expected to be diagnosed with invasive cervical cancer in the U.S. in 2020, with approximately 4,200 deaths.[9] Cervical cancer remains one of the leading causes of cancer death in women globally, with over 311,000 women dying annually; the vast majority of these women being in the developing world.[10] Routine medical examinations and the human papillomavirus (HPV) vaccine have lowered the incidence of cervical cancer in the developed world. Despite these advances, women are still diagnosed with cervical cancer, which often recurs or becomes metastatic.

**About Tisotumab Vedotin**
Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) composed of Genmab’s fully human monoclonal antibody specific for tissue factor and Seattle Genetics’ ADC technology that utilizes a protease-cleavable linker that covalently attaches the microtubule-disrupting agent monomethyl auristatin E (MMAE) to the antibody and releases it upon internalization, inducing target cell death. In cancer biology, tissue factor is a protein that can promote tumor growth, angiogenesis and metastases.[1] Based on its high expression on many solid tumors and its rapid internalization, tissue factor was selected as a target for an ADC approach. Tisotumab vedotin is being co-developed by Genmab and Seattle Genetics, under an agreement in which the companies share all costs and profits for the product on a 50:50 basis.

Tisotumab vedotin is being evaluated in ongoing clinical trials as monotherapy in a range of solid tumors, including recurrent and/or metastatic cervical cancer, ovarian cancer and in combination with other commonly used therapies in recurrent or metastatic cervical cancer. These trials are evaluating tisotumab vedotin on a weekly or every three weeks dosing schedule.

**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 three 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, Arzerra® (ofatumumab, under agreement with Novartis AG), for the treatment of certain chronic lymphocytic leukemia indications in the U.S., Japan and certain other territories 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. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. A subcutaneous formulation of ofatumumab is in development by Novartis for the treatment of 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, the HexaBody® 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.

**Contact:**
Marisol Peron, Corporate Vice President, Communications & Investor Relations
T: +1 609 524 0065; E: mmp@genmab.com

**For Investor Relations:**
Andrew Carlsen, Senior Director, Investor Relations
T: +45 3377 9558; E: acn@genmab.com

*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.*



[1] Van de Berg YW et al. Blood 2012; 119:924.
[2] Miller et al., Gynecol Oncol 2008; 110:65.
[3] Bookman et al., Gynecol Oncol 2000; 77:446.
[4] Garcia et al., Am J Clin Oncol 2007; 30:428.
[5] Monk et al., J Clin Oncol 2009; 27:1069.
[6] Santin et al., Gynecol Oncol 2011; 122:495.
[7] Schilder et al., Gynecol Oncol 2005; 96:103
[8] Chung HC et al. J Clin Oncol 2019; 37:1470.
[9] National Cancer Institute SEER. "Cancer Stat Facts: Cervix Uteri Cancer." Available at https://seer.cancer.gov/statfacts/html/cervix.html. Last accessed April 2020.
[10] Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 countries https://www.iarc.fr /news-events/global-cancer-statistics-2018-globocan-estimates-of-incidence-and-mortality-worldwide-for-36-cancers-in-185-countries/.

Company Announcement no. 26
CVR no. 2102 3884
LEI Code 529900MTJPDPE4MHJ122

Genmab A/S
Kalvebod Brygge 43
1560 Copenhagen V
Denmark

**Attachment**

- 290620_CA26_innovaTV 204 Topline