Genmab and Seagen Present Interim Results From the innovaTV 205 Study for Tisotumab Vedotin Combination Therapy Treatment of Recurrent or Metastatic Cervical Cancer at ESMO Virtual Congress 2021

Media Release

- **Tisotumab Vedotin in Combination with Carboplatin Showed Encouraging, Durable Anti-Tumor Activity as First-Line Treatment**
- **Tisotumab Vedotin in Combination with Pembrolizumab Showed Encouraging, Durable Anti-Tumor Activity in Previously Treated Patients**

COPENHAGEN, Denmark, and BOTHELL, Wash.; September 19, 2021 - Genmab A/S (Nasdaq: GMAB) and Seagen Inc. (Nasdaq: SGEN) today presented interim data from two cohorts of the Phase 1b/2 innovaTV 205 multi-cohort, open-label trial of tisotumab vedotin in recurrent or metastatic cervical cancer at the European Society for Medical Oncology (ESMO) Virtual Congress 2021 as part of a featured mini oral presentation. Initial results from these two dose expansion cohorts of the study showed encouraging and durable anti-tumor activity with tisotumab vedotin in combination with carboplatin (Cohort D) as first-line therapy for patients with advanced cervical cancer who had not received prior systemic therapy, with a 55% objective response rate (ORR) and with tisotumab vedotin in combination with pembrolizumab (Cohort F) for patients with advanced cervical cancer who experienced disease progression after 1-2 lines of prior systemic therapy, with a 38% ORR. Both combinations demonstrated a manageable and acceptable safety profile, with no new safety signals identified.

“For patients diagnosed with recurrent or metastatic cervical cancer, there is a need for additional treatment options in the first-, second- and third-line settings,” said Ignace B. Vergote, M.D., Ph.D., co-founder of European Network of Gynaecological Oncological Trial groups (ENGOT), and lead investigator on the innovaTV 205/ENGOT-cx8/GOG-3024 clinical trial. “Interim results from the innovaTV 205 study show the potential for tisotumab vedotin to treat these patients, with encouraging response rates in combination with carboplatin and also in combination with pembrolizumab.”

“We are pleased to share the initial results from the innovaTV 205 study, as these data build upon our understanding of the potential for tisotumab vedotin as a combination therapy in first- and second-line treatment of recurrent or metastatic cervical cancer,” said Jan van de Winkel, Ph.D., Chief Executive Officer, Genmab. “We recognize the need for new therapies for patients with cervical cancer globally and are committed to advancing the tisotumab vedotin development program.”

“As we advance our clinical development program for tisotumab vedotin into earlier lines of therapy in cervical cancer, we’re encouraged by these interim results of the combination cohorts with tisotumab vedotin,” said Roger Dansey, M.D., Chief Medical Officer, Seagen. “Based on these results from the innovaTV 205 study, we also plan to evaluate tisotumab vedotin further in various combinations in first-line metastatic or recurrent cervical cancer.”

Tisotumab Vedotin (TV) + Carboplatin (Carbo) in First-line (1L) or + Pembrolizumab (Pembro) in Previously Treated (2L/3L) Recurrent or Metastatic Cervical Cancer (r/mCC): Interim Results of ENGOT-cx8/GOG-3024/innovaTV 205 Study (Presentation #723MO, mini oral presentation on Sunday, September 19)

1L TV + Carbo Dose Expansion Cohort Interim Results

Within this cohort, recurrent or metastatic cervical cancer patients who had not received any prior systemic therapy were given the recommended Phase 2 dose of tisotumab vedotin 2.0 mg/kg plus carboplatin AUC 5 Q3W.

Efficacy:

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- The primary endpoint of ORR was 55% (n= 18/33 patients), with four patients achieving complete responses and 14 patients achieving partial responses.
- Median time to response was 1.4 months (range 1.1-4.4), with median follow up of 7.9 months and median duration of response of 8.3 months (95% CI: 4.2-NR).
- Median progression-free survival (PFS) was 9.5 months (95% CI: 4.0-NR).

Safety:

- Grade ≥3 adverse events (AE) occurred in 78.8% of patients (n=26/33), with 57.6% (n=19/33) of patients experiencing Grade ≥3 AEs related to treatment with tisotumab vedotin.
- Adverse events of special interest (AESI) included ocular events (Grade 1-2: 57.6%; Grade ≥3: 9.1%), bleeding (Grade 1-2: 51.5%; Grade ≥3: 6.1%) and peripheral neuropathy (Grade 1-2: 48.5; Grade ≥3: 12.1%).

2L/3L TV + Pembro Dose Expansion Cohort Results Interim Results

Within this cohort, recurrent or metastatic cervical cancer patients who had received 1-2 prior systemic therapies were given the recommended Phase 2 dose of tisotumab vedotin 2.0 mg/kg plus pembrolizumab 200 mg Q3W.

Efficacy:

- The primary endpoint of ORR was 38% (n=13/34 patients), with two patients achieving complete responses and 11 patients achieving partial responses.
- Median time to response was 1.4 months (range 1.3-5.8), with median follow-up of 13.0 months and a median duration of response of 13.8 months (95% CI: 2.8-NR).
- Median PFS was 5.6 months (95% CI: 2.7-13.7).

Safety:

- Grade ≥3 AEs occurred in 74.3% of patients (n=26/35), with 45.7% (n=16/35) of patients experiencing Grade ≥3 AEs related to treatment with tisotumab vedotin.
- AESI included ocular events (Grade 1-2: 51.4%; Grade ≥3: 2.9%), bleeding (Grade 1-2: 57.1%; Grade ≥3: 8.6%) and peripheral neuropathy (Grade 1-2: 37.1%; Grade ≥3: 2.9%), with one patient experiencing a Grade 4 bleeding event.

Additionally, Genmab and Seagen presented data from dose-escalation cohorts of the innovaTV 205 study at the 2021 International Gynecologic Cancer Society (IGCS) Annual Meeting held August 30 – September 2, 2021.

About Cervical Cancer

Cervical cancer originates in the cells lining the cervix. In 2021, an estimated 14,480 new cases of invasive cervical cancer will be diagnosed in the U.S., and 4,290 women will die from the disease.[1] 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 are in the developing world.[2] Routine medical examinations and human papillomavirus (HPV) vaccines 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. Current therapies for previously treated recurrent 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.[3,4,5,6,7,8,9,10]

About the innovaTV 205 Trial

The innovaTV 205 trial (also known as ENGOT-cx8/GOG-3024) is a Phase 1b/2 open-label, multi-center trial of tisotumab vedotin monotherapy and in combination with bevacizumab, pembrolizumab, or carboplatin in patients with recurrent or metastatic cervical cancer. The study consists of two parts: dose

escalation (Cohorts A, B, and C) and dose expansion (Cohorts D, E, F and G). Patients enrolled in the dose escalation cohorts have progressed during or after standard of care therapy or are intolerant or ineligible to receive standard of care treatments. The primary objective is to identify and establish the maximum tolerated dose and Recommended Phase 2 Dose (RP2D) of tisotumab vedotin as combination therapy. Within the dose expansion cohorts, patients with recurrent or metastatic cervical cancer who have not previously received prior systemic therapy are treated in Cohorts D and E, with patients who have progressed on or after standard of care treatments evaluated in Cohorts F and G.

For more information about the innovaTV 205 clinical trial and the study collaborators, visit here, and to learn more about other clinical trials with tisotumab vedotin, visit clinicaltrials.gov.

About Tisotumab Vedotin
Tisotumab vedotin is an antibody-drug conjugate (ADC) composed of Genmab's fully human monoclonal antibody specific for tissue factor and Seagen's 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 programmed cell death. In cancer biology, tissue factor is a cell-surface protein and is associated with tumor growth, angiogenesis, metastasis and poor prognosis.[11] Tissue factor was selected as a target for an ADC approach based on its increased levels of expression on multiple solid tumors and its rapid internalization.

Tisotumab vedotin is being evaluated in a global Phase 3, randomized clinical trial called innovaTV 301 versus investigator's choice of chemotherapy in recurrent or metastatic cervical cancer. The primary endpoint is overall survival, and secondary endpoints include progression-free survival, duration of response, objective response rate, safety and tolerability. Enrollment is ongoing and the study is intended to support global registrations. More information about the innovaTV 301 clinical trial, including enrolling sites, is available here. In addition, tisotumab vedotin is being evaluated in ongoing clinical trials as monotherapy in recurrent or metastatic cervical cancer, ovarian cancer, and other solid tumors and in combination with commonly used therapies in recurrent or metastatic cervical cancer.

Additional clinical studies for tisotumab vedotin include Phase 2 studies in second-/third-line recurrent or metastatic cervical cancer as monotherapy (innovaTV 204), a Phase 2 study in first-/second-line recurrent or metastatic cervical cancer as monotherapy or in combination with other agents (innovaTV 205) and additional studies in various solid tumors.

About Genmab
Genmab is an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates, including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company 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.

About Seagen
Seagen is a global biotechnology company that discovers, develops and commercializes transformative cancer medicines to make a meaningful difference in people's lives. Seagen is headquartered in the

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Seattle, Washington area, and has locations in California, Canada, Switzerland and the European Union. For more information on our marketed products and robust pipeline, visit www.seagen.com and follow @SeagenGlobal on Twitter.

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

Genmab Forward Looking Statements
This Media Release 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 Media Release 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.

Seagen Forward Looking Statements
Certain of the statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of tisotumab vedotin including its efficacy, safety and therapeutic uses, the clinical development program for tisotumab vedotin and the potential for the innovaTV 301 trial to support global registrations. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the difficulty and uncertainty of pharmaceutical product development, the risk of adverse events or safety signals, the inability to show sufficient activity in current and future clinical trials and the possibility of adverse regulatory actions. More information about the risks and uncertainties faced by Seagen is contained under the caption "Risk Factors" included in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 filed with the Securities and Exchange Commission. Seagen disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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[1] Cancer Stat Facts: Cervical Cancer. National Cancer Institute website. https://seer.cancer.gov/statfacts/html/cervix.html. Accessed September 13, 2021.
[2] Bray et al., CA Cancer J Clin 2018; 0:1-31.
[3] Miller et al., Gynecol Oncol 2008; 110:65.
[4] Santin et al., Gynecol Oncol 2011; 122:495.
[5] Bookman et al., Gynecol Oncol 2000; 77:446.
[6] Garcia et al., Am J Clin Oncol 2007; 30:428.
[7] Monk et al., J Clin Oncol 2009; 27:1069.
[8] Santin et al., Gynecol Oncol 2011; 122:495.
[9] Schilder et al., Gynecol Oncol 2005; 96:103.
[10] Chung HC et al. J Clin Oncol 2019; 37:1470.
[11] Rondon et al. Semin Thromb Hemost 2019; 45:396–412.