



Genmab and Seattle Genetics to Initiate New Study of Novel Antibody-Drug Conjugate Tisotumab Vedotin in Cervical Cancer

Company Announcement

- Phase II study of tisotumab vedotin in patients with advanced cervical cancer
- Study provides opportunity for accelerated approval and is expected to begin in the coming months

Copenhagen, Denmark and Bothell, Washington; October 10, 2017 – Genmab A/S (Nasdaq Copenhagen: GEN) and Seattle Genetics, Inc. (NASDAQ: SGEN) announced today a decision to start a Phase II study of tisotumab vedotin in patients with recurrent and/or metastatic cervical cancer. The study could provide the basis for a regulatory application for approval. Tisotumab vedotin consists of a tissue factor (TF)-targeted antibody linked to the cell-killing agent monomethyl auristatin E (MMAE). TF is a protein expressed on a broad range of solid tumors. The Phase II trial is single arm and includes about 100 patients with recurrent or metastatic cervical cancer who relapsed or progressed after standard of care treatment. The companies plan to start enrolling patients by the first half of 2018.

"We are very pleased to see the clinical development of tisotumab vedotin progress in patients with cervical cancer – an area with a strong unmet medical need. The study provides an opportunity for accelerated registration. We look forward to the continuing development of this promising first-in-class antibody-drug conjugate," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

"Standard therapies for previously treated recurrent and/or metastatic cervical cancer generally result in response rates of less than 15 percent and a median overall survival of six to eight months," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "Based on promising data from the Phase I/II clinical trial of tisotumab vedotin in recurrent and/or metastatic cervical cancer and feedback from the Food and Drug Administration (FDA) on the planned trial, we and Genmab are advancing the program into a potentially registrational study for these patients with high unmet medical need."

About the Phase II study

The single arm, multicenter Phase II study (GCT1015-04) of tisotumab vedotin monotherapy is expected to enroll about 100 patients with recurrent or metastatic cervical cancer who have experienced disease progression on or after platinum containing chemotherapy and who have received or are ineligible for bevacizumab. The primary endpoint of the study is overall response rate (ORR) as assessed by independent review of RECIST v1.1 criteria. The main secondary endpoints are duration of response (DoR) and safety.

About Cervical Cancer

Cervical cancer originates in the cells lining the cervix, which connects the uterus to the birth canal. About 13,000 women are expected to be diagnosed with cervical cancer in the US in 2017, with an estimated 4000 deaths.¹ Globally, it was estimated that 527,000 people would be diagnosed and 265,000 would die from the disease in 2012, the vast majority of these patients being in the developing world.² Routine medical examinations and the human papillomavirus (HPV) vaccine have had a positive impact on the incidence of cervical cancer in the developed world. Despite these advances, women are still diagnosed with cervical cancer, which can have a devastating impact, particularly in the recurrent or metastatic setting. Standard therapies for previously treated recurrent/metastatic cervical cancer generally result in response rates of less than 15 percent and a median overall survival of 6 to 8 months.³⁻¹⁰

About Tisotumab Vedotin

Tisotumab vedotin is an antibody-drug conjugate (ADC) composed of Genmab's human antibody that binds to tissue factor (TF) and Seattle Genetics' ADC technology that utilizes a cleavable linker and the

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cytotoxic drug monomethyl auristatin E (MMAE). TF is a protein involved in tumor signaling and angiogenesis. Based on its high expression on many solid tumors and its rapid internalization, TF was selected as a target for an ADC approach. Tisotumab vedotin is being evaluated in ongoing Phase I/II clinical studies for solid tumors and a Phase II trial in recurrent and/or metastatic cervical cancer is planned to start by the first half of 2018. Tisotumab vedotin is being co-developed by Genmab and Seattle Genetics, under an agreement in which the companies share all future costs and profits for the product on a 50:50 basis.

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 has two approved antibodies, DARZALEX[®] (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra[®] (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications, other blood cancers, and solid tumors. A subcutaneous formulation of ofatumumab is in development for 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, and the HexaBody[®] platform which creates effector function enhanced antibodies. 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. For more information visit www.genmab.com.

About Seattle Genetics

Seattle Genetics is an innovative biotechnology company dedicated to improving the lives of people with cancer through novel antibody-based therapies. The company's industry-leading antibody-drug conjugate (ADC) technology harnesses the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells. Seattle Genetics commercializes ADCETRIS® (brentuximab vedotin) for the treatment of several types of CD30-expressing lymphomas. The company is also advancing a robust pipeline of novel therapies for solid tumors and blood-related cancers designed to address significant unmet medical needs and improve treatment outcomes for patients. More information can be found at www.seattlegenetics.com and follow @SeattleGenetics on Twitter

Forward Looking Statement for Genmab

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 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 <u>www.genmab.com</u>. 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[®]; the Y-shaped Genmab logo[®];

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Forward Looking Statement for Seattle Genetics

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, its possible use in treatment of cervical cancer, the timing, size or conduct of the Phase II clinical trial, and the possibility that the trial and resulting data could support registration or accelerated approval of tisotumab vedotin. 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 inability of tisotumab vedotin to show sufficient activity in the clinical setting referenced above and in future potential clinical trials, the risk of adverse events associated with tisotumab vedotin and regulatory actions which may affect the future development of our drug candidates or those of our collaborators. More information about the risks and uncertainties faced by Seattle Genetics is contained under the caption "Risk Factors" included in the company's Quarterly Report on Form 10-Q for the quarter ended August 1, 2017 filed with the Securities and Exchange Commission. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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¹ National Cancer Institute SEER. "Cancer Stat Facts: Cervix Uteri Cancer." Available at https://seer.cancer.gov/statfacts/html/cervix.html. Accessed September 2017.

² Cancer Research UK. "Cervical cancer statistics." Available at http://www.cancerresearchuk.org/health-

professional/cancer-statistics/statistics-by-cancer-type/cervical-cancer/mortality#heading-Five. Accessed September 2017.

- ³ Miller et al., Gynecol Oncol 2008; 110:65
- ⁴ Bookman et al., Gynecol Oncol 2000; 77:446
- ⁵ Garcia et al., Am J Clin Oncol 2007; 30:428
- ⁶ Muggia et al., J Clin Oncol 2009; 27:1069
- ⁷ Monk et al., J Clin Oncol 2009; 27:1069
- ⁸ Santin et al., Genecol Oncol 2011; 122:495
- ⁹ Schellens, J Clin Oncol 35, 2017 (suppl; abstr 5514)
- ¹⁰ Hollebecque et al., J Clin Oncol 35, 2017 (suppl; abstr 6025)