



Genmab and Seagen Announce U.S. FDA Filing Acceptance for Priority Review of Tisotumab Vedotin Biologics License Application for Patients with Recurrent or Metastatic Cervical Cancer

April 9, 2021

Company Announcement

- **FDA action date is Oct 10, 2021**
- **BLA submission supported by positive pivotal innovaTV 204 trial results presented at the European Society of Medical Oncology Virtual Congress 2020**

COPENHAGEN, Denmark and BOTHELL, Wash.; April 09, 2021 – Genmab A/S (Nasdaq: GMAB) and Seagen Inc. (Nasdaq: SGEN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the Biologics License Application (BLA) seeking accelerated approval for tisotumab vedotin. This BLA requests FDA approval of tisotumab vedotin for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of Oct 10, 2021. Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) directed to tissue factor (TF), a cell-surface protein expressed on multiple solid tumors including cervical cancer, and is associated with tumor growth, angiogenesis, metastasis and poor prognosis.¹

"We are pleased that the tisotumab vedotin BLA has been accepted with Priority Review by the FDA as there is an unmet need for effective therapies for women with recurrent or metastatic cervical cancer, who have disease progression on or after chemotherapy," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "This is an important milestone for Genmab as it brings us closer to our goal of bringing differentiated therapies to patients and transforming cancer treatment."

The FDA's filing of the tisotumab vedotin BLA with Priority Review marks an important step forward for this ADC as a potential treatment for patients with recurrent or metastatic cervical cancer," said Roger Dansey, M.D., Chief Medical Officer at Seagen. "We are collaborating closely with the FDA throughout the review process to make this important therapy available to patients."

The BLA for tisotumab vedotin was submitted in February 2021. The submission is based on the results of the innovaTV 204 pivotal phase 2 single-arm clinical trial evaluating tisotumab vedotin as monotherapy in patients with previously treated recurrent or metastatic cervical cancer. These data were presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.

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.² 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.³ 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.⁴⁻¹⁰

About the 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 or without bevacizumab. Additionally, patients were eligible if they had received up to two prior lines of therapy in the recurrent or metastatic setting. In the study, 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 Seagen, European Network of Gynaecological Oncological Trial Groups (ENGOT) and the Gynecologic Oncology Group (GOG) Foundation. For more information about the phase 2 [innovaTV 204](#) clinical trial and other clinical trials with tisotumab vedotin, please visit www.clinicaltrials.gov.

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 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 target cell death. In cancer biology, tissue factor is a cell-surface protein and associated with tumor growth, angiogenesis, metastasis and poor prognosis.¹ Based on its elevated expression in multiple 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 Seagen, 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 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. 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. These trials are evaluating tisotumab vedotin

on a weekly or every three-week dosing schedule. More information about the [innovaTV 301 clinical trial](#), including enrolling sites, as well as other ongoing clinical trials is available at www.clinicaltrials.gov.

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 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.

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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.

Genmab A/S and/or its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; DuoBody in combination with the DuoBody logo®; HexaBody®; HexaBody in combination with the HexaBody logo®; DuoHexaBody®; HexElect®; and UniBody®. Kesimpta® is a trademark of Novartis AG or its affiliates. DARZALEX® and DARZALEX FASPRO® are trademarks of Johnson & Johnson. TEPEZZA® is a trademark of Horizon Therapeutics Ireland DAC.

Seagen Forward Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the potential FDA approval of tisotumab vedotin for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy based on the results of the innovaTV 204 trial, the timing of any potential FDA approval and the therapeutic potential 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 without limitation the possibility that the Biologics License Application submission based on the innovaTV 204 trial may not be ultimately approved by the FDA in a timely manner or at all or with the requested label; that subsequent clinical trials may fail to establish sufficient efficacy; that adverse events or safety signals may occur; and that adverse regulatory actions may occur. More information about the risks and uncertainties faced by Seagen is contained under the caption "Risk Factors" included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 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.

References

¹ Rondon et al. Semin Thromb Hemost 2019; 45:396–412.

² National Cancer Institute SEER. "Cancer Stat Facts: Cervix Uteri Cancer." Available at <https://seer.cancer.gov/statfacts/html/cervix.html>. Last accessed April 2020.

³ 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/>.

⁴ Miller et al., Gynecol Oncol 2008; 110:65.

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.

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Attachment

- [040921 CA26 TV204 BLA filing Acceptance](#)