

Genmab and Seattle Genetics Present Data from Tisotumab Vedotin innovaTV 204 Pivotal Trial in Recurrent or Metastatic Cervical Cancer at ESMO Virtual Congress 2020

Media Release

COPENHAGEN, Denmark and BOTHELL, Wash., 21 September 2020

- Data featured in late-breaking proffered paper oral presentation
- Biologics license application submission planned to support accelerated approval pathway with the FDA

[Genmab A/S](#) (Nasdaq: GMAB) and [Seattle Genetics, Inc.](#) (Nasdaq: SGEN) today presented data from the innovaTV 204 pivotal phase 2, single-arm clinical trial evaluating tisotumab vedotin as monotherapy in patients with previously treated recurrent and/or metastatic cervical cancer at the **European Society for Medical Oncology (ESMO) Virtual Congress 2020. Patients had previously received a doublet chemotherapy and, if eligible, bevacizumab as first-line therapy. Results from the trial showed a 24 percent confirmed objective response rate (ORR) by independent central review 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. Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) directed to tissue factor (TF), which is prevalent on solid tumors including cervical cancer and can promote tumor growth, angiogenesis and metastasis.¹**

Current 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.¹⁻⁸

“Following resistance to or progression on first-line standard of care therapy, there are limited treatment options for women with metastatic cervical cancer,” said Robert L. Coleman, M.D., Chief Scientific Officer for US Oncology Research and lead investigator of the innovaTV 204 clinical trial. “The current treatment approaches for this disease setting have low objective response rates with poor outcomes. The results of the tisotumab vedotin phase 2 clinical trial are encouraging as they demonstrate clinically meaningful, durable responses with a manageable side effect profile.”

“We are encouraged by the innovaTV 204 trial results, which suggests that tisotumab vedotin as a monotherapy could potentially become an important option for women with metastatic and or recurrent cervical cancer,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. “Seattle Genetics and Genmab are committed to making a difference in the lives of cancer patients and we look forward to working with the FDA with a goal to make this potential treatment option available to women as quickly as possible.”

“Tisotumab vedotin has demonstrated meaningful clinical activity in patients with recurrent and/or metastatic cervical cancer for whom there is a high unmet need for new therapies,” said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. “Based on these results, we look forward to submitting a Biologics License Application to the FDA under the accelerated approval pathway.”

Data presented at [ESMO](#) include the primary endpoint of confirmed ORR as assessed by independent central review in 101 patients treated with tisotumab vedotin in the trial. Secondary endpoints included DOR, time to response, progression-free survival (PFS), overall survival (OS), safety and tolerability.

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Tisotumab Vedotin in Previously Treated Recurrent or Metastatic Cervical Cancer: Results from the Phase 2 innovaTV 204/GOG-3023/ENGOT-cx6 Study (Abstract #3435, late-breaking proffered paper oral presentation at 17:04 CET on Monday, September 21, 2020)

Efficacy:

- The primary endpoint of ORR (complete response + partial response) showed a 24 percent confirmed ORR [95% Confidence Interval (CI): 15.9%-33.3%], including 7 patients (7 percent) with a complete response and 17 patients (17 percent) with a partial response.
 - After a median follow-up of 10 months, the median DOR was 8.3 months (95% CI: 4.2, not reached).
- The median time to response was 1.4 months (range, 1.1-5.1), with activity generally observed within the first two treatment cycles.
- Subgroup analyses demonstrated that responses were generally consistent across subgroups regardless of tumor histology, lines of prior therapy, responses to prior systemic regimen, and doublet chemotherapy with bevacizumab as first-line treatment.
- The median PFS was 4.2 months (95% CI: 3.0, 4.4) and the six-month PFS rate was 30 percent (95% CI: 20.8, 40.1).
- The median OS was 12.1 months (95% CI: 9.6, 13.9) and the six-month OS rate was 79 percent (95% CI: 69.3, 85.6).

Safety:

- The most common treatment-related adverse events (greater than or equal to 20 percent) included alopecia (Grade 1/2 at 38 percent), epistaxis (nose bleeds, Grade 1/2 at 30 percent), nausea (Grade 1/2 at 27 percent), conjunctivitis (Grade 1/2 at 26 percent), fatigue (Grade 1/2 at 24 percent, Grade 3 or higher at 2 percent) and dry eye (Grade 1/2 at 23 percent). Most treatment-related adverse events were Grade 1 or 2 and no new safety signals were reported. One death due to septic shock was considered by the investigator to be related to therapy.
- Pre-specified adverse events of interest with tisotumab vedotin treatment included ocular events, bleeding and peripheral neuropathy. Ocular adverse events considered to be related to therapy that occurred in patients were mostly mild to moderate (Grade 1 at 25 percent, Grade 2 at 27 percent, Grade 3 at 2 percent) of which a majority of the events resolved (86 percent) and were managed with an eye care plan. Bleeding events considered to be related to therapy that occurred in patients were mostly mild (Grade 1 at 34 percent, Grade 2 at 3 percent, Grade 3 at 2 percent) of which a majority of the events resolved (90 percent). The most common bleeding events included Grade 1 epistaxis (28 percent). Peripheral neuropathy events considered to be related to therapy were mostly mild to moderate (Grade 1 at 17 percent, Grade 2 at 9 percent, Grade 3 at 7 percent) and managed with dose modifications. Resolution of peripheral neuropathy was limited by follow-up period.

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 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.

About the innovaTV 204 Trial

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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 and/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 in collaboration with European Network of Gynaecological Oncological Trial Groups (ENGOT) and Gynecologic Oncology Group (GOG). For more information about the phase 2 [innoVA TV 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 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 metastasis.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 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.

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 the following 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, Kesimpta[®] (subcutaneous ofatumumab, under agreement with Novartis AG), for the treatment of adults with relapsing forms of multiple sclerosis in the U.S. 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. The first approved Genmab created therapy, Arzerra[®] (ofatumumab, under agreement with Novartis AG), approved for the treatment of certain chronic lymphocytic leukemia indications, is available in Japan and is also available in other territories via compassionate use or oncology access programs. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. 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[®]

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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.

About Seattle Genetics

Seattle Genetics, Inc. is a global biotechnology company that discovers, develops and commercializes transformative cancer medicines to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) and PADCEV® (enfortumab vedotin-ejfv) use the Company's industry-leading antibody-drug conjugate (ADC) technology. ADCETRIS is approved in certain CD30-expressing lymphomas, and PADCEV is approved in certain metastatic urothelial cancers. TUKYSA® (tucatinib), a small molecule tyrosine kinase inhibitor, is approved in certain HER2-positive metastatic breast cancers. The company is headquartered in the Seattle, Washington area, with locations in California, Switzerland and the European Union. For more information on our robust pipeline, visit www.seattlegenetics.com and follow [@SeattleGenetics](https://twitter.com/SeattleGenetics) on Twitter.

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Genmab Forward Looking Statement

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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.

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Seattle Genetics Forward Looking Statement

Certain of the statements made in this press release are forward looking, such as those, among others, relating to plans to submit a Biologics License Application (BLA) to FDA under FDA's Accelerated Approval program based on the results of the innovaTV 204, 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 the possibility of delays in the submission of a BLA to the FDA, that the data from innovaTV 204 may not be sufficient to support accelerated approval of tisotumab vedotin, 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 Seattle Genetics is contained under the caption "Risk Factors" included in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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, except as required by law.

References:

- ¹ Van de Berg YW et al. Blood 2012;119:924.
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- ⁴ Garcia et al., Am J Clin Oncol 2007; 30:428.
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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/>.