



# Genmab and Seattle Genetics Announce Tisotumab Vedotin Data to be Presented at ESMO 2018 Congress

## Media Release

• Data presented from updated analysis of full innovaTV 201 expansion cohort in recurrent or metastatic cervical cancer

**Copenhagen, Denmark and BOTHELL, Wash.,** October 9, 2018 – Genmab A/S (Nasdaq Copenhagen: GEN) and Seattle Genetics, Inc. (Nasdaq: SGEN) announced today that updated clinical data from the innovaTV 201 Phase II study evaluating tisotumab vedotin in patients with recurrent and/or metastatic cervical cancer will be presented as a poster at the European Society for Medical Oncology (ESMO) 2018 Congress taking place in Munich, Germany from October 19 to 23, 2018. Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) designed to target the Tissue Factor antigen, which is expressed on a broad range of solid tumors.

"We look forward to presenting an update on the expanded cervical cancer cohort data showing that tisotumab vedotin continues to demonstrate tolerability and clinical activity in heavily pretreated patients with cervical cancer. We anticipate publishing the final data from this cohort in the future," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "In the past year, the development program of tisotumab vedotin has also been expanded with additional trials and indications, and we are excited about the continued growth of this program."

"In the recurrent and metastatic cervical cancer setting, there remains an unmet need for new treatment options," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "We are pleased to be collaborating with Genmab to advance tisotumab vedotin in the potentially pivotal innovaTV 204 clinical trial in cervical cancer and to evaluate its potential in a broad range of other solid tumors."

Details of Poster Presentation:

Title: A Phase IIa study of tisotumab vedotin in patients with previously treated recurrent or metastatic cervical cancer: updated analysis of full cervical expansion cohort Presenter: Nicole Concin, M.D. Medical University of Innsbruck, Austria Abstract #: 963P Session: Poster Display Session: Biomarkers, Gynaecological cancers, Haematological malignancies, Immunotherapy of cancer, New diagnostic tools, NSCLC - early stage, locally advanced & metastatic, SCLC, Thoracic malignancies, Translational research Date and Time: October 20, 12:30-13:30 CEST Location: Hall A3 Poster Area

The abstract is available on the ESMO website at www.esmo.org.

### About the innovaTV 201 (GEN701) Study

The innovaTV 201 study is a 170 patient, two-part Phase I/II study of tisotumab vedotin in eight types of solid tumors: ovarian, cervical, endometrial, bladder, prostate, esophageal, lung, and head and neck. Part 1 is a classical 3+3 dose escalation design testing various doses of tisotumab vedotin once every three weeks to establish the recommended Phase II (RP2D) and maximum tolerated dose as well as the safety profile of tisotumab vedotin. Part 2 of the study investigates all eight indications in parallel expansion cohorts. The cervical cancer cohort includes 55 patients. Patients receive 2.0 mg/kg (=RP2D) of tisotumab vedotin once every three weeks. The primary objective of this part of the study is to further investigate the safety profile of tisotumab vedotin and preliminary efficacy.

### About Tisotumab Vedotin

Genmab A/S Kalvebod Brygge 43 1560 Copenhagen V, Denmark Tel: +45 7020 2728 www.genmab.com Media Release no. 09 Page 1/3 CVR no. 2102 3884 LEI Code 529900MTJPDPE4MHJ122





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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 cytotoxic drug monomethyl auristatin E (MMAE). TF is a protein involved in tumor cell 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 or planned Phase II trials in recurrent and/or metastatic cervical cancer, ovarian cancer and other solid tumors. Tisotumab vedotin is being co-developed by Genmab and Seattle Genetics.

#### **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<sup>®</sup> (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra<sup>®</sup> (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications and other blood cancers. 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<sup>®</sup> platform for generation of bispecific antibodies, the HexaBody<sup>®</sup> platform, which creates effector function enhanced antibodies and the HexElect<sup>™</sup> platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency. 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, Inc. is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people's lives. ADCETRIS<sup>®</sup> (brentuximab vedotin) utilizes the company's industry-leading antibody-drug conjugate (ADC) technology and is currently approved for the treatment of multiple CD30-expressing lymphomas. Beyond ADCETRIS, the company has established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing pivotal trials for solid tumors. Enfortumab vedotin for metastatic urothelial cancer and tisotumab vedotin for metastatic cervical cancer utilize our proprietary ADC technology. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies to build a portfolio of proprietary immuno-oncology agents in clinical trials targeting hematologic malignancies and solid tumors. The company is headquartered in Bothell, Washington, and has a European office in Switzerland. For more information on our robust pipeline, visit www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

### Forward Looking Statement for Genmab

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 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

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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 benefits and uses as monotherapy, and the referenced Phase I/II clinical trial. 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 the risk of adverse events of tisotumab vedotin, including the potential for newly-emerging safety signals, delays in planned clinical trial initiations, enrollment and conduct, obtaining data from clinical trials, and anticipated regulatory submissions and approvals in each case for a variety of reasons, including the difficulty and uncertainty of pharmaceutical product development, unexpected adverse events and/or adverse regulatory action, possible required modifications to clinical trials and the inability to provide information and institute safety mitigation measures as required by the FDA or other regulatory authorities from time to time, failure to properly conduct or manage the company's clinical trials and failure of clinical results to support continued development or regulatory approvals, in which case our clinical trials may be delayed or discontinued. 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 guarter ended June 30, 2018 filed with the Securities and Exchange Commission. Seattle Genetics disclaims any intention or obligation to update or revise any forwardlooking statements, whether as a result of new information, future events or otherwise, except as required by law.

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