Genmab and Seagen Present First Data on Tisotumab Vedotin (TIVDAK®) in Patients with Head and Neck Squamous Cell Carcinoma

Media Release

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- **Data from the innovaTV 207 global phase 2 trial to be presented at the American Society for Radiation Oncology (ASTRO) 2022 Multidisciplinary Head and Neck Cancers Symposium**

Genmab A/S (Nasdaq: GMAB) and Seagen Inc. (Nasdaq: SGEN) will present preliminary data from the innovaTV 207 global, open-label, multicenter phase 2 trial of tisotumab vedotin (TIVDAK®) as a monotherapy in patients with squamous cell carcinoma of the head and neck (SCCHN) who experienced disease progression on or after a first-line platinum-containing regimen and a checkpoint inhibitor. Early results showed tisotumab vedotin demonstrated a manageable safety profile and promising preliminary antitumor activity in this patient population with the primary endpoint of confirmed objective response rate (ORR) per investigator, achieved by 16 percent of patients (95% CI: 5.5 to 33.7). Findings will be presented as part of a plenary session at the American Society for Radiation Oncology (ASTRO) 2022 Multidisciplinary Head and Neck Cancers Symposium on February 25.

“There is a significant unmet need for additional treatment options for patients diagnosed with squamous cell carcinoma of the head and neck that has progressed despite the use of chemotherapy,” said David S. Hong, M.D., deputy chair of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center and lead investigator of the innovaTV 207 clinical trial. “These preliminary data provide important insight into the safety of tisotumab vedotin in this tumor type and demonstrate the value of exploring this potential use further in the innovaTV 207 trial.”

The SCCHN cohort of the innovaTV 207 trial enrolled 31 patients with a median age of 65 (range 47 to 78) years whose disease progressed on or after systemic therapy. Patients received 2 milligrams (mg)/kilogram (kg) tisotumab vedotin (maximum dose: 200 mg per infusion) intravenously on day one of each 21-day cycle. The secondary endpoints included disease control rate (DCR), progression-free survival (PFS) per investigator and overall survival (OS). DCR per investigator was 58.1 percent (95% CI: 39.1 to 75.5), median PFS was 4.2 months (95% CI: 2.7 to 4.8), median follow-up was 10.0 months (95% CI: 8.5 to 13.1) and median OS was 9.4 months (95% CI: 8.1 to 11.8). Adverse events were consistent with the known safety profile of tisotumab vedotin: twenty-one (67.7%) patients developed Grade ≥3 treatment-emergent adverse events (TEAEs); most commonly (≥10% of patients) anemia (16.1%), pneumonia (12.9%), and dyspnea (12.9%). Incidence of treatment-emergent serious adverse events (SAEs) was 51.6%, and incidence of treatment-related SAEs was 6.5% (grade 3 hemoptysis [n=1] and grade 3 post-procedural hemorrhage [n=1]).

See TIVDAK U.S. Important Safety Information, including Boxed Warning, below.

“We recognize the high medical need for additional treatment options for patients with head and neck cancers,” said Jan van de Winkel, Ph.D., Chief Executive Officer, Genmab. “These initial data results are encouraging and underscore the importance of our ongoing clinical trial program that will assess the potential utility of tisotumab vedotin in various cancers.”

For more information about the ongoing phase 2 innovaTV 207 clinical trial of tisotumab vedotin, please visit www.clinicaltrials.gov (Identifier: NCT03485209).

“The presentation of these preliminary data represents another step forward in our work to advance the tisotumab vedotin development program,” said Roger Dansey, M.D., Chief Medical Officer, Seagen. “In partnership with Genmab, we will continue to recruit additional patients for trials to further investigate

tisotumab vedotin in patients with squamous cell carcinoma of the head and neck, including its potential use as a combination therapy."

About the innovaTV 207 Trial
The phase 2 innovaTV 207 clinical trial evaluates the activity, safety, and tolerability of tisotumab vedotin in selected solid tumors with high tissue factor (TF) expression. The trial is a global, multicenter, open label basket trial which will enroll an estimated 532 adult patients with relapsed, locally-advanced or metastatic disease in separate tumor-specific cohorts. The primary endpoint of the trial is confirmed ORR per investigator, defined as the proportion of patients who achieve a confirmed complete or partial response. Key secondary endpoints include confirmed and unconfirmed ORR, DCR, duration of response, PFS, OS, safety and tolerability. For more information about the phase 2 innovaTV 207 clinical trial of tisotumab vedotin, please visit www.clinicaltrials.gov (Identifier: NCT03485209).

About Tisotumab Vedotin
Tisotumab vedotin-tftv (TIVDAK®) is an antibody-drug conjugate (ADC) composed of Genmab's human monoclonal antibody directed to tissue factor (TF) 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. Nonclinical data suggests that the anticancer activity of tisotumab vedotin is due to the binding of the ADC to TF expressing cancer cells, followed by internalization of the ADC-TF complex, and release of MMAE via proteolytic cleavage. MMAE disrupts the microtubule network of actively dividing cells, leading to cell cycle arrest and apoptotic cell death. In vitro, tisotumab vedotin also mediates antibody-dependent cellular phagocytosis and antibody-dependent cellular cytotoxicity.

In September 2021, the U.S. Food and Drug Administration granted accelerated approval for tisotumab vedotin (TIVDAK**)** in patients with previously treated recurrent or metastatic cervical cancer. TIVDAK is the first and only approved ADC for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

Indication
TIVDAK is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information

BOXED WARNING: OCULAR TOXICITY
TIVDAK caused changes in the corneal epithelium and conjunctiva resulting in changes in vision, including severe vision loss, and corneal ulceration. Conduct an ophthalmic exam at baseline, prior to each dose, and as clinically indicated. Adhere to premedication and required eye care before, during, and after infusion. Withhold TIVDAK until improvement and resume, reduce the dose, or permanently discontinue, based on severity.

Warnings and Precautions
Ocular Adverse Reactions occurred in 60% of patients with cervical cancer treated with TIVDAK across clinical trials. The most common were conjunctival adverse reactions (40%), dry eye (29%), corneal adverse reactions (21%), and blepharitis (8%). Grade 3 ocular adverse reactions occurred in 3.8 % of patients, including severe ulcerative keratitis in 3.2% of patients. One patient experienced ulcerative keratitis with perforation requiring corneal transplantation. Cases of symblepharon were reported in patients with other tumor types treated with TIVDAK at the recommended dose. In innovaTV 204, 4% of

patients experienced visual acuity changes to 20/50 or worse including 1% of patients who experienced a visual acuity change to 20/200. Of the patients who experienced decreased visual acuity to 20/50 or worse, 75% resolved, including the patient who experienced decreased visual acuity to 20/200.

Refer patients to an eye care provider for an ophthalmic exam including visual acuity and slit lamp exam at baseline, prior to each dose, and as clinically indicated. Adhere to premedication and required eye care to reduce the risk of ocular adverse reactions. Promptly refer patients to an eye care provider for any new or worsening ocular signs and symptoms. Withhold dose, reduce the dose, or permanently discontinue TIVDAK based on the severity of the adverse reaction.

Peripheral Neuropathy (PN) occurred in 42% of cervical cancer patients treated with TIVDAK across clinical trials; 8% of patients experienced Grade 3 PN. PN adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (11%), peripheral sensorimotor neuropathy (5%), motor neuropathy (3%), muscular weakness (3%), and demyelinating peripheral polyneuropathy (1%). One patient with another tumor type treated with TIVDAK at the recommended dose developed Guillain-Barre syndrome. Monitor patients for signs and symptoms of neuropathy. For new or worsening PN, withhold, dose reduce, or permanently discontinue TIVDAK based on the severity of PN.

Hemorrhage occurred in 62% of cervical cancer patients treated with TIVDAK across clinical trials. The most common all grade hemorrhage adverse reactions were epistaxis (44%), hematuria (10%), and vaginal hemorrhage (10%). Grade 3 hemorrhage occurred in 5% of patients. Monitor patients for signs and symptoms of hemorrhage. For patients experiencing pulmonary or CNS hemorrhage, permanently discontinue TIVDAK. For Grade ≥2 hemorrhage in any other location, withhold until bleeding has resolved, blood hemoglobin is stable, there is no bleeding diathesis that could increase the risk of continuing therapy, and there is no anatomical or pathologic condition that can increase the risk of hemorrhage recurrence. After resolution, either resume treatment or permanently discontinue TIVDAK.

Pneumonitis: Severe, life-threatening, or fatal pneumonitis can occur in patients treated with antibody-drug conjugates containing vedotin, including TIVDAK. Among patients with cervical cancer treated with TIVDAK across clinical trials, 2 patients (1.3%) experienced pneumonitis, including 1 patient who had a fatal outcome.

Monitor patients for pulmonary symptoms of pneumonitis. Infectious, neoplastic, and other causes for symptoms should be excluded through appropriate investigations.

Withhold TIVDAK for patients who develop persistent or recurrent Grade 2 pneumonitis and consider dose reduction. Permanently discontinue TIVDAK in all patients with Grade 3 or 4 pneumonitis.

Embryo-Fetal Toxicity: TIVDAK can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TIVDAK and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TIVDAK and for 4 months after the last dose.

Adverse Reactions
In the innovaTV 204 clinical trial (n=101), serious adverse reactions occurred in 43% of patients; the most common (≥3%) were ileus (6%), hemorrhage (5%), pneumonia (4%), PN, sepsis, constipation, and pyrexia (each 3%). Fatal adverse reactions occurred in 4% of patients who received TIVDAK, including septic shock, pneumonitis, sudden death, and multisystem organ failure (each 1%).

Adverse reactions leading to permanent discontinuation occurred in 13% of patients receiving TIVDAK; the most common (≥3%) were PN (5%) and corneal adverse reactions (4%). Adverse reactions leading to

dose interruption occurred in 47% of patients; the most common (≥3%) were PN (8%), conjunctival adverse reactions (4%), and hemorrhage (4%). Adverse reactions leading to dose reduction occurred in 23% of patients; the most common (≥3%) were conjunctival adverse reactions (9%) and corneal adverse reactions (8%).

The most common (≥25%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (52%), fatigue (50%), lymphocytes decreased (42%), nausea (41%), PN (39%), alopecia (39%), epistaxis (39%), conjunctival adverse reactions (37%), hemorrhage (32%), leukocytes decreased (30%), creatinine increased (29%), dry eye (29%), prothrombin international normalized ratio increased (26%), activated partial thromboplastin time prolonged (26%), diarrhea (25%), and rash (25%).

Drug interactions

Strong CYP3A4 Inhibitors: Concomitant use with strong CYP3A4 inhibitors may increase unconjugated monomethyl auristatin E (MMAE) exposure, which may increase the risk of TIVDAK adverse reactions. Closely monitor patients for TIVDAK adverse reactions.

Use in Specific Populations

Moderate or Severe Hepatic Impairment: MMAE exposure and adverse reactions are increased. Avoid use.

Lactation: Advise lactating women not to breastfeed during TIVDAK treatment and for at least 3 weeks after the last dose.

Please see full prescribing information, including BOXED WARNING for TIVDAK here.

About Genmab
Genmab is an international biotechnology company with a core purpose to improve the lives of people with cancer. For more than 20 years, Genmab's vision to transform cancer treatment has driven its passionate, innovative and collaborative teams to invent next-generation antibody technology platforms and leverage translational research and data sciences, fueling multiple differentiated cancer treatments that make an impact on people's lives. To develop and deliver novel therapies to patients, Genmab has formed 20+ strategic partnerships with biotechnology and pharmaceutical companies. Genmab's proprietary pipeline includes bispecific T-cell engagers, next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates.

Genmab 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 and follow us on Twitter.com/Genmab.

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 the company's 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.

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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 statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of tisotumab vedotin, its possible efficacy, safety and therapeutic uses, the innovaTV 207 clinical trial, the tisotumab vedotin development program, plans with respect to additional trials of tisotumab vedotin in patients with squamous cell carcinoma of the head and neck, including its potential use as a combination therapy, and other planned clinical trial activities. 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 settings referenced above, the risk of adverse events or safety signals, difficulties and delays in planned clinical trial initiations, enrollment and conduct or in obtaining data from clinical trials, 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, and the possibility that clinical results may fail to support continued development. 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, 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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