Genmab Announces Multiple Abstracts to be Presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

Media Release

Copenhagen, Denmark, May 26, 2022

- **Multiple epcoritamab (DuoBody®-CD3xCD20) poster presentations highlighting data in a variety of treatment settings and hematologic malignancies**
- **Oral presentation of tisotumab vedotin first-line combination study in patients with recurrent or metastatic cervical cancer**
- **Several abstracts evaluating Genmab owned and partnered programs accepted for presentation**

Genmab A/S (Nasdaq: GMAB) announced today that multiple abstracts evaluating several investigational medicines in the company's pipeline, or created using Genmab's innovative drug development platforms, will be presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, being held at McCormick Place, in Chicago, IL, and virtually, June 3-7. The presentations will include data from multiple arms of the phase 1b/2 EPCORE™ NHL-2 clinical trial, evaluating the safety and preliminary efficacy of epcoritamab (DuoBody-CD3xCD20), an investigational subcutaneous bispecific antibody, in combination with standard-of-care therapies for the treatment of various types of B-cell non-Hodgkin lymphoma (NHL), including first-line, high-risk diffuse large B-cell lymphoma (DLBCL), relapsed or refractory DLBCL, and relapsed or refractory follicular lymphoma (FL). Epcoritamab is being co-developed by Genmab and AbbVie (NYSE: ABBV).

In addition, several abstracts evaluating tisotumab vedotin (TIVDAK®) in various tumor types will be presented, including an oral presentation of the innovaTV 205 study evaluating tisotumab vedotin in combination with carboplatin or pembrolizumab in first-line patients with recurrent or metastatic cervical cancer (r/mCC). Tisotumab vedotin is being co-developed by Genmab and Seagen (Nasdaq: SGEN), under an agreement in which the companies share costs and profits for the product on a 50:50 basis.

Results from several clinical trials evaluating Janssen Biotech, Inc. (Janssen's) subcutaneous formulation of daratumumab, and Janssen's bispecific programs leveraging Genmab's DuoBody technology platform, will be presented. Daratumumab is being developed by Janssen under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab, and the companies have a research and license agreement to create and develop bispecific antibodies using Genmab's DuoBody technology platform.

All abstracts accepted for presentation have been published on the ASCO website.

"This year's ASCO provides a great opportunity for Genmab to share data evaluating epcoritamab, our first-in-class approved medicine tisotumab vedotin, and our innovative technologies, which reinforce our commitment to delivering new therapeutic options to patients in need," said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. "Through our own research and development, and through industry partnerships, Genmab is developing differentiated therapies with the goal of transforming the future of cancer treatment."

Abstracts accepted for presentation at ASCO include:

Epcoritamab (DuoBody-CD3xCD20):

- Abstract #: 7523. First-line treatment with subcutaneous (SC) epcoritamab (epco) + R-CHOP in patients (pts) with high-risk diffuse large B-cell lymphoma (DLBCL): phase 1/2 data update; Falchi et al. Saturday, June 4, 2022, 8:00-11:00 a.m. CDT/9:00 p.m.-12:00 p.m. EDT.

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- Abstract #: 7524. Subcutaneous epcoritamab with rituximab + lenalidomide (R^2) in patients (pts) with relapsed or refractory (R/R) follicular lymphoma (FL): update from phase 1/2 trial; Falchi et al. Saturday, June 4, 2022, 8:00-11:00 a.m. CDT/9:00 p.m.-12:00 p.m. EDT.
- Abstract #: 7528. Subcutaneous epcoritamab + R-DHAX/C in patients (pts) with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) eligible for autologous stem cell transplant (ASCT): preliminary phase 1/2 results; Abrisqueta et al. Saturday, June 4, 2022, 8:00-11:00 a.m. CDT/9:00 p.m.-12:00 p.m. EDT.
- Abstract #: 7527. Epcoritamab (epco) with gemcitabine + oxaliplatin (GemOx) in patients (pts) with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) ineligible for autologous stem cell transplant (ASCT) induces high response rate even in pts failing CAR T therapy; Brody et al. Saturday, June 4, 2022, 8:00-11:00 a.m. CDT/9:00 p.m.-12:00 p.m. EDT.
- Abstract #: 7576. DLBCL Cell of Origin Typing and Whole Transcriptome Analysis using Single Slides with HTG EdgeSeq; Loya, et al. Saturday, June 4, 2022, 8:00-11:00 a.m. CDT/9:00 p.m.-12:00 p.m. EDT.

Tisotumab Vedotin:

- Abstract #: 5507. Tisotumab vedotin (TV) + pembrolizumab (pembro) in first-line (1L) recurrent or metastatic cervical cancer (r/mCC): Interim results of ENGOT Cx8/GOG 3024/innovaTV 205; D. Lorusso et al. Monday, June 6, 2022, 8:00-11:00 a.m. CDT/9:00 a.m.-12:00 p.m. EDT.
- Abstract#: TPS5603. Trial in progress update on ENGOT-cx8/GOG-3024/innovaTV 205: Addition of a new cohort of tisotumab vedotin (TV) + pembrolizumab (pembro) + carboplatin (carbo) ± bevacizumab (bev) in first line (1L) recurrent/metastatic cervical cancer (r/mCC); I. Vergote et al. Saturday, June 4, 2022, 1:15-4:15 p.m. CDT/2:15-5:15 p.m. EDT.
- Abstract #: TPS6100. innovaTV 207: New combination dosing cohorts in the open label phase 2 study of tisotumab vedotin in solid tumors; X. Le et al. Monday, June 6, 2022, 1:15-4:15 p.m. CDT/2:15 p.m.-5:15 p.m. EDT.
- Abstract #: 5532. Factors Associated with Receipt of Second-Line Recurrent or Metastatic Cervical Cancer Treatment in the US: A Retrospective Administrative Claims Analysis; K. Sonawane et al. Saturday, June 4, 2022, 1:15-4:15 p.m. CDT/2:15-5:15 p.m. EDT.
- Abstract #: 5523. Cervical Cancer Geographical Burden Analyzer: An Interactive, Open-Access Tool For Understanding Geographical Disease Burden in Recurrent or Metastatic Cervical Cancer Patients; T. Castellano et al. Saturday, June 4, 2022, 1:15-4:15 p.m. CDT/2:15-5:15 p.m. EDT
- Abstract #: E17520. Productivity losses under various second-line recurrent or metastatic cervical cancer treatment scenarios in the US; T. Ayer et al.
- Abstract #: E17525. Patterns of Care in Medicaid-Enrollees with recurrent or metastatic Cervical Cancer; C. A. Leath et al.

Daratumumab:

- Subcutaneous daratumumab (DARA SC) versus active monitoring in patients (pts) with high-risk smoldering multiple myeloma (SMM): randomized, open-label, phase 3 AQUILA study; Dimopoulos et al.
- Time to response, duration of response, and patient-reported outcomes (PROs) with daratumumab (DARA) plus lenalidomide and dexamethasone (D-Rd) vs lenalidomide and dexamethasone (Rd) alone in transplant-ineligible patients with newly diagnosed multiple myeloma (NDMM): subgroup analysis of the phase 3 MAIA study; Facon et al.
- Efficacy and safety of daratumumab (DARA) in pediatric and young adult patients (pts) with relapsed/refractory T-cell acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LL): results from the phase 2 DELPHINUS study; Hogan et al.

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- Daratumumab (DARA) + lenalidomide, bortezomib, and dexamethasone (RVd) in Black patients (pts) with transplant-eligible newly diagnosed multiple myeloma (NDMM): an updated subgroup analysis of GRIFFIN; Nooka et al.
- Daratumumab (DARA) + lenalidomide, bortezomib, and dexamethasone (RVd) in transplant-eligible newly diagnosed multiple myeloma (NDMM): a post hoc analysis of sustained minimal residual disease (MRD) negativity from GRIFFIN; Rodriguez et al.
- Daratumumab (DARA) in combination with bortezomib plus dexamethasone (D-Vd) or lenalidomide plus dexamethasone (D-Rd) in relapsed or refractory multiple myeloma (RRMM): subgroup analysis of the phase 3 CASTOR and POLLUX studies in patients (pts) with early or late relapse after initial therapy; Spencer et al.

About Epcoritamab
Epcoritamab is an investigational IgG1-bispecific antibody created using Genmab's proprietary DuoBody technology. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to elicit an immune response towards target cell types. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B-cells and induces T cell mediated killing of CD20+ cells.[i] Epcoritamab was developed with selective, silencing mutations that may limit systemic, non-specific activity.[ii] CD20 is expressed on B-cells and a clinically validated therapeutic target in many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.[iii,iv] Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' broad oncology collaboration.

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-tftv (TIVDAK) in adult patients with previously treated recurrent or metastatic cervical cancer with disease progression on or after chemotherapy, making it the first and only approved ADC for these patients. The ongoing clinical trial InnovaTV 301, an open label, randomized, global trial, is intended as the confirmatory trial for use in verifying and describing the clinical benefit and as support for US and global regulatory applications.

TIVDAK (tisotumab vedotin-tftv) U.S Indication & Important Safety Information
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.

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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.

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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 DARZALEX® (daratumumab)
DARZALEX® (daratumumab) is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration approval to treat certain multiple myeloma indications. Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. The subcutaneous formulation of daratumumab (daratumumab and

hyaluronidase-fihj) is the first subcutaneous CD38 antibody approved for the treatment of certain multiple myeloma indications and the first and only approved treatment for certain patients with light-chain (AL) amyloidosis.[v, vi, vii]

Please see local country prescribing information for all labeled indication and safety information.

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.

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[i] Engelbert et al. "DuoBody-CD3xCD20 induces potent T-cell-mediated killing of malignant B cells in preclinical models and provides opportunities for subcutaneous dosing." EBioMedicine. 2020 Feb;52: 102625. doi: 10.1016/j.ebiom.2019.102625. Epub 2020 Jan 23. PMID: 31981978; PMCID: PMC6992935.
[ii] Van der Horst, et al. "Epcoritamab induces potent anti-tumor activity against malignant B-cells from patients with DLBCL, FL and MCL, irrespective of prior CD20 monoclonal antibody treatment." Blood Cancer Journal, 18 February 2021; https://doi.org/10.1038/s41408-021-00430-6.

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[iii]Rafiq, Sarwish, et al. "Comparative Assessment of Clinically Utilized CD20-Directed Antibodies in Chronic Lymphocytic Leukemia Cells Reveals Divergent NK Cell, Monocyte, and Macrophage Properties." Journal of Immunology (Baltimore, Md. 1950), U.S. National Library of Medicine, 15 Mar. 2013, www.ncbi.nlm.nih.gov/pmc/articles/PMC3631574/.
[iv]Singh, Vijay, et al. "Development of Novel Anti-Cd20 Monoclonal Antibodies and Modulation in Cd20 Levels on Cell Surface: Looking to Improve Immunotherapy Response." Journal of Cancer Science & Therapy, U.S. National Library of Medicine, Nov. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4939752/.
[v]DARZALEX Prescribing information, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761036 Last accessed July 2021.
[vi]DARZALEX Summary of Product Characteristics, available at https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex Last accessed June 2021.
[vii]DARZALEX *FASPRO* Prescribing information, available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761145 Last accessed June 2021.