Genmab to Showcase Data in Various Patient Populations to be Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting

Media Release

COPENHAGEN, Denmark; May 23, 2024

- **Six oral and poster presentations will highlight breadth of clinical program and potential utility of epcoritamab-bysp in patients with difficult-to-treat lymphomas across multiple lines of therapy and histologies where high unmet needs exist**
- **Results from two studies evaluating tisotumab vedotin in patients with head and neck squamous cell carcinoma and recurrent or metastatic cervical cancer accepted for oral and poster presentations, respectively**
- **First presentation of Phase 2 study of acasunlimab (also known as GEN1046/BNT311) in patients with previously treated metastatic non-small cell lung cancer (mNSCLC)**

Genmab A/S (Nasdaq: GMAB) announced today that multiple abstracts evaluating epcoritamab, a T-cell engaging bispecific antibody administered subcutaneously, tisotumab vedotin, an antibody-drug conjugate (ADC), and acasunlimab (also known as GEN1046/BNT311), an investigational bispecific antibody, will be presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago, IL and virtually, May 31-June 2, 2024.

“The data being presented this year at ASCO demonstrate Genmab’s significant progress towards our mission to develop novel antibody therapies with the goal of improving the lives of people impacted by cancer,” said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab.

Presentations will include data from multiple clinical trials evaluating the efficacy and safety of epcoritamab in a variety of treatment settings and patient populations, including a rapid oral presentation evaluating epcoritamab in combination with rituximab and lenalidomide (R2) in patients with previously untreated follicular lymphoma (FL) and a second rapid oral presentation showcasing results from the pivotal and cycle 1 dose optimization cohorts of EPCORE NHL-1 evaluating epcoritamab in patients with relapsed/refractory (R/R) FL.

Data from the Phase 2 innovaTV 207 trial, evaluating tisotumab vedotin in pretreated patients with relapsed/metastatic head and neck squamous cell carcinoma will be presented during a rapid oral session. Additionally, results from the Phase 3 innovaTV 301 trial evaluating tisotumab vedotin in patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy will be presented.

Finally, data from the Phase 2 clinical trial evaluating acasunlimab as monotherapy and in combination with pembrolizumab in patients with previously treated metastatic non-small cell lung cancer (mNSCLC) will be presented for the first time during a poster presentation.

The safety and efficacy of these investigational medicines have not been established for these uses.

Virtual mid- to late-stage pipeline update at ASCO 2024
On Monday, June 3, at 9:00 AM CDT (10:00 AM EDT/4:00 PM CEST), Genmab will host a review of data presented at ASCO from its mid- to late-stage pipeline. The event will be virtual and webcast live. Details, including the webcast link and registration will be available on www.genmab.com. This meeting is not an official program of the ASCO Annual Meeting.

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All abstracts accepted for presentation have been published and may be accessed online via the ASCO Meeting Library.

Abstracts accepted for presentation at ASCO:

Epcoritamab:

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
7014	Epcoritamab with rituximab + lenalidomide (R2) in previously untreated (1L) follicular lymphoma (FL) and epcoritamab maintenance in FL: EPCORE NHL 2 arms 6 and 7	Rapid Oral	June 2, 4:30-6:00 PM CDT
7015	EPCORE NHL 1 follicular lymphoma (FL) cycle (C) 1 optimization (OPT) cohort: Expanding the clinical utility of epcoritamab in relapsed or refractory (R/R) FL	Rapid Oral	June 2, 4:30-6:00 PM CDT
7029	Subcutaneous Epcoritamab (SC epcor) administered outpatient (outpt) for relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL): Results from Phase 2 EPCORE NHL-6	Poster	June 3, 9:00 AM-12:00 PM CDT
7032	Epcoritamab + R-DHAX/C in transplant-eligible patients (pts) with high-risk relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL)	Poster	June 3, 9:00 AM-12:00 PM CDT
7037	Subcutaneous epcoritamab + GemOx in patients with relapsed or refractory DLBCL: Updated results from EPCORE NHL-2	Poster	June 3, 9:00 AM-12:00 PM CDT
7039	Extended follow-up results beyond 2.5 years from the pivotal NHL-1 EPCORE trial: Subcutaneous epcoritamab monotherapy in patients with relapsed/refractory large B-cell lymphoma (R/R LBCL)	Poster	June 3, 9:00 AM-12:00 PM CDT
TPS7084	EPCORE FL-2: Phase 3 trial of epcoritamab with rituximab and lenalidomide (R2) vs chemoimmunotherapy or R2 in previously untreated follicular lymphoma	Poster	June 3, 9:00 AM-12:00 PM CDT

Tisotumab Vedotin:

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
6012	Tisotumab vedotin in head and neck squamous cell carcinoma: updated analysis from innovaTV 207 Part C	Rapid Oral	June 3, 8:00-9:30 AM CDT
5531	Tisotumab vedotin in 2L/3L recurrent or metastatic cervical cancer: subsequent therapy data from ENGOT-cx12/GOG-3057/innovaTV 301	Poster	June 3, 9:00 AM-12:00 PM CDT

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Acasunlimab:

Abstract Number	Abstract Title	Type of Presentation	Date/Time of Presentation
2533	Acasunlimab (DuoBody-PD-L1x4-1BB) alone or in combination with pembrolizumab (pembro) in patients (pts) with previously treated metastatic non-small cell lung cancer (mNSCLC): initial results of a randomized, open-label, Phase 2 trial	Poster	June 1, 9:00 AM-12:00 PM CDT

About Epcoritamab
Epcoritamab-bysp is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody® technology and administered subcutaneously. 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 is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration.

Epcoritamab has received regulatory approval in certain lymphoma indications in several territories. Use of epcoritamab in FL is not approved in the U.S. or in the EU or in any other territory. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. The companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization.

Genmab and AbbVie continue to evaluate the use of epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies. This includes four ongoing phase 3, open-label, randomized trials including a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL compared to investigators choice chemotherapy (NCT: 04628494), a trial evaluating epcoritamab in combination with R-CHOP in adult participants with newly diagnosed DLBCL (NCT: 05578976), a trial evaluating epcoritamab in combination with rituximab and lenalidomide in patients with R/R FL (NCT: 05409066), and a trial evaluating epcoritamab in combination with rituximab and lenalidomide (R2) compared to chemotherapy in patients with previously untreated FL (NCT: 06191744). The safety and efficacy of epcoritamab has not been established for these investigational uses.

About Tisotumab Vedotin
Tisotumab vedotin is an antibody-drug conjugate (ADC) composed of Genmab's human monoclonal antibody directed to tissue factor (TF) and Pfizer'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 suggest 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. Tisotumab vedotin is co-owned by Genmab and Pfizer, under an agreement in which the companies share costs and profits for the product on a 50:50 basis.

Tisotumab vedotin has received full approval by the U.S. FDA for the treatment of adult patients with recurrent or metastatic cervical cancer (r/mCC) with disease progression on or after chemotherapy. Tisotumab vedotin in HNSCC is not approved in any country, including the U.S. and the EU.

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About Acasunlimab (GEN1046/BNT311)
Acasunlimab (GEN1046/BNT311) is an investigational PD-L1x4-1BB bispecific antibody fusing Genmab's proprietary DuoBody® technology platform and BioNTech's proprietary immunomodulatory antibodies. Acasunlimab is designed to elicit an antitumor response via conditional activation of 4-1BB on T cells and natural killer (NK) cells, which is strictly dependent on simultaneous binding of the PD-L1 arm. Acasunlimab is being developed in collaboration with BioNTech SE under a license and collaboration agreement and is currently in Phase 2 of development.

Please visit www.clinicaltrials.gov for more information about Genmab's clinical trials.

About Genmab
Genmab is an international biotechnology company with a core purpose of guiding its unstoppable team to strive toward improving the lives of patients with innovative and differentiated antibody therapeutics. For 25 years, its passionate, innovative and collaborative team has invented next-generation antibody technology platforms and leveraged translational, quantitative and data sciences, resulting in a proprietary pipeline including bispecific T-cell engagers, antibody-drug conjugates, next-generation immune checkpoint modulators and effector function-enhanced antibodies. By 2030, Genmab's vision is to transform the lives of people with cancer and other serious diseases with knock-your-socks-off (KYSO®) antibody medicines.

Established in 1999, Genmab is headquartered in Copenhagen, Denmark, with international presence across North America, Europe and Asia Pacific. For more information, please visit Genmab.com and follow us on LinkedIn and X.

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[i] Engelberts 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;52:102625. DOI: 10.1016/j.ebiom.2019.102625