HuMax-TF-ADC and Daratumumab Data to Be Presented at 2015 ASCO Annual Meeting

Company Announcement

- First clinical data from Phase I study of HuMax®-TF-ADC in solid tumors
- Oral presentation on Phase II study of daratumumab in double refractory multiple myeloma
- Additional data on daratumumab, Arzerra® (ofatumumab) and HuMax-AXL-ADC to be presented
- Abstracts available online at ASCO website

Copenhagen, Denmark; May 13, 2015 – Genmab A/S (OMX: GEN) announced today that data on HuMax-TF-ADC, daratumumab, ofatumumab and HuMax-AXL-ADC will be presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, May 29 – June 2. Key presentations will include the first preliminary clinical data from the Phase I study of HuMax-TF-ADC in solid tumors and comprehensive data from the Phase II study of daratumumab in double refractory multiple myeloma. With the exception of the Phase II daratumumab data, which has been designated as a late breaking abstract by ASCO, the abstracts have been published at the ASCO website at http://abstracts.asco.org.

HuMax-TF-ADC Phase I Data

Preliminary safety and efficacy data from a Phase I dose escalation study of HuMax-TF-ADC to treat multiple solid tumors will be presented in a poster presentation at the ASCO meeting. Data for 18 patients is included in the abstract for this ongoing study. Preliminary data show a manageable safety profile with no dose limiting toxicities at doses of HuMax-TF-ADC of up to 1.8 mg/kg and preliminary evidence of anti-tumor efficacy was observed, including prolonged disease stabilization in an ovarian cancer patient (23 weeks), two castration resistant prostate cancer (CRPC) patients (18 and 36 weeks) and a confirmed partial response (PR) in a patient with cervical cancer. Data from further patients will be included in the poster at the time of the presentation including observed dose limiting toxicities in the 2.2 mg/kg cohort. Part 2 of the study will now be expanded from 30 to 80 patients, bringing the total patients in this study to approximately 110 patients.

Abstract details: A phase I, first-in-human study to evaluate the tolerability, pharmacokinetics and preliminary efficacy of HuMax-tissue factor-ADC (TF-ADC) in patients with solid tumors – Abstract #2570, Poster session, Sunday, May 31, 8:00AM to 11:30AM CDT

List of Further Abstracts to Be Presented

Daratumumab

Phase 2 study of daratumumab (DARA) monotherapy in patients with ≥3 lines of prior therapy or double refractory multiple myeloma (MM): 54767414MMY2002 (Sirius) – Late breaking abstract #LBA8512, Oral Presentation, Tuesday, June 2, 11:21AM to 11:33AM CDT

*This abstract has been designated a late breaking abstract and the embargo will be lifted on Saturday May 30 at 6:30AM CDT. The abstract will be included in a press briefing by ASCO on Saturday, May 30 from 8:00AM to 9:00AM CDT.*

Twin randomized studies of daratumumab (DARA; D) plus standard of care (lenalidomide/dexamethasone or bortezomib/dexamethasone [DRd or DVd]) versus Rd or Vd alone in relapsed or refractory multiple myeloma (MM): 54767414MMY3003 (Pollux) and 54767414MMY3004 (Castor) - Abstract #TPS8609, Poster session, Sunday, May 31, 8:00AM to 11:30AM CDT

A randomized open-label study of bortezomib, melphalan, and prednisone (VMP) versus daratumumab (DARA) plus VMP in patients with previously untreated multiple myeloma (MM) who are ineligible for high-
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dose therapy: 5476414MMY3007 (Alcyone) – Abstract #TPS8608, Poster session, Sunday, May 31, 8:00AM to 11:30AM CDT

Assessing clinical response in multiple myeloma (MM) patients treated with monoclonal antibodies (mAbs): Validation of a daratumumab IFE reflex assay (DIRA) to distinguish malignant M-protein from therapeutic antibody – Abstract #8590, Poster session, Sunday, May 31, 8:00AM to 11:30AM CDT

Pre-clinical translational studies of daratumumab in patients with myeloma or AL amyloidosis undergoing autologous hematopoietic stem cell transplantation (SCT) – Abstract #8587, Poster session, Sunday, May 31, 8:00AM to 11:30AM CDT

Ofatumumab
Results of a phase III randomized, controlled study sponsored by Gilead Sciences, evaluating the efficacy and safety of idelalisib (IDELA) in combination with ofatumumab (OFA) for previously treated chronic lymphocytic leukemia (CLL) – Abstract #7023, Poster Session, Sunday, May 31, 8:00AM to 11:30AM CDT

HuMax-AXL-ADC
Preclinical efficacy studies using HuMax-Axl-ADC, a novel antibody-drug conjugate targeting Axl-expressing solid cancers – Abstract #3066, Poster session, Saturday, May 30, 8:00AM to 11:30AM CDT

About HuMax-TF-ADC
HuMax-TF-ADC is an antibody-drug conjugate (ADC) composed of a human antibody against tissue factor (TF) conjugated to Seattle Genetics' clinically validated cytotoxic drug. HuMax-TF-ADC is being developed for the treatment of solid cancers. Based on its high expression on many solid tumors and its rapid internalization, TF is a suitable target for an ADC approach. Genmab is developing HuMax-TF-ADC using Seattle Genetics' ADC technology under an agreement between the companies.

About daratumumab
Daratumumab is a human CD38 monoclonal antibody with broad-spectrum killing activity. Daratumumab is in clinical development for multiple myeloma (MM) and non-Hodgkin's lymphoma (NHL). Daratumumab targets the CD38 molecule which is highly expressed on the surface of multiple myeloma cells. Daratumumab may also have potential in other cancers on which CD38 is expressed, including diffuse large B-cell lymphoma, chronic lymphocytic leukemia, acute lymphoblastic leukemia, plasma cell leukemia, acute myeloid leukemia, follicular lymphoma and mantle cell lymphoma. Daratumumab has been granted Breakthrough Therapy Designation from the US FDA. In August 2012, Genmab granted Janssen Biotech, Inc. an exclusive worldwide license to develop and commercialize daratumumab.

About ofatumumab
Arzerra (ofatumumab) is a human monoclonal antibody that is designed to target the CD20 molecule found on the surface of chronic lymphocytic leukemia (CLL) cells and normal B lymphocytes.

In the United States, Arzerra is approved for use in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate. In the European Union, Arzerra is approved for use in combination with chlorambucil or bendamustine for the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy. In more than 50 countries worldwide, Arzerra is also indicated as monotherapy for the treatment of patients with CLL who are refractory after prior treatment with fludarabine and alemtuzumab.

Arzerra is not approved anywhere in the world in combination with idelalisib for previously untreated chronic lymphocytic leukemia.
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Please see full Prescribing Information, including Boxed WARNING for Arzerra (ofatumumab).

Arzerra is marketed under a co-development and collaboration agreement between Genmab and Novartis.

About HuMax-AXL-ADC
HuMax-AXL-ADC is an antibody-drug conjugate (ADC) combining a high affinity human monoclonal antibody against AXL with Seattle Genetics’ clinically validated cytotoxic drug. AXL is a signaling molecule involved in multiple processes of tumor development and progression. The target molecule is highly expressed on a variety of solid cancers. Genmab is developing HuMax-AXL-ADC using Seattle Genetics’ ADC technology under a license agreement between the companies.

About Genmab
Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer. Founded in 1999, the company currently has one marketed antibody, Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and daratumumab in clinical development for multiple myeloma and non-Hodgkin’s lymphoma, in addition to other clinical programs, and an innovative pre-clinical pipeline. Genmab’s technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, and the HexaBody® platform which creates effector function enhanced antibodies. Genmab’s deep antibody expertise is expected to provide a stream of future product candidates. Partnering of selected innovative product candidates and technologies is a key focus of Genmab’s strategy and the company has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

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This Company Announcement 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 www.genmab.com. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement nor to confirm such statements in relation to actual results, unless required by law.

Genmab A/S and its subsidiaries own the following trademarks: Genmab®, the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo™; the DuoBody logo®; the HexaBody logo™; HuMax®, HuMax-CD20®, DuoBody®, HexaBody® and UniBody®. Arzerra® is a trademark of Novartis Pharma AG.