Genmab Announces Phase 3 Study Evaluating Epcoritamab in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma

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**Company Announcement**

- **First Phase 3 study of epcoritamab as part of broad clinical development plan with AbbVie**
- **Diffuse Large B-cell Lymphoma is the most common form of non-Hodgkin’s lymphoma worldwide**

**About the Study**

The Phase 3, open-label, randomized study (GCT3013-05) will include approximately 480 patients with relapsed or refractory DLBCL who failed or are ineligible for autologous stem cell transplant (ASCT). Patients will be randomized to receive either subcutaneous epcoritamab or one of two chemotherapy regimens as per investigator’s choice, either rituximab, gemcitabine and oxaliplatin (R-GemOx) or bendamustine and rituximab (BR).

**About Diffuse Large B-cell Lymphoma**

DLBCL is aggressive and the most common form of non-Hodgkin’s lymphoma worldwide, with 36% of DLBCL patients in the U.S. expected to die from their disease within five years of diagnosis.\(^1\) Prevalence rates are expected to increase, driven by growth in aging populations.\(^2\)

“In collaboration with AbbVie, we have planned a broad, expansive, accelerated epcoritamab clinical development plan to maximize the potential of this promising bispecific antibody, with the ultimate goal of bringing new differentiated treatment options as soon as possible to patients. We look forward to the data from this first Phase 3 trial, especially for relapsed or refractory DLBCL patients as it remains an area of high unmet medical need,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

**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 tumors to elicit an immune response towards malignant cells. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B cells and induces T cell mediated killing of lymphoma B cells.\(^5\) CD20 is a clinically validated therapeutic target, and is expressed on many B-cell malignancies, including diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and chronic lymphocytic leukemia.\(^7,8\) Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies’ broad oncology collaboration.

**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 is the creator of the following approved antibodies: DARZALEX® (daratumumab, under agreement with Janssen Biotech, Inc.) for the treatment of certain multiple myeloma indications in territories including the U.S., Europe and Japan, Kesimpta® (subcutaneous olaratumab, under agreement with Novartis AG), for the treatment of adults with relapsing forms of multiple sclerosis in the U.S. and TEPEZZA® (teprotumumab, under agreement with Roche granting sublicense to Horizon Therapeutics plc) for the treatment of thyroid eye disease in the U.S. A subcutaneous formulation of daratumumab, known as DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) in the U.S., has been approved in the U.S. and Europe for the treatment of adult patients with certain multiple myeloma indications. The first approved Genmab created therapy, Arzerra® (ofatumumab, under agreement with Novartis AG), approved for the treatment of certain chronic lymphocytic leukemia indications, is available in Japan and is also available in other territories via compassionate use or oncology access programs. Daratumumab is in clinical development by Janssen for the treatment of additional multiple myeloma indications, other blood cancers and amyloidosis. Genmab also has a broad and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, the HexaBody® platform, which creates effector function enhanced antibodies, the HexaElect® platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency and the DuoHexaBody® platform, which enhances the potential potency of bispecific antibodies through hexamerization. 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. Genmab is headquartered in Copenhagen, Denmark with sites in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan.
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