

Genmab Announces Phase 3 Trial of Tisotumab Vedotin in Recurrent or Metastatic Cervical Cancer

Media Release

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- **Initiation of a global phase 3 trial for tisotumab vedotin versus investigator's choice chemotherapy in recurrent or metastatic cervical cancer**

Genmab A/S (Nasdaq: GMAB) announced today the initiation of innovaTV 301 trial, a global phase 3 study to evaluate the efficacy of tisotumab vedotin compared to chemotherapy in patients with recurrent or metastatic cervical cancer who have received one or two prior lines of systemic therapy. The innovaTV 301 trial is a global, randomized phase 3 trial in which tisotumab vedotin will be compared with physician's choice single agent chemotherapy.

"Currently, there is no established standard of care for women with recurrent or metastatic cervical cancer, who have disease progression after first or second line of therapy. There is a need for a novel, safe and effective treatment option that can improve the clinical outcome for these patients," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We look forward to the innovaTV 301 trial which is designed to support potential regulatory applications for marketing approval globally and serve as a confirmatory trial for a potential accelerated approval in the US for patients with metastatic or recurrent cervical cancer."

About the innovaTV 301 Trial

The open label, randomized, global, phase 3 trial of tisotumab vedotin versus chemotherapy will enroll approximately 482 patients with recurrent or metastatic cervical cancer who have received one or two prior lines of systemic therapy for their recurrent or metastatic disease. Eligible patients will be randomized to receive either tisotumab vedotin 2.0 mg/kg every three weeks or investigator's choice of chemotherapy. The primary endpoint of the study is overall survival. This global study will be sponsored and performed by Seagen Inc. in collaboration with Genmab, European Network of Gynaecological Oncological Trial Groups (ENGOT) and the Gynecologic Oncology Group (GOG).

About Tisotumab Vedotin

Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) composed of Genmab's fully human monoclonal antibody specific for tissue factor 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 and releases it upon internalization, inducing target cell death. In cancer biology, tissue factor is a protein that can promote tumor growth, angiogenesis and metastasis.¹ Based on its high expression on many solid tumors and its rapid internalization, tissue factor was selected as a target for an ADC approach. Tisotumab vedotin is being co-developed by Genmab and Seagen, under an agreement in which the companies share all costs and profits for the product on a 50:50 basis.

Tisotumab vedotin is being evaluated in ongoing clinical trials as monotherapy in a range of solid tumors, including recurrent and/or metastatic cervical cancer, ovarian cancer, and other solid tumors and in combination with commonly used therapies in recurrent or metastatic cervical cancer. These trials are evaluating tisotumab vedotin on a weekly or every three-week dosing schedule.

About Cervical Cancer

Cervical cancer originates in the cells lining the cervix. Over 13,500 women are expected to be diagnosed with invasive cervical cancer in the U.S. in 2020, with approximately 4,200 deaths.² Cervical cancer remains one of the leading causes of cancer death in women globally, with over 311,000 women dying annually; the vast majority of these women being in the developing world.³ Routine medical examinations

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and human papillomavirus (HPV) vaccines have lowered the incidence of cervical cancer in the developed world. Despite these advances, women are still diagnosed with cervical cancer, which often recurs or becomes metastatic.

About Genmab

Genmab is an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates, including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company 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.

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References

¹ Van de Berg YW et al. Blood 2012; 119:924.

² National Cancer Institute SEER. "Cancer Stat Facts: Cervix Uteri Cancer." Available at <https://seer.cancer.gov/statfacts/html/cervix.html>. Last accessed April 2020.

³ Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 countries <https://www.iarc.fr/news-events/global-cancer-statistics-2018-globocan-estimates-of-incidence-and-mortality-worldwide-for-36-cancers-in-185-countries/>.