NEWS RELEASE

Genexine Abstract on GX-188E and GX-I7 Triple Combination Therapy in HNSCC Is Released at 2023 ASCO Annual Meeting

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- Triple combination using Genexine's DNA vaccine GX-188E, its long-acting Interleukin-7 GX-I7 and Keytruda showed a major pathological response rate of 63.6% in a phase 2 trial, satisfying primary evaluation criteria
- A promising new therapeutic option for HPV-positive HNSCC patients as a neoadjuvant therapy

SEOUL, South Korea--(BUSINESS WIRE)-- Genexine (KQ 095700, CEO Neil Warma), a publicly traded, clinical-staged Korean biopharmaceutical company committed to the discovery and development of novel biologics for the treatment of unmet medical needs,announced the publication of an abstract of its phase 2 clinical trial on triple combination neoadjuvant therapy for HNSCC (head and neck squamous cell carcinoma) in the ASCO (American Society of Clinical Oncology). The study evaluated the DNA vaccine GX-188E (tirvalimogene teraplasmid) and the lymphopenia-correcting immune-oncology drug GX-I7 (efineptakin alfa) in combination with immune checkpoint inhibitor Keytruda® (pembrolizumab).

The phase 2 investigator-initiated clinical trial (IIT) being conducted in South Korea led by Professor Hye-Ryun Kim, Division of Medical Oncology of Yonsei University Severance Hospital, and jointly conducted with a research team of Professor Yoon Woo Koh, Department of Otolaryngology, enrolled a total of 11 patients with HPV-positive cervical cancer who were scheduled for surgery. The patients received Keytruda 200mg on day 1 and 22, Genexine's GX-188E DNA vaccine 2mg on day 1, 8, 22 and GX-I7 on day 8 to amplify the number of T cells before surgery. The primary endpoint evaluated the major pathological response (MPR) and other evaluation criteria included safety, recurrence rate and survival rate.

All 11 patients who participated in the trial underwent surgery as planned after neoadjuvant therapy with no increase in surgical delay or surgical complications. Seven patients (63.6%) showed a major pathological response (MPR), and four patients (36.3%) achieved a pathological complete response (pCR), indicating satisfactory primary evaluation variables. Furthermore, comparative analysis of the tissue before and after combination therapy revealed an increase in follicular helper T cells (CD4+) and reactivation of killer T cells (CD8+) in the tumor microenvironment.

Using AI-based analysis technology, the triple combination therapy was found to increase the density of tumor-infiltrating lymphocytes (TIL) and completely transform tumors classified as immune-desert or immune-excluded types into inflamed tumors.

Professor Hye-Ryun Kim, who led the clinical trial, said, “Through this clinical study conducted for human papillomavirus (HPV)-positive HNSCC patients, the efficacy and safety of the triple combination therapy appear to be confirmed, and the therapy could become an effective new treatment strategy for HPV positive HNSCC patients in the future."

"We are pleased by these early data in this important trial as this is the first time this combination therapy has been used,” said Neil Warma, President and CEO of Genexine. “Head and neck cancer remains such a serious unmet need and we believe there is potential to expand the label for GX-188E beyond cervical cancer to include HNSCC."

HNSCC cancer is one of the malignant tumors that occur on the patient's facial area and is commonly caused by factors such as smoking and high-risk HPV infection. While various treatment methods such as surgery, radiation therapy and chemotherapy have been used in the past, the size of the surgical area can significantly impact the patient's quality of life. Therefore, immunotherapy has been gaining attention as a treatment option along with the development of immune checkpoint inhibitors. The results of this study will be presented in a poster session at the ASCO 2023 Annual Meeting, which will be held in Chicago from June 2 to 6, 2023.

Details of the poster presentation are as follows:

Abstract Title	Neoadjuvant pembrolizumab, GX-188E, and GX-I7 in patients with human papillomavirus-16- and/or 18-positive head and neck squamous cell carcinoma: Single-arm, phase 2 trial with single cell transcriptomic analysis and artificial intelligence-powered spatial analysis.
Session Title	Head and Neck Cancer
Abstract Number	6075
Date and Time	June 5, 2023, 1:15 - 4:15 PM

About Genexine

Genexine, Inc. is a publicly traded, clinical-stage biotechnology company focused on developing and commercializing immunotherapeutics and next-generation long-acting biologics. Its primary technology platforms are Therapeutic DNA vaccine technology and hyFcR fusion technology. The Company has multiple products in clinical development including several undergoing Phase 3 registration trials. The Company's proprietary pipeline includes GX-188 (tirvalimogene teraplasmid) for cervical cancer, GX-I7 (efineptakin alfa) for multiple cancers, GX-H9 (eftansomatropin alfa) for Pediatric Growth Hormone Deficiency and GX-E4 for CKD-induced anemia, among others. Genexine has established multiple partnerships with global companies in order to expedite product development and commercialization and create significant value. Genexine is listed on the Korean exchange (KOSDAQ: 095700) and is headquartered in Seoul, Korea. Genexine is committed to the well-being and care of patients worldwide.

Forward Looking Statements

This press release contains forward-looking statements regarding the business of Genexine, Inc. ("Genexine"). Any statement describing Genexine's goals, expectations, financial or other projections, intentions or beliefs, development plans and the commercial potential of Genexine's drug development pipeline, including without limitation GX-I7 (efineptakin alfa), GX-188E, GX-H9 (eftansomatropin alfa), GX- E4 is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to risks and uncertainties, particularly those challenges inherent in the process of discovering, developing and commercialization of new drug products that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs.

Genexine's forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Genexine's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Genexine. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Genexine's programs are described in additional detail in Genexine's annual reports on DART (Data Analysis, Retrieval and Transfer System) internet site (**https://dart.fss.or.kr/**) of the Korean Financial Services Commission. Genexine assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

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