Company Announcement

Nykode Therapeutics Initiates Phase 2 Trial of VB10.16 in Second Line HPV16-Positive Cervical Cancer

Oslo, Norway, April 19, 2024 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced the initiation of the Phase 2 clinical trial VB-C-04. The trial evaluates VB10.16, the company's off-the-shelf therapeutic cancer vaccine candidate for HPV16-positive cancers, alone or in combination with Roche's checkpoint inhibitor atezolizumab (Tecentriq®[1]) in patients with HPV16-positive, PD-L1-positive, recurrent, or metastatic cervical cancer.

Step 1 of VB-C-04 is a two-arm Phase 2 trial evaluating the efficacy and safety of VB10.16 alone or in combination with atezolizumab in patients with recurrent or metastatic cervical cancer refractory to first-line treatment with pembrolizumab plus chemotherapy +/- bevacizumab.

The Phase 2 trial (GOG-3091) will be conducted in the United States (U.S.) in collaboration with The GOG Foundation, Inc. (GOG Foundation)), a U.S. based not-for-profit organization with the purpose of promoting excellence in the quality and integrity in clinical trials in gynecologic malignancies. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancer of the ovary (including surface peritoneal malignancies), uterus (including endometrium, soft tissue sarcoma, and gestational trophoblastic neoplasia), cervix, and vulva.

Dr. Bradley Monk, Director of GOG, said "Today marks an important step forward in our efforts to advance cancer treatment with the initiation of the Phase 2 trial of VB10.16 in second line HPV16-positive cervical cancer. This is a collaborative effort between GOG and Nykode, introducing a novel and promising approach to address a significant unmet medical need. As we embark on this Phase 2 trial, we are optimistic about the potential impact on reshaping the landscape of cancer care and look forward to contributing to advancements that can make a meaningful difference in patients' lives."

"Initiating the VB10.16 trial for HPV16-positive cervical cancer addressing a high unmet medical need, is a significant step in our clinical development strategy," said Klaus Edvardsen, Chief Development Officer of Nykode Therapeutics. "The encouraging clinical profile and favorable tolerability exhibited by VB10.16 in combination with atezolizumab among patients with advanced HPV16 positive cervical cancer observed in VB-C-02 supports our dedication to advancing VB10.16 as an innovative immunotherapy for HPV16 positive cancers."

Atezolizumab is supplied by Roche. Nykode retains all commercial rights to VB10.16 worldwide.

[1] Tecentriq® is a registered trademark of the Roche Group.

About VB10.16
VB10.16 is a potentially first-in-class off-the-shelf therapeutic DNA-based cancer vaccine candidate in development for the treatment of human papillomavirus type 16 (HPV16)-positive cancers. The cancer vaccine is designed based on Nykode's Vaccibody™ technology platform of targeting antigens to antigen presenting cells. VB10.16 has reported promising data from a Phase 2 trial in advanced PD-L1 positive cervical cancer patients (NCT04405349) in combination with atezolizumab with mOS not reached, but at least 24 months at the time of analysis. The vaccine-induced significant HPV16-specific T cell responses that were correlated with clinical responses. The candidate has also demonstrated favorable clinical data in a Phase 1/2a study in pre-cancerous HPV16-induced high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3) demonstrating a statistically significant correlation of immune responses and clinical responses. Nykode is currently investigating VB10.16 in VB-C-03, an open-label, dose-finding Phase 1/2a trial evaluating VB10.16 in combination with MSD's PD-1 inhibitor KEYTRUDA® (pembrolizumab) in patients with HPV16-positive, PD-L1-positive, recurrent, or metastatic head and neck squamous cell carcinoma (HNSCC) in addition to the VB-C-04 trial initiated today.

About the Phase 2 Trial
The Phase 2 VB-C-04 trial (NCT06099418) is designed to evaluate the efficacy and safety of VB10.16. Step 1 is randomized and will evaluate VB10.16 as a monotherapy, and in combination with Roche's checkpoint inhibitor atezolizumab as a second line treatment in patients with recurrent or metastatic cervical cancer. Step 1 of the trial is expected to enroll 60 patients with disease progression after combination treatment with pembrolizumab, chemotherapy +/- bevacizumab into the trial. Step 2 is intended to enroll additional patients in one cohort after reviewing the data from Step 1.

About Cervical Cancer
Cervical cancer is the fourth leading cause of cancer death in women worldwide and is most frequently diagnosed between the ages of 35 and 44. Each year around 600,000 women are diagnosed with cervical cancer worldwide. Almost all cases are caused by human papillomavirus (HPV) infection and HPV16 accounts for more than half of all cervical cancer cases. Approximately 80% of patients with cervical cancer have squamous cell carcinoma and most other patients have adenocarcinomas. Cervical cancer is often curable when detected early and effectively managed, but treatment options are more limited in advanced disease stages or when the cancer has spread.

About Nykode Therapeutics
Nykode Therapeutics is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies with a focus on the treatment of cancer and autoimmune diseases. Nykode's modular vaccine technology specifically targets antigens to antigen presenting cells (APC), which have been shown to induce a broad, strong and long-lasting antigen specific immune response in cancer, which correlates with clinical responses.

Nykode's lead product candidates are VB10.16, a therapeutic vaccine for the treatment of HPV16 induced malignancies which demonstrated favorable safety and efficacy results from its Phase 2 trial

for the treatment of cervical cancer. VB10.16 is being expanded into multiple trials for treatment of head and neck cancer and cervical cancer. VB10.NEO, an individualized cancer neoantigen vaccine, is exclusively out-licensed to Genentech, a member of the Roche Group.

The Company's partnerships include Genentech within oncology and a multi-target collaboration with Regeneron in oncology and infectious diseases.

Nykode is also utilizing its APC-targeted technology to create an inverse vaccine platform for the potential use in autoimmune disorders, organ transplant rejections, anti-drug antibody reactions and allergy.

Nykode Therapeutics' shares are traded on the Oslo Stock Exchange (OSE: NYKD). Further information about Nykode Therapeutics can be found at http://www.nykode.com.

About The GOG Foundation, Inc. (www.gog.org)
The GOG Foundation, Inc. is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis, and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancer of the ovary (including surface peritoneal malignancies), uterus (including endometrium, soft tissue sarcoma, and gestational trophoblastic neoplasia), cervix, and vulva. The GOG Foundation is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, oncology nurses, biostatisticians (including those with expertise in bioinformatics), basic scientists, quality of life experts, data managers, and administrative personnel.

About GOG Partners
Supported by industry, GOG Partners is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners shares the same mission of the GOG Foundation dedicated to transforming the care in Gynecologic Oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network.

Forward-looking statements for Nykode Therapeutics

This announcement and any materials distributed in connection with this announcement may contain certain forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect the company's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of material factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements.

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