



## Company Announcement

### **Nykode Therapeutics Announces Collaboration with The GOG Foundation, Inc. to Conduct the VB-C-04 Trial in Advanced Cervical Cancer**

- *Potentially registrational VB-C-04 trial in the U.S. expected to initiate 4Q 2023*
- *The GOG Foundation, Inc. (GOG) is a U.S. based not-for-profit organization with the purpose of promoting excellence in the quality and integrity in clinical trials; GOG's mission is to transform the standard of care in gynecologic cancers*

Oslo, Norway, February 10, 2023 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced a collaboration with the GOG Foundation, Inc. to conduct a clinical trial of VB10.16 in combination with an immune checkpoint inhibitor for the treatment of advanced cervical cancer in the U.S. The VB-C-04 trial will evaluate the combination therapies in patients with cervical cancer that have progressed following first line treatment. Nykode has previously reported positive interim data from the Phase 2 VB-C-02 trial in Europe in patients with heavily pre-treated advanced cervical cancer. VB10.16, wholly owned by Nykode, is a potentially first-in-class off-the-shelf therapeutic cancer vaccine candidate in development for the treatment of HPV16-positive cancers.

“Based on the positive interim data and in line with our potential registrational trial strategy, we look forward to starting the VB-C-04 trial in the U.S. The trial is aimed at providing a fast path to making VB10.16 available to patients,” said Klaus Edvardsen, Chief Development Officer of Nykode Therapeutics.

“We are excited to collaborate with the GOG Foundation, a leading organization with unparalleled expertise in bringing best-in-class new treatments to patients,” said Michael Engsig, Chief Executive Officer of Nykode Therapeutics. “The GOG Foundation has a long history of successfully working with innovative companies, gynecologic oncology clinical sites and U.S. regulators. The advice and support from the GOG Foundation will increase the quality and facilitate the execution for bringing VB10.16 forward towards the patients in need. We look forward to engaging with the GOG Foundation on execution of the potential registrational trial, VB-C-04.”



Since 1970, the GOG Foundation has conducted more than 350 clinical trials in the U.S. with 400 participating sites and 115,000 patients. The results of the GOG Foundation's clinical trials have influenced the standard of care for numerous malignant gynecologic neoplasms.

"We are thrilled to partner with Nykode Therapeutics to conduct VB-C-04, a ground-breaking study to investigate Nykode's therapeutic cancer vaccine candidate for the treatment of patients with advanced cervical cancer. VB10.16, which utilizes Nykode's unique immunotherapy platform, has the potential to meaningfully improve standard of care for patients with HPV16-positive cervical cancer whose cancer has progressed after initial immunotherapy. This clinical situation has quickly become an area of high unmet medical need, and while we have made progress with other novel therapies, we remain dedicated to maximizing our patients' treatment options and choices. We look forward to working with Nykode on VB-C-04 to advance our shared mission of delivering transformative therapies to patients with cervical cancer and other gynecologic malignancies to help our patients live as long as possible and feel as good as possible," said Leslie Randall, MD, MAS, Cervical Cancer Advisor for the GOG Partners in the GOG Foundation.

"Despite recent advances in cervical cancer care, we still have gaps in treatment strategies, particularly those who have received prior checkpoint therapy. As we continue to explore opportunities to capitalize on recent improvements in cervical cancer outcomes, innovative approaches and novel therapies are required. The VB-C-04 study in patients with recurrent cervical cancer with prior checkpoint inhibitor experience delivers this and offers an opportunity to continue to change the landscape and survival impact for our patients," notes principal investigator of the study, Ritu Salani, MD, MBA, Director, Division of Gynecologic Oncology, David Geffen School of Medicine at UCLA.

#### **About The GOG Foundation, Inc.**

The GOG Foundation is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. For nearly 50 years, the GOG Foundation has been a trusted resource in the field of gynecologic oncology research. 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, vagina, 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 VB10.16**

VB10.16 is a potentially first-in-class off-the-shelf therapeutic 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 positive interim data from a Phase 2 trial in heavily



pre-treated cervical cancer patients (NCT04405349). The analysis demonstrated a favorable safety profile, with responses observed in both PD-L1 positive and negative patients (ORR 27% and 17%, respectively). The vaccine-induced significant HPV16-specific T cell responses were associated 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.

### **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 (arising from cells lining the bottom of the cervix) and most other patients have adenocarcinomas (arising from glandular cells in the upper cervix). 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 for the treatment of cancer and infectious diseases. Nykode's modular vaccine technology specifically targets antigens to Antigen Presenting Cells, which are essential for inducing rapid, strong and long-lasting antigen specific immune responses and eliciting efficacious clinical responses.

Nykode's lead product candidates are VB10.16, a therapeutic vaccine for the treatment of human papilloma virus (HPV)-16 induced malignancies which demonstrated positive interim efficacy and safety results from its Phase 2 trial for the treatment of cervical cancer; and VB10.NEO, an individualized cancer neoantigen vaccine, which is exclusively out-licensed to Genentech, a member of the Roche Group. Additionally, Nykode is conducting a Phase 1/2 trial with next-generation COVID-19 vaccine candidates.

The Company's partnerships include Genentech within oncology, a multi-target collaboration with Regeneron within oncology and infectious diseases and a collaboration with Adaptive Biotechnologies for COVID-19 T cell vaccine development.

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



**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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