



Company Announcement

Nykode Therapeutics Announces Topline Conclusions Affirming Prolonged Clinical Benefits from Matured Survival Data in Phase 2 C-02 Trial in Advanced Cervical Cancer

- *Updated survival data from Phase 2 trial (C-02) in advanced cervical cancer affirm prolonged benefits and indicate a synergistic treatment effect of Nykode's VB10.16 and atezolizumab (Tecentriq®).*
- *New analysis closely mirrors previously reported positive outcome. At the time of the updated analysis, observation time for remaining patients was at least 24 months compared to at least 12 months at the previous reported outcome.*
- *Updated C-02 survival data support the accelerated development of VB10.16, including the potential US pivotal trial C-04 in recurrent or metastatic cervical cancer, and advancing of the program into earlier stages of cervical cancer and expanding into head and neck cancer.*
- *Nykode will present detailed data in a future scientific publication and at a forthcoming conference.*

Oslo, Norway, March 21, 2024 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced key conclusions from the updated analysis from the Phase 2 VB-C-02 trial. The trial investigates the use of Nykode's wholly-owned off-the-shelf therapeutic cancer vaccine candidate VB10.16 in combination with Roche's checkpoint inhibitor atezolizumab in patients with recurrent or metastatic HPV16-positive cervical cancer.

The updated results, which closely mirror the previously reported positive C-02 outcomes, affirm prolonged benefits and indicate a synergistic treatment effect of VB10.16 plus atezolizumab compared to the historical controls of monotherapy with checkpoint inhibitors. The updated analysis' observation time for the remaining patients was at least 24 months, compared to at least 12 months at the previously reported outcome.

"I am thrilled with these data which yet again underscore the strength of our Nykode technology. The strength and durability of the clinical response points to a unique and highly differentiated therapy and we continue our efforts to bring VB10.16 to patients as fast as possible. We are more confident than ever in the transformative potential of Nykode's immunotherapies," said Michael Engsig, CEO.

"Today's update is a significant milestone not just for the VB-C-02 trial but for the entire VB10.16 development program and Nykode's technology platform at large," stated Klaus Edvardsen, Chief Development Officer. "The extended survival and sustained efficacy we're observing compared to



historical data on atezolizumab monotherapy underscore our confidence in VB10.16 and the upcoming potentially registrational trial.”

Nykode has a focused strategy to develop VB10.16, including a potentially US registrational trial C-04 in recurrent/metastatic cervical cancer and a C-03 trial in first-line head and neck cancer, two areas with a high unmet medical need. The company is also planning to move VB10.16 into early-stage cervical cancer.

Nykode is committed to advancing the field of immunotherapy and sharing its research findings with the broader scientific community in line with their publication guidelines. To this end, the company will present the detailed data from the Phase 2 VB-C-02 trial in a future scientific publication and at a forthcoming medical conference.

Nykode wishes to thank the patients, their families and the investigators for their participation and contribution to the VB-C-02 trial.

About the VB-C-02 trial

VB-C-02 is a multi-center, single arm, open-label Phase 2 trial to assess the efficacy, immunogenicity and safety of VB10.16 in combination with the PD-L1 inhibitor atezolizumab in patients with advanced or recurrent, non-resectable HPV16-positive cervical cancer. Patients received treatment with VB10.16 in combination with atezolizumab for up to one year. The trial enrolled 52 patients at sites in Europe. Additional information about the VB-C-02 trial is available at clinicaltrials.gov (NCT04405349).

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 greater than 25 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.

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 HPV16-Driven Cancers

One of the emerging challenges within oncology is the virus-induced cancer types, with Human Papillomavirus (HPV) being one of the most prominent. There are several types of high-risk HPV causing cancers, HPV16 being one of the most common, with more than 130,000 new cases in the U.S. and EU per year. Using a therapeutic cancer vaccine targeted specifically towards the HPV16 infected cells in the tumors, such as Nykode's cancer vaccine VB10.16, represents a novel immunotherapeutic treatment option. By combining a therapeutic cancer vaccine with the checkpoint inhibitors and/or other general immune therapies, the tumors can be attacked by the cancer-specific T cells from several angles with the aim of improving patient outcomes.

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, a member of the Roche Group, 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>.

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.



Contact for Nykode Therapeutics ASA:

Alexandra Deschner, Head of IR
Nykode Therapeutics ASA
IR@nykode.com

Nykode Therapeutics ASA

Oslo Science Park
Gaustadalléen 21
N-0349 Oslo, Norway