Company Announcement

Nykode Therapeutics Announces Strategic Repositioning of VB10.16 to Focus on Locally Advanced Cervical Cancer and Recurrent Metastatic Head and Neck Cancer

- *Strategic repositioning of VB10.16 development activities focused on locally advanced cervical cancer and recurrent metastatic head and neck cancer, building on positive feedback from key opinion leaders and potential future partners.*
- *Prioritization of these indications is driven by their significant unmet medical needs, clear regulatory paths to approval, and high commercial potential.*
- *Recent changes in standard-of-care have extended the timelines for the C-04 trial, making it less attractive as a fast-to-market strategy.*
- *Nykode has therefore decided to discontinue the C-04 trial to ensure financial and human resources are concentrated on these promising indications.*
- *The decision is expected to reduce VB10.16 development costs by over $25 million, which combined with our planned partnering strategy, will substantially extend the company's cash runway.*

Oslo, Norway, August 21, 2024 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced a strategic repositioning for VB10.16, 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.

As part of the strategic repositioning, the company has decided to focus the development of VB10.16 on locally advanced cervical cancer and recurrent metastatic head and neck cancer. This decision follows a comprehensive strategic review, which considered the timing of development activities, the need to optimize financial and human resources, and positive feedback from key opinion leaders, alongside input from potential future partners.

Recent changes in standard-of-care has extended the timelines for the C-04 trial, diminishing its viability as a fast-to-market strategy. In light of this, Nykode has decided to discontinue the C-04 trial to concentrate the company's financial and human resources on more promising indications. The decision is expected to reduce the VB10.16 development costs by over $25 million, which combined with our planned partnering strategy, will substantially extend the company's cash runway.

Michael Engsig, Chief Executive Officer of Nykode Therapeutics, stated: “The decision to focus on locally advanced cervical cancer and recurrent metastatic head and neck, and discontinue the C-04 trial in 2L cervical cancer, is part of our strategic repositioning to concentrate resources on the most commercially promising areas where we create significant benefits for patients in need, while generating value for shareholders. We remain highly enthusiastic about the broad potential of VB10.16 to make a meaningful difference in the lives of patients with HPV-driven cancers. While we regret the impact of excluding 2L cervical cancer from our immediate pipeline, we are eager to advance VB10.16 where we see the highest likelihood of clinical efficacy and the greatest market potential.

Klaus Edvardsen, Chief Research & Development Officer of Nykode Therapeutics, added: “Our commitment to developing VB10.16 as a treatment option for patients with HPV-driven cancers remains strong. To focus our efforts on indications with the clearest path to registration, we have decided to discontinue our work on recurrent/metastatic cervical cancer to concentrate on locally advanced cervical cancer, which is supported by the C-02 data demonstrating the vaccine's capability of deepening responses and maintaining clinical benefit for a prolonged period. We extend our gratitude to the partners involved in developing the C-04 trial and look forward to continuing our work on VB10.16."

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).

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 Head & Neck Cancer
The number of patients with squamos cell head and neck cancer (HNSCC) has risen substantially during the last decades and around 660,000 patients globally are now diagnosed yearly. This rise in incidence in HNSCC is mainly attributable to HPV infections. HPV 16 accounts for nearly 90% of such cases. HNSCC can be managed effectively in early stages, however, most patients are diagnosed at advanced stages where treatment outcomes are less favorable.

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.

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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