Company Announcement

Nykode announces expanded clinical development plan for its lead cancer vaccine VB10.16 in HPV16-positive cancers

- *A trial in advanced cervical cancer will be initiated in 4Q2023 with potential registrational intent*
- *Dose-finding Phase 1/2a trial in 1st line patients with advanced head and neck squamous cell carcinoma to begin in 1H2023*
- *Evaluate and plan for expansion into HPV16-positive anal, penile, vaginal and vulvar cancer*
- *Expanding clinical program into PD-L1 negative tumors*

Management will host a webcast today at 11 a.m. CET (in Norwegian) and 4 p.m. CET / 10 a.m. ET (in English) to discuss the development plan

Company selected to present at the 41st Annual J.P. Morgan Healthcare Conference in January 2023

Oslo, Norway, December 20, 2022 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced an expanded clinical development plan for VB10.16, the Company's wholly-owned cancer vaccine, for the treatment of HPV16-positive cancers with high unmet need. Nykode Management will host a webcast today, December 20, 2022, to discuss the development plan at 11 a.m. CET (in Norwegian) and 4 p.m. CET/10 a.m. ET (in English).

VB10.16 is an off-the-shelf therapeutic cancer vaccine specifically designed to treat HPV16-induced malignancies. The drug candidate has reported interim data from VB-C-02, a Phase 2 trial in heavily pre-treated cervical cancer patients. 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 that were associated with clinical responses.

"Today we announce our expanded VB10.16 development plan underlining our confidence in the product candidate's potential to treat a broad group of HPV-related cancer patients with significant unmet need. These indications constitute a large potential market opportunity for Nykode. Our potential registrational trial strategy disclosed today in advanced cervical cancer could provide a fast path to making VB10.16 available to patients. I am excited by our ambitious VB10.16 development plans and our recently signed agreements supporting the development. We remain committed to taking full advantage of the potential of VB10.16 and Nykode's technology platform," said Michael Engsig, Chief Executive Officer of Nykode Therapeutics.

Klaus Edvardsen, Chief Development Officer of Nykode Therapeutics, stated: "The interim results from our C-02 Phase 2 trial show the ability of VB10.16 to improve clinical outcomes in heavily pre-treated patients with advanced cervical cancer. Our next trial in advanced cervical cancer will focus on patients who failed first line treatment including checkpoint inhibitor treatment. In this patient group with limited treatment options and a significant unmet need, we aim for a potential registrational trial."

Expanded VB10.16 Clinical Development Plan

Cervical Cancer

Nykode is planning to conduct a single arm trial, VB-C-04, with potential registrational intent in 2nd line immune checkpoint inhibitor refractory advanced cervical cancer patients. The trial will be conducted in the United States and initiated in the fourth quarter of 2023.

Head and Neck Cancer

Nykode is planning to conduct an open-label, dose-finding, single arm Phase 1b/2a trial of VB10.16 in combination with pembrolizumab in patients with first line HPV16-postive, recurrent or metastatic squamous cell head and neck cancer as described in Nykode's announcement on December 6, 2022. The trial, VB-C-03, will evaluate the overall response rate, safety, tolerability, and antigen specific immune response of the combination therapies. Nykode expects to enroll patients in Europe during the first half of 2023.

Basket Trial

Nykode expects to collaborate on an investigator-initiated basket trial to evaluate VB10.16 in combination with a PD-L1 inhibitor in patients diagnosed with HPV16-positive anal, penile, vaginal and/or vulvar cancer who are no longer eligible for curative treatments. The trial is expected to enroll patients with both PD-L1 positive and PD-L1 negative tumors.

Nykode will continue to study VB10.16 in patients with PD-L1 negative tumors to investigate VB10.16's potential for a dedicated trial in such a patient population.

Webcast

Investors and analysts are invited to join a webcast presentation of the VB10.16 development plan conducted by Michael Engsig, Chief Executive Officer, and Klaus Edvardsen, Chief Development Officer, today, December 20, 2022 at:

11 a.m. CET / 5 a.m. ET which will be conducted in Norwegian

4 p.m. CET / 10 a.m. ET which will be conducted in English

The slide presentation and live and archived webcast can be accessed in the Investors section of the Company's website at https://nykode.com/investors/financial-reports-and-presentations.

41st Annual J.P. Morgan Healthcare Conference

Nykode Management will present at the 41st Annual J.P. Morgan Healthcare Conference, taking place January 9-12, 2023, in San Francisco, California.

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 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.

Contact for Nykode Therapeutics ASA:

Chief Business Officer, Agnete Fredriksen
Nykode Therapeutics ASA
IR@nykode.com

Nykode Therapeutics ASA

Oslo Science Park
Gaustadalléen 21
N-0349 Oslo, Norway