

Company Announcement

Nykode Therapeutics Announces FDA Approval of IND for VB-C-04, a Trial of VB10.16 in HPV16-Positive Cervical Cancer

- *FDA approval of IND for VB-C-04 trial.*
- *Nykode to further elaborate on trial design and development strategy at upcoming capital markets day in New York on September 20.*

Oslo, Norway, September 5, 2023 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced FDA approval of its investigational new drug (IND) application for the Phase 2 clinical trial. The trial is designed to evaluate VB10.16, the Company's wholly owned off-the-shelf therapeutic cancer vaccine candidate for HPV16-positive cancers, in combination with Roche's PD-L1 inhibitor atezolizumab (Tecentriq®¹) in patients with HPV16-positive, PD-L1-positive, recurrent or metastatic cervical cancer. Nykode is on track to initiate the trial in the fourth quarter of 2023.

"We are excited to open the IND for the C-04 trial with VB10.16. It is an important milestone" said Michael Engsig, CEO of Nykode Therapeutics. "We look forward to presenting the trial design and the overall VB10.16 development strategy at our Capital Markets Day in New York on September 20, 2023."

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

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

About VB.1016

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 data from a Phase 2 trial in advanced cervical cancer patients (NCT04405349) in combination with atezolizumab with mOS not reached but greater than 25 months at the time of analysis in PD-L1+ patients. The vaccine-induced significant HPV16-specific T cell responses 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.



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, infectious diseases and autoimmune diseases. Nykode's modular vaccine technology specifically targets antigens to Antigen Presenting Cells, which have been shown to induce broad, strong and long-lasting antigen specific immune responses and elicit 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 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.

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

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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