

## Company Announcement

### **Nykode Therapeutics Announces Expansion of Clinical Collaboration with Roche to Evaluate VB10.16 in Combination with anti-PD-L1 in the next trial in Advanced Cervical Cancer**

- *Potentially registrational trial with Nykode's lead candidate VB10.16 and Roche's atezolizumab (Tecentriq®) in the U.S. is expected to be initiated 4Q 2023*

Oslo, Norway, June 1, 2023 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced that it has expanded the clinical collaboration and supply agreement with Roche to cover evaluation of VB10.16, Nykode's wholly owned off-the-shelf therapeutic cancer vaccine candidate, in combination with Roche's cancer immunotherapy atezolizumab in patients with advanced cervical cancer who have progressed on pembrolizumab plus chemotherapy +/- bevacizumab as first line treatment. The VB-C-04 trial is expected to be initiated in the U.S. in the fourth quarter of 2023 with registrational intent, which provides a potential fast-to-market path.

Under the terms of the agreement, Nykode will sponsor and fund the planned clinical trial, and Roche will provide atezolizumab. Nykode retains all commercial rights to VB10.16 worldwide.

Nykode has recently reported positive safety and efficacy results from the Phase 2 VB-C-02 trial in Europe in advanced cervical cancer patients with VB10.16 in combination with atezolizumab. The results showed an overall response rate (ORR) of 29%, median overall survival (mOS) not reached but greater than 25 months at the time of analysis, and 6.3 months median progression free survival (mPFS) in PD-L1+ patients. In the patient population most relevant for the upcoming VB-C-04 trial, PD-L1+ patients with one prior line of systemic treatment, ORR was 40% and disease control rate was 80% with mPFS of 16.9 months and mOS not reached but greater than 25 months at the time of analysis.

“We look forward to expanding our collaboration with Roche to bring the combination of VB10.16 and atezolizumab to cervical cancer patients with limited treatment options. Cervical cancer has a poor prognosis, and the recent positive clinical data from VB-C-02 has strengthened our commitment to contribute with a well-tolerated treatment that can potentially prolong the life of these women. The trial provides a potential fast path to market for VB10.16.” said Michael Engsig, CEO of Nykode Therapeutics. “Overall, the collaboration speaks to our shared confidence in the unique potential of VB10.16, the platform, and the synergy between our vaccine candidates and atezolizumab. In



addition to the existing VB-C-02 and the new VB-C-04 collaboration, Roche continues to be a valuable partner under our collaboration agreement covering development of individualized vaccines for a broad range of cancers.”

The VB-C-04 trial will be conducted together with GOG Foundation, a U.S.-based not-for-profit organization with expertise in bringing best-in-class new treatments to patients.

#### **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 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 and infectious 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.

#### **Contact for Nykode Therapeutics ASA:**

Chief Business Officer, Agnete Fredriksen  
Nykode Therapeutics ASA  
[IR@nykode.com](mailto:IR@nykode.com)

#### **Nykode Therapeutics ASA**

Oslo Science Park  
Gaustadalléen 21  
N-0349 Oslo, Norway