



## Company Announcement

### **Nykode Therapeutics announces positive final results from its Phase 2 trial of VB10.16 in combination with PD-L1 inhibitor atezolizumab in advanced cervical cancer**

- *The results showed median overall survival greater than 25 months (not reached) and 6.3 months median progression free survival in PD-L1+ patients*
  - *VB10.16 was safe and well tolerated in combination with atezolizumab*
- *Nykode plans to initiate a potentially registrational trial in PD-L1+ patients with HPV16-positive advanced cervical cancer in the U.S. in 4Q 2023*

Oslo, Norway, April 18, 2023– Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced positive final results from the Phase 2 VB-C-02 trial. The trial investigates the use of Nykode’s therapeutic cancer vaccine candidate VB10.16 in combination with Roche’s cancer immunotherapy Tecentriq® (atezolizumab) in patients with advanced or recurrent, non-resectable HPV16-positive cervical cancer. The trial enrolled 52 patients, of which 48% had PD-L1+ tumors, who were treated for up to one year and followed for an additional 12 months.

“We are extremely encouraged by the unprecedented data that indicates a doubling of the survival of PD-L1+ patients with advanced cervical cancer compared to treatment alternatives. Not only do we see patients on average live longer, but 7 of the 14 patients who received all treatments are still alive without signs of progression. This is a landmark day for VB10.16 and for Nykode’s technology and we are excited to move the cancer vaccine forward towards the market for the benefit of patients,” said Michael Engsig, Chief Executive Officer of Nykode Therapeutics.

As previously announced the company is planning an ambitious development strategy to take VB10.16 further in advanced cervical cancer and into head and neck cancer. The data announced today supports the next steps which focus on PD-L1+ patients with up to one prior line of systemic therapy.

“The data give us confidence as we now plan to initiate a potentially registrational trial in the U.S. during 4Q this year in advanced cervical cancer and work to accelerate expansion of our VB10.16



program with the goal of reaching all addressable patient populations with HPV16-positive cancers,” said Klaus Edvardsen, Chief Development Officer of Nykode.

“The unmet medical need in patients with advanced cervical cancer is still high”, said Professor Peter Hillemanns, Director of the Departments of Gynecology, Obstetrics and Breast Cancer at Hannover University Hospital, Germany and principal investigator of the C-02 trial. “These findings especially on median progression free survival and median overall survival indicate that VB10.16 may give meaningful added clinical benefit with prolonged responses and survival compared to existing standard of care in this setting”.

The results showed a median overall survival of more than 25 months (median has not yet been reached) and a median progression free survival of 6.3 months in PD-L1+ patients. The median overall survival for the overall population, which also includes patients with PD-L1- tumors, was 16.9 months, while the median progression free survival was 4.1 months. With overall response rate (ORR) of 29% in PD-L1+ patients (19% in overall population) and disease control rate (DCR) of 75% in PD-L1+ (60% in overall population) the final analysis confirms the previously reported positive response rates from the interim analysis. The duration of response in the overall population was 17.1 months. In PD-L1+ patients with one prior line of systemic treatment ORR was 40% and DCR 80% with a median progression free survival of 16.9 months and median overall survival more than 25 months (not reached).

VB10.16 in combination with atezolizumab was well-tolerated and has a safety profile comparable to checkpoint inhibitor monotherapy reported in literature.



### **Webcast**

Investors and analysts are invited to join a webcast presentation of the updated results conducted by CEO Michael Engsig and other members of the management team tomorrow, April 19, 2023 at:

11 a.m. CET / 5 a.m. ET (in Norwegian)

4 p.m. CET / 10 a.m. ET (in English)

The slide presentation is attached to this announcement and is available in the Investors section of the Company's website at <https://nykode.com/investors>. The live and archived webcast of the presentation can be accessed in the Investors section of the Company's website at <https://nykode.com/investors/financial-reports-and-presentations>.

### **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](https://clinicaltrials.gov) (NCT04405349).

### **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. The vaccine is currently in development for the treatment of HPV16-positive advanced cervical cancer. Nykode is planning a potentially registrational trial (VB-C-04) in advanced cervical cancer which will focus on patients who progressed after first line treatment including checkpoint inhibitor treatment. In addition, Nykode plans to expand into other HPV16-positive indications including first line HPV16-positive, recurrent or metastatic squamous cell head and neck where VB10.16 will be tested in combination with pembrolizumab.

### **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 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 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 which correlates with 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 safety and efficacy 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 COVID19 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.



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