Company Announcement

Nykode Therapeutics Announces Publication of Phase 2 VB-C-02 Data Confirming Prolonged Benefit and Definitive Vaccination Effects

- *Final data from the Phase 2 VB-C-02 trial were published in the peer-reviewed BMJ Journal for ImmunoTherapy of Cancer.*
- *VB10.16 in combination with atezolizumab (Tecentriq®) demonstrated a favorable safety profile across 52 enrolled patients.*
- *The data affirm the prolonged benefit and definitive vaccination effect observed in the interim analysis (efficacy population includes 47 patients), as previously announced.*
- *Anti-tumor activity was observed with an overall response rate (ORR) of 19.1%, increasing to 29.2% for PD-L1-positive patients and 40.0% for PD-L1-positive patients with one prior line of systemic anti-cancer treatment (SACT).*
- *Durable efficacy was demonstrated with a median progression-free survival (mPFS) of 4.1 months and a median overall survival (mOS) of 21.3 months in the total efficacy population.*
- *Among PD-L1-positive patients, mPFS was 6.3 months, extending to 15.8 months for those with one prior line of SACT, while mOS reached 24.7 months and was not reached for PD-L1-positive patients with one prior line of SACT.*

Oslo, Norway, January 8, 2025 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced the publication of a manuscript entitled “Safety and efficacy of the therapeutic DNA-based vaccine VB10.16 in combination with atezolizumab in persistent, recurrent or metastatic HPV16-positive cervical cancer: a multicenter, single-arm phase 2a study” in the peer-reviewed BMJ “Journal for ImmunoTherapy of Cancer” (JITC). The trial investigated the use of Nykode’s wholly owned off-the-shelf therapeutic cancer vaccine candidate VB10.16 in combination with Roche’s checkpoint inhibitor atezolizumab in patients with persistent and recurrent or metastatic HPV16-positive cervical cancer.

As previously communicated, the published results confirm prolonged clinical benefits and indicate a potential synergistic treatment effect of VB10.16 in combination with atezolizumab compared to what has previously been reported for checkpoint inhibitor monotherapy. In this analysis the remaining patients were followed for up to 24 months, compared to at least 12 months in the previously reported data cut-off.

The trial demonstrated an ORR of 19.1% in the efficacy population. With the extended 12-month follow-up period to the end of the trial, both mPFS and mOS increased compared to what has previously been reported, reaching 4.3 months and 21.3 months, respectively.

In the subpopulation of PD-L1-positive patients (n=24) the ORR increased to 29.2% resulting in further improved mPFS and mOS of 6.3 months and 24.7 months, respectively.

Among PD-L1-positive patients with one prior line of SATC (n=15), the ORR increased to 40.0%, and mPFS and mOS further improved to 15.8 months and not reached, respectively.

"Compared to historical data on checkpoint inhibitor monotherapy in highly similar patient populations, the final VB10.16 C-02 data strongly indicate an extended survival benefit and sustained efficacy of the combination of VB10.16 and atezolizumab. We are thrilled to see the data published in full for the first time, enabling in-depth discussions with the medical community on the best path forward for VB10.16," said Michael Engsig, CEO of Nykode.

"As many cancer vaccines increasingly target earlier lines of treatment, including adjuvant setting, we are proud to demonstrate strong and durable efficacy in advanced-stage cervical cancer. Furthermore, the increased efficacy observed in patients receiving second-line therapy compared to later lines underscores the strong potential of this combination therapy and highlights a promising area for further exploration with our cancer vaccines across various lines of therapy."

The manuscript is available here

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 human papillomavirus type 16 (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 (NCT04405349).

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 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 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-L1 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 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 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.NEO, an individualized cancer neoantigen vaccine, is being investigated in a trial with more than 10 different indications.

The Company's partnerships include 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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