Company Announcement

Nykode Therapeutics announces positive interim results from its Phase 2 trial with VB10.16 in combination with immune checkpoint inhibitor atezolizumab in advanced cervical cancer

VB10.16 in combination with atezolizumab demonstrated an ORR of 21%, including 2 CRs and 6 PRs, in a heavily pre-treated population of patients with HPV16-positive advanced cervical cancer

VB10.16 in combination with atezolizumab demonstrated a very high DCR of 64%

Anti-tumor activity of VB10.16 in combination with atezolizumab was observed both in PD-L1 positive patients (ORR of 27%; DCR of 77%) and PD-L1 negative patients (ORR of 17%; DCR of 58%)

Management to host webcast presentation of the interim results today, May 9, 2022 at 2 p.m. CET / 8 a.m. ET

Oslo, Norway, May 9, 2022 – Nykode Therapeutics AS (Euronext Growth (Oslo): NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of vaccines and novel immunotherapies, today announced positive interim results from its Phase 2 VB C-02 trial of VB10.16, its wholly-owned therapeutic cancer vaccine, in combination with the PD-L1 inhibitor atezolizumab in patients with HPV16-positive advanced cervical cancer. Interim results from 39 patients with a median follow up of 6 months show an ORR of 21%—including two patients who achieved a complete response and six who achieved a partial response—and a very high disease control rate of 64%. The trial enrolled a heavily pre-treated patient population with more than two thirds of the patients having received at least two previous systemic lines of treatment.

Interestingly, anti-tumor activity was observed in both PD-L1 positive (ORR of 27% and DCR of 77%) and PD-L1 negative patients (ORR of 17% and DCR of 58%) indicating a potential clinical benefit also in the PD-L1 negative population. In addition, a DCR of 71% was observed in patients with non-inflamed tumors, including both immune desert and T cell excluded tumors. Together these findings suggest a differentiated anti-tumor response pattern of the combination treatment compared to checkpoint inhibitor monotherapy.

“We are thrilled to report these positive interim safety and efficacy results from our Phase 2 trial with VB10.16, which showed evidence of durable anti-tumor activity in a heavily pre-treated population of patients with late-stage cervical cancer,” said Michael Engsig, Chief Executive Officer of Nykode Therapeutics. “These interim results support Nykode’s unique approach of targeting Antigen-Presenting Cells (APCs), designed to produce a robust and long-lasting CD8 killer T cell response against cancer cells. We look forward to reporting updated efficacy data readouts from the Phase 2 trial during the first half of 2023 as we continue to advance our cervical cancer program.”

Immunological analyses of the peripheral T cell responses demonstrated an increased HPV16-specific IFNγ T cell immune response post-vaccination in the majority of subjects and were associated with clinical efficacy indicating the induction of clinically relevant T cell responses. Clearance of circulating HPV16 DNA was significantly correlated with clinical response and progression free survival suggesting ctDNA may be an early marker of response to treatment in cervical cancer. VB10.16 is potentially a first-in-class therapeutic vaccine against HPV16-positive cervical cancer.

"The patients who were treated with VB10.16 in combination with atezolizumab in the C-02 trial were heavily pre-treated and are prone to progress quickly,” 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. “It is very encouraging to see that a majority of patients experienced a clinical benefit and that many patients had durable responses. The combination of VB10.16 and atezolizumab was also well tolerated by patients.”

“Treatment advances within the area of advanced cervical cancer have been limited though checkpoint inhibitors have demonstrated clinical efficacy in some patients. The unmet need is still high, and we are very pleased to see a high disease control rate and durable responses in these heavily pre-treated HPV16+ cervical cancer patients. The anti-tumor activity seen in both non-inflamed and PD-L1 negative populations may potentially open up a new subset of patients for treatment. These findings indicate that VB10.16 may give a meaningful added clinical benefit compared to the existing standard of care treatment in this setting. We would like to thank all the investigators, patients and their relatives for participating in this trial. Without all of you the advances of VB10.16 would not have been possible,” added Siri Torhaug, Chief Medical Officer of Nykode Therapeutics.

VB10.16 was generally safe and well tolerated, with 10% of patients experiencing Grade 3 or more treatment-related adverse events, indicating no increased toxicity compared with atezolizumab monotherapy and a favorable safety profile that is consistent with previously published data for the Nykode DNA vaccine technology platform.

Nykode expects to report updated efficacy data read-outs from VB C-02 during the first half of 2023.

Webcast

Investors and analysts are invited to join a webcast presentation of the interim results conducted by CEO Michael Engsig and other members of the management team today, May 9, 2022 at 2 p.m. CET

/ 8 a.m. ET. The slide presentation will be available in the Investors section of the Company's website at https://nykode.com/investors following the event. 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 of patients with advanced or recurrent, non-resectable HPV16-positive cervical cancer. Patients received treatment with VB10.16 in combination with the PD-L1 inhibitor atezolizumab for up to one year. The main aim of the trial was to assess the efficacy, immunogenicity and safety of VB10.16 when given in combination with atezolizumab. The trial is now fully enrolled with 52 patients enrolled at sites in Europe, and the pre-planned second interim analysis was performed at the cut-off date of 14 February 2022. Nykode has previously reported positive interim safety data from the trial.

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 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 candidate has demonstrated favorable clinical data in a Phase I/IIa 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. VB10.16 is currently being investigated in the VB C-02 trial in patients with advanced or recurrent, non-resectable HPV16-positive cervical cancer.

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 vaccines and 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 16 induced malignancies which is in Phase 2 for the treatment of cervical cancer; and VB10.NEO, a cancer neoantigen vaccine, which is exclusively out licensed to Genentech and is in Phase 1b for the treatment of locally advanced and metastatic tumors and Phase 1/2a for the treatment of melanoma, lung-, head and neck, renal-, and bladder cancer. Additionally, Nykode has initiated a Phase 1/2 trial in 2021 with its two next-generation COVID-19 vaccine candidates.

The Company's partnerships include Roche and 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 Euronext Growth (Oslo), a trading platform operated by Euronext, the leading Pan-European market infrastructure. The ticker code is NYKD. Further information about Nykode Therapeutics may be found at http://www.nykode.com.

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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.