Company Announcement

Nykode Therapeutics Initiates Phase 1/2a Trial of VB10.16 in First Line HPV16-Positive Head and Neck Cancer

Oslo, Norway, September 29, 2023 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced the initiation of the Phase 1/2a clinical trial. The trial evaluates VB10.16, the Company's wholly owned off-the-shelf therapeutic cancer vaccine candidate for HPV16-positive cancers, in combination with MSD's (Merck & Co., Rahway, NJ, USA) PD-1 inhibitor KEYTRUDA®[1] (pembrolizumab) in first line (1L) setting in patients with HPV16-positive, PD-L1-positive, recurrent or metastatic head and neck squamous cell carcinoma (HNSCC).

"Initiating the VB10.16 trial for HPV16-positive head and neck cancer, is a significant step in our clinical strategy," said Michael Engsig, CEO of Nykode Therapeutics. "The strong results in advanced cervical cancer patients in VB-C-02 boost our confidence in VB10.16's potential for HPV16-positive HNSCC. The VB-C-03 trial launch shows our commitment to expanding VB10.16 as an innovative immunotherapy for HPV16 cancers across more indications and treatment stages."

VB-C-03 is a Phase 1/2a open-label, dose-finding trial investigating safety, tolerability, and efficacy. It consists of two consecutive phases, a dose escalation phase (Phase 1) and a dose expansion phase (Phase 2a), testing VB10.16 in doses up to 9 mg, in combination with pembrolizumab in a 1L setting in patients with HPV16-positive, PD-L1-positive HNSCC. The trial will take place in Europe.

"The C-03 trial is our first trial in a first line setting. We are encouraged by the C-02 trial which showed that moving up in the treatment line may further improve the clinical outcome. In addition, we are exclusively focusing on the subset of patients with PD-L1+ tumors as these were found to demonstrate the best efficacy in the C-02 trial. We will also be testing doses up to 9 mg, three times higher than previously used. All in all, we are eager to see the potential clinical benefit for the important head and neck cancer patient population," said Klaus Edvardsen, Chief Development Officer of Nykode Therapeutics.

Merck will supply KEYTRUDA, while Nykode retains all commercial rights to VB10.16 worldwide.

[1]KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About the Phase 1/2a Trial
The open-label, dose-finding Phase 1/2a trial will evaluate the safety, immunogenicity, and anti-tumor activity of VB10.16 in combination with MSD's PD-1 inhibitor KEYTRUDA® (pembrolizumab) in patients with HPV16-positive, PD-L1-positive, recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) who are eligible for pembrolizumab monotherapy. The trial consists of two consecutive phases, a dose escalation phase (Phase 1) and a dose expansion phase (Phase 2a). The trial will determine the biological optimal dose of VB10.16 in combination with a fixed dose of pembrolizumab and elicited by doses of 3 mg, 6 mg, and 9 mg VB10.16. The trial will take place in Europe. More information is available at ClinicalTrials.gov Identifier: NCT06016920.

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 estimated to be 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 trial 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 Head and Neck Cancer
Every year, around 660,000 patients globally are diagnosed with HNSCC. HPV16 accounts for nearly 90% of such cases. HNSCC can be managed effectively in early stages, however, most patients are diagnosed at advanced stages where treatment outcomes are less favorable.

About Nykode Therapeutics
Nykode Therapeutics is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies with a focus on treatment of cancer and autoimmune diseases. Nykode's modular vaccine technology specifically targets antigens to APC, which have been shown to induce broad, strong and long-lasting antigen specific immune responses which correlates with clinical responses in cancer.

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; 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 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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