Company Announcement

Nykode Therapeutics Doses First Patient in Abili-T Phase II Randomized Trial evaluating Abi-suva in HPV16-Positive, PD-L1-Positive Recurrent or Metastatic Head and Neck Cancer Patients

Oslo, Norway, May 7, 2026 — Nykode Therapeutics ASA (OSE: NYKD), a clinical stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today confirmed the dosing of the first patient in Abili-T, a randomised Phase II clinical trial evaluating abi-suva (formerly VB10.16) in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) versus pembrolizumab alone as first-line treatment for patients with HPV16-positive, PD-L1-positive recurrent or metastatic head and neck squamous cell carcinoma (1L r/m HNSCC).

The initiation of Abili-T marks a pivotal milestone in Nykode's clinical development programme and reinforces the Company's strategy to advance abi-suva as a targeted immunotherapy for the significant unmet medical need that exists in HPV16-driven cancers.

"Initiating the first patient in the Abili-T trial is an important step forward for Nykode and most importantly for patients with first-line recurrent/metastatic head and neck squamous cell carcinoma who continue to have significant unmet medical needs," said Michael Engsig, Chief Executive Officer at Nykode Therapeutics. "*Abi-suva is designed to generate strong and durable HPV16-specific immune responses and we look forward to generating data in a randomized setting. We are grateful to the clinical investigators and patients participating in this study."*

"There is a significant unmet need for patients with HPV16-driven head and neck cancer, particularly in the first-line setting," said Åse Bratland, Coordinating Investigator of the Abili-T trial, The Norwegian Radium Hospital, Oslo University Hospital. *"Abi-suva is designed to generate a targeted and durable immune response and combining it with pembrolizumab may offer a meaningful new approach for these patients. We are hopeful that this study will provide important insights and, ultimately, lead to improved outcomes."*

Abili-T is a randomised, open-label, multicentre Phase II trial evaluating abi-suva in combination with pembrolizumab versus pembrolizumab alone as first-line treatment in patients with HPV16-positive, PD-L1-positive recurrent or metastatic head and neck squamous cell carcinoma (1L r/m HNSCC).

The trial will enroll approximately 100 patients across 40 sites in Europe and Canada. Patients will be randomised to receive either abi-suva in combination with pembrolizumab or pembrolizumab alone. The primary endpoints are progression-free survival (PFS) and objective response rate (ORR). Secondary endpoints include duration of response (DOR), disease control rate (DCR), and overall survival (OS).

The Abili-T trial follows the successful completion of three prior clinical studies with abi-suva, VB-C-01, VB-C-02 and VB-C-03, which established the safety and tolerability of abi-suva as monotherapy and in

combination with checkpoint inhibitors and demonstrated a strong and durable clinical effect in patients with advanced HPV16-driven cancers.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. KEYTRUDA® has been supplied by MSD for the Abili-T trial according to the clinical trial collaboration and supply agreement between Nykode and MSD.

Disease Background and Market Opportunity

The combined incidence of HPV16-positive HNSCC in the EU and US is approximately 63,000 new cases annually and the incidence of HPV16-driven HNSCC is rising.

Despite recent advances in immuno-oncology, patients with recurrent or metastatic HNSCC continue to face a significant unmet medical need. Current standard of care achieves an objective response rate of 19% and a median overall survival of 12.3 months. The majority of treatments currently in development for HNSCC are focused on HPV-negative disease, leaving the HPV16-positive patient population particularly underserved.

Beyond HNSCC, abi-suva has the potential to address a broader HPV16-driven cancer population including cervical, anal, vulvar and penile cancers with an annual incidence of approximately 134,000 patients annually in Europe and the US. This broader opportunity is supported by the clinical data generated in the VB-C-02 trial, which demonstrated strong and durable clinical effects in advanced cervical cancer patients, and in the VB-C-01 demonstrating a promising efficacy and favorable safety profile and confirmed the induction of robust HPV16-specific T-cell responses in pre-cancerous lesions (CIN).

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 immunotherapy 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 abi-suva, a therapeutic immunotherapy for the treatment of HPV16 induced malignancies which demonstrated favorable safety and efficacy results from its Phase 2 trial for the treatment of late-line r/m cervical cancer. Abi-suva is currently being further developed in first line head and neck cancer with the randomized Abili-T trial with interim results within 2027. VB10.NEO, an individualized cancer neoantigen immunotherapy, has been investigated in two trials with more than 10 different indications.

Nykode is also utilizing its APC-targeted technology to create an immune tolerance 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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