

# **Company Announcement**

# Nykode Announces Updated Strategy to Increase Value for Patients and Shareholders, Prioritizing VB10.16 as the Lead Value Driver

- Nykode presents a highly focused strategy prioritizing core assets with the greatest potential to deliver significant clinical and commercial impact.
- VB10.16 prioritized as lead value driver, with a focus on initiating a new randomized controlled trial in HPV16 driven 1st-line recurrent/metastatic head and neck cancer (1L r/m HNSCC) designed to demonstrate clinical efficacy and support continued advancement of the asset.
- VB10.NEO development streamlined, with targeted investments focused on strengthening its
  position as the most attractive unencumbered individualized neoantigen therapy, leveraging
  anticipated peer data readouts.
- Tolerance platform further advanced, aiming to leverage the differentiated technology with bestin-class potential and pursuing partnerships to accelerate development.
- Disciplined execution and financial focus to reach key inflection points within the expected cash runway.
- Additional high-caliber Board members, including a new Chair, expected to be elected at the Annual General Meeting in 2026, with the current Chair remaining on the Board.

Oslo, Norway, August 27, 2025 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced its updated corporate strategy, in line with the commitment made at its first quarter results in May 2025. The updated strategy includes prioritization of VB10.16 as the lead clinical asset and value driver, given the Company's increasing conviction in its potential to treat HPV16 positive cancers. As a natural step in the development of VB10.16, the WHO has accepted the International Non-proprietary Name (INN) abipapogene suvaplasmid (abi-suva).

Michael Engsig, Chief Executive Officer, commented: "Nykode's updated strategy is about focus, execution, and creating value for patients and the Company's shareholders. Abi-suva (VB10.16) targets a highly attractive commercial market and, with its potential to set a new standard of care, addresses a patient population with few effective treatment options. Furthermore, we see VB10.NEO positioned as the most attractive unpartnered individualized neoantigen therapy, ready to leverage peer readouts expected within the next 18 months. In parallel, our tolerance platform has the potential to open the door to breakthrough treatments in autoimmune diseases. With a focused pipeline and key inflection points within our estimated cash runway, we are advancing our most promising assets with disciplined capital allocation, ensuring that Nykode is well-positioned to deliver meaningful results for patients and attractive returns for shareholders."



## Abi-suva (formerly VB10.16): Lead Value Driver

At the core of the updated strategy is abi-suva, Nykode's lead asset and highest priority for new investment. A randomized, open-label, multicenter Phase 2 trial, referred to as Abili-T, will evaluate abi-suva in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, pembrolizumab (KEYTRUDA®1) versus pembrolizumab alone as first-line treatment for human papilloma virus (HPV)16-positive, PD-L1-positive recurrent or metastatic head and neck squamous cell carcinoma (1L r/m HNSCC).

The trial will enroll up to 100 patients and is powered to deliver robust efficacy data in combination with pembrolizumab, the current standard-of-care for PD-L1-positive 1L r/m HNSCC patients. Interim analyses for efficacy are planned throughout the trial, with the first expected during 2027.

Unmet need in 1L r/m HNSCC remains high. The selected trial population represents a well-characterized subgroup of patients with limited durable treatment options and rising incidence. Despite recent advances in 1L r/m HNSCC, HPV16-positive patients remain an underserved subgroup with limited durable treatment options. Abi-suva may offer additional benefits without added toxicity, making it particularly relevant for this vulnerable patient population.

Abi-suva is an off-the-shelf therapeutic cancer vaccine with a favorable safety profile and demonstrated clinical activity in HPV16-positive, late-line r/m cervical cancer. In the VB-C-02 trial, abi-suva in combination with atezolizumab (Tecentriq®), achieved a median overall survival of 24.7 months in PD-L1-positive patients which is more than double what has been reported with immune checkpoint inhibitor monotherapy. Importantly, strong and durable responses generated in this study were correlated with the patient's immune response. Furthermore, preliminary data from the ongoing VB-C-03 trial indicate similar level of added benefit of abi-suva on top of pembrolizumab in 1st line head and neck cancer.

Agnete Fredriksen, Co-founder & Chief Scientific Officer, added: "Abi-suva has been tested in three clinical trials, two complete and one ongoing. The trials VB-C-02 and VB-C-01 provided strong and consistent efficacy signals. The preliminary data from the ongoing VB-C-03 trial indicate similar level of added benefit of abi-suva. This reinforces our confidence in abi-suva's potential to deliver meaningful benefit to patients and provides a strong rationale for advancing abi-suva into a randomized setting."

#### VB10.NEO: Well-positioned as best unencumbered individualized therapy

With an established supply chain, an in-house Al-powered epitope selection algorithm and strong durable clinical immune responses, VB10.NEO is well-positioned to attract potential partners following key peer data readouts expected within the next 18 months.

Nykode will make targeted, limited investments to further strengthen VB10.NEO's standing as the most attractive unencumbered INT asset.

<sup>&</sup>lt;sup>1</sup> KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.



# Best-in-Class Antigen-Specific Immune Tolerance Platform

Nykode will increase investments to accelerate the development of its antigen-specific immune tolerance (ASIT) platform. Recent advancements support best-in-class potential specifically reducing unwanted, disease-causing immune responses. The addressable field of ASIT covers a broad range of autoimmune diseases, allergy and organ transplant rejections. Nykode will further substantiate the platform's potential and explore partnerships to advance development and diversify indications.

# **Partnering Strategy**

Nykode's updated strategy with focused advancement of the three prioritized programs aligns valuegenerating with optionality to enter strategic partnerships in oncology and autoimmune indications.

## **Capital Allocation and Cash Runway**

With this disciplined and sharper strategic focus, the Company's current cash runway is expected to extend into 2029. This guidance is predicated on a positive outcome of the pending tax case, while a ruling against Nykode would result in a cash runway extending into 2028. As of June 30, 2025, Nykode had a strong cash position of USD 70.0 million, excluding a non-current receivable of USD 32.2 million related to the pending tax case.

# **Future Board Composition**

In line with the Company's ambitions, and as previously stated, Nykode plans to further strengthen its governance and expertise in selected strategic areas by expanding the Board with additional high-caliber members, including a new Chair, to help guide the next phase of the Company's evolution. These new members are expected to be elected at the Company's Annual General Meeting in spring 2026.

#### About Abipapogene Suvaplasmid (formerly VB10.16)

Abipapogene Suvaplasmid (abi-suva) 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. Abi-suva has reported promising data from a Phase 2 trial in late-line PD-L1 positive r/m 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 abi-suva in VB-C-03, an open-label, dose-finding Phase 1/2a trial evaluating abi-suva in combination with MSD's PD-L1 inhibitor pembrolizumab (KEYTRUDA®) in 1L patients with HPV16-positive, PD-L1-positive, recurrent, or metastatic head and neck squamous cell carcinoma (HNSCC).



#### **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 oncogenic viruses. There are several types of cancer-causing high-risk HPV's causing cancers, HPV16 being one of the most common, with more than 130,000 new cancer 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 abi-suva (VB10.16), represents a novel immunotherapeutic treatment option. By combining a therapeutic cancer vaccine with the immune 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.

#### Cervical Cancer

Globally, the greatest burden of HPV-related cancers is cervical cancer. 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.

#### Head and Neck Cancer

In the United States and other high-income countries, head and neck cancer has now surpassed cervical cancer as the most common HPV related malignancy. In head and neck squamous cell carcinoma (HNSCC), there's a significant unmet need for improved therapies, particularly for recurrent or metastatic cases. While immune checkpoint inhibition is now part of standard treatment for recurrent or metastatic HNSCC in general, there are no established therapeutic treatments specifically for HPV-related HNSCC.

#### **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 head and neck cancer. 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.

#### Contact:

Alexandra Deschner, Head of IR Nykode Therapeutics ASA IR@nykode.com

# **Nykode Therapeutics ASA**

Oslo Science Park Gaustadalléen 21 N-0349 Oslo, Norway

#### 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.