



## Company Announcement

### **Nykode Therapeutics Announces Presentation of Positive Immunogenicity Results from Phase 1/2a Study of VB10.NEO, an Individualized Therapeutic Cancer Vaccine, at the Neoantigen-Based Therapies Summit**

- *VB10.NEO induced a T cell response in 95% of the patients, including expansion of both novel and pre-existing T cells*
- *The responses were broad, and the majority of the encoded neoepitopes were immunogenic and induced a CD8 T cell response*
- *Multiple vaccinations boosted the breadth and magnitude of the immune response*
- *Most T cell responses were maintained for at least one year*
- *The data supports the APC-targeted Vaccibody platform's unique ability to induce broad and long-lasting immune response, including CD8 T cells with the desired profile known to kill tumor cells*
- *VB10.NEO was generally safe and well-tolerated in patients with solid tumors*

Oslo, Norway, October 26, 2022 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced the presentation of positive preliminary safety and immunogenicity results from its Phase 1/2a study of VB10.NEO, a proprietary individualized therapeutic DNA cancer vaccine, in patients with locally advanced or metastatic solid tumors. The data will be presented today at the Neoantigen-Based Therapies Summit in Boston, Massachusetts. Nykode is developing VB10.NEO worldwide in partnership with Genentech, a member of the Roche Group.

Michael Engsig, Nykode's Chief Executive Officer, stated: "I am thrilled with these clinical data which confirm our position at the forefront of the fully individualized cancer immunotherapy field. We believe individualized neoantigen-based immunotherapies will transform the treatment of cancer, and we are excited to continue the journey with our partners at Genentech, a global leader in immuno-oncology."

Klaus Edvardsen, Nykode's Chief Development Officer, stated: "The data presented today show that VB10.NEO induces a broad, strong and long-lasting CD8 T cell response against patient-specific tumors, in addition to being safe and well-tolerated in combination with other anti-cancer treatments. The data continue to substantiate our differentiated platform technology and support its huge potential

within individualized cancer treatments. We are happy to have such strong partners as Genentech for continued development.”

### **Summary of Safety Results**

41 patients were dosed with VB10.NEO. The data show that VB10.NEO was generally safe and well-tolerated in patients with solid tumors when administered in combination with various anti-cancer treatments. The most common adverse events reported were fatigue (34%) and diarrhea (27%). The observed adverse events are generally consistent with the known safety profiles of checkpoint inhibitors, chemotherapy, as well as other targeted cancer therapies, with no overt signs of add-on toxicity.

### **Summary of Immunogenicity Results**

22 patients were included in the interim analysis. Blood samples were collected at baseline, week 11, 22, 34 and 54, to assess immune response to individual neoepitopes by ELISpot.

- A neoantigen-specific immune response was observed in all patients (ranging from 3-20 neoepitopes)
- A vaccine-induced T cell response was observed in 95% of patients, inducing expansion of both novel and pre-existing T cells
- The responses were broad and the majority of the neoepitopes included in the vaccines were immunogenic
- Polyfunctional Th1 CD4 and Tc1 CD8 T cell responses were observed
- Ranging from 53% to 100% (or 85% on average) of the neoepitopes induced a CD8 T cell response. Cytotoxic CD8 T cells are known to be important for killing tumor cells
- The breadth and magnitude of immune response increased upon multiple vaccinations
- Responses to the majority of the neoepitopes were maintained for at least one year

### **Additional information**

More details on the results will be available in a slide presentation in the Investors section of the Company’s website at <https://nykode.com/investors/financial-reports-and-presentations>.

### **About the Phase 1/2a Trial**

VB N-01 is an open-label first-in-human Phase 1/2a study to evaluate safety, feasibility and efficacy of multiple dosing with individualized VB10.NEO or VB10.NEO and bempedaldesleukin (NKTR-214) immunotherapy in patients with locally advanced or metastatic melanoma, NSCLC, clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of head and neck, who did not reach



complete responses with current standard of care immune checkpoint blockade. More information is available at [clinicaltrials.gov](https://clinicaltrials.gov): identifier NCT03548467.

### **About VB10.NEO**

VB10.NEO is a proprietary individualized DNA-based neoantigen vaccine in development for the treatment of locally advanced or metastatic solid tumors under an exclusive, worldwide clinical collaboration with Genentech, a member of the Roche group. The vaccine is designed to be produced on-demand according to the neoantigen profile of an individual patient. Neoantigens are proteins generated by tumor-specific mutations not present in normal tissues and are thus an attractive target for cancer immunotherapy as they may be recognized as foreign by the immune system.

Nykode is currently conducting two clinical studies evaluating VB10.NEO: VB N-01 and VB N-02. VB N-01 is an open-label Phase 1/2a basket study to evaluate the safety and efficacy of multiple dosing with VB10.NEO in patients with locally advanced or metastatic cancer (NCT03548467). VB N-02 is an open-label Phase 1B, dose-escalation study of the safety- and antigen-specific immune responses elicited by VB10.NEO in combination with Roche's checkpoint inhibitor atezolizumab in patients with locally advanced and metastatic tumors (NCT05018273).

### **About Nykode Therapeutics**

Nykode Therapeutics is a clinical-stage biopharmaceutical company dedicated to the discovery and development of 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 (HPV)-16 induced malignancies which demonstrated positive interim efficacy and safety 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. Additionally, Nykode is conducting a Phase 1/2 trial with next-generation COVID-19 vaccine candidates.

The Company's partnerships include 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 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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