

## Company Announcement

### **Nykode Therapeutics announces first subject dosed with its T cell focused next-generation SARS-CoV-2 vaccine candidate**

- First subject dosed with Nykode Therapeutics' T cell focused SARS-CoV-2 vaccine candidate. This is part of the ongoing Phase 1/2 two-arm clinical trial VB-D-01 designed to specifically address emerging variants of concern, including Omicron<sup>1</sup>
- The T cell focused vaccine candidate (VB10.2210) encodes 96 clinically validated T cell epitopes spanning a total of eight SARS-CoV-2 proteins, including Spike. These Spike- and non-Spike T cell epitopes have been identified and validated by Adaptive Biotechnologies using their immune medicine platform
- Initial analysis indicates that no epitopes outside the Spike are affected by the Omicron variant

Oslo, Norway, December 28, 2021 – Nykode Therapeutics AS (Euronext Growth (Oslo): NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of vaccines and novel immunotherapies, announced today the first subject has been dosed with its T cell focused next-generation SARS-CoV-2 vaccine candidate in its VB-D-01 Phase 1/2 trial (NCT05069623). The T cell specific vaccine is designed to prime T cells, potentially generating a broad immune response against current and future variants. The VB-D-01 trial is a two-arm, open label, dose escalation and dose expansion study to evaluate the safety, reactogenicity and immunogenicity of both the T cell specific/VB10.2210 and the RBD/VB10.2129 vaccine candidates in healthy, previously vaccinated subjects.

Siri Torhaug, Chief Medical Officer of Nykode Therapeutics, commented: “The emergence of the Omicron variant highlights the paramount need for next-generation COVID vaccines designed to be minimally impacted by future variants of concern such as Omicron. Dosing the first subject with our T

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<sup>1</sup>The Omicron variant of the SARS-CoV-2 virus, first identified in South Africa on November 9, 2021, was designated a variant of concern by the World Health Organization (WHO) on November 26, 2021. Early data suggests that Omicron carries an increased risk of re-infection, and genetic sequence analysis has revealed several mutations in the Spike protein, which may reduce clinical effectiveness of current vaccines and/or therapeutic antibodies.

cell focused vaccine candidate in this second arm of our COVID-19 vaccine trial is a remarkable milestone. We are also very pleased with the speed at which this was achieved.”

Mikkel W. Pedersen, Chief Scientific Officer of Nykode Therapeutics, continued: “The role of the cellular immune response to SARS-CoV-2 mediated by T cells reflects untapped potential.

It has been shown that virus specific T cell responses in vaccinated human subjects coincide with rapid protection and are associated with milder disease in COVID-19 patients. While current Spike-based vaccine approaches generate limited T cell responses and uncertain long-term protection, the emergence of SARS-CoV-2 variants with a high number of mutations in the Spike protein as seen with Omicron calls for novel T cell vaccine strategies. Nykode’s vaccine candidate VB10.2210 targets select validated T cell epitopes specific to a total of eight SARS-CoV-2 proteins using our modular APC (Antigen Presenting Cells)-targeted vaccine technology platform, which has been observed to drive strong T cell responses. Our T cell based approach has the potential to generate longer, durable immunity and resistance to emerging variants.”

The T cell epitope vaccine candidate, VB10.2210, encodes a combination of conserved and immunodominant T cell epitope hotspots spanning multiple SARS-CoV-2 antigens. The vaccine candidate encodes 96 immunogenic T cell epitopes identified and validated by Adaptive Biotechnologies following analysis of more than 6,500 samples. T cells are the adaptive immune system’s first responders to detect any pathogen. They quickly multiply and circulate in the blood to find and destroy infected cells shortly after infection, often before symptoms appear, thus preventing development of disease. In addition, T cells can “remember” prior infections and can kill pathogens if they reappear. In contrast, the antibodies produced by the current COVID vaccines bind to the virus to prevent it from infecting cells. However, research shows that SARS-CoV-2 antibodies and to a lesser extent, T cells, produced by natural infection or current Spike-based vaccines decline over time and become off-target as the virus mutates. It is the expected substantial loss of neutralization from antibodies that may adversely impact the overall protection provided by available SARS-CoV-2 vaccines.

Agnete B. Fredriksen, Chief Innovation and Strategy Officer of Nykode Therapeutics, added: “Increasing evidence suggests that T cells play a key role in preventing severe and symptomatic disease in vaccine recipients and may provide protection against new and emerging virus strains. Our new T cell vaccine candidate was designed and selected in collaboration with Adaptive Biotechnologies. We believe that the combination of Adaptive’s validated T cell epitopes with our modular vaccine technology platform that drives broad CD8 T cell immune responses could result in a significantly differentiated COVID-19 vaccine and as a potential universal booster to available vaccines.”

In the VB-D-01 trial, the two vaccine candidates are being tested both in a dose escalation phase using three dose levels, and a dose expansion phase with a selected dose. Single versus two-dose administrations of each vaccine will also be explored in the dose escalation phase. This is being



conducted in Norway at the Oslo University Hospital, and the Haukeland University Hospital, Bergen. The Research Council of Norway supports this important development program.

### **Webcast**

CEO Michael Engsig and other members of management will host a webcast on January 5, 2022 at 4 p.m. CET / 10 a.m. EST to give a company update and present its SARS-CoV-2 vaccine candidates. The live and archived webcast can be accessed in the Investors section of the Company's website at <https://nykode.com/investors/financial-reports-and-presentations>.

### **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 cancer and infectious diseases. Nykode Therapeutics' 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 elicit efficacious clinical responses.

Its 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 Therapeutics has initiated a Phase 1/2 trial in 2021 with its two next-generation COVID-19 vaccine candidates.

The Company has collaborations with Roche, Genentech and Nektar Therapeutics within oncology, a multi-target collaboration with Regeneron within oncology and infectious diseases and collaborate 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.