Company Announcement

Nykode Therapeutics Announces Advances in Clinical Pipeline and Research

- *On-track to leverage promising Phase 2 cervical cancer data with FDA clearance to start a potentially registrational trial in 2023, and expansion into head and neck, two areas with high unmet need.*
- *Previously un-published data from both VB10.16 and VB10.NEO, substantiates the long-lasting immune responses which supports development opportunities in both advanced and earlier treatment settings.*
- *Partnership with Regeneron moving closer to lead selection and preliminary "breaking tolerance" data.*
- *Compelling data across different autoimmune disease models opens a commercially attractive new therapeutic vertical.*

Oslo, Norway, September 20, 2023 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, announces significant advances in its clinical pipeline and research at the Capital Markets Day in New York.

"We are excited to lay out our path to building shareholder value through a focused strategy to develop VB10.16 in advanced cancer with a significant further upside in early-stage cancer. We today present additional data from both our VB10.16 and VB10.NEO programs supporting a differentiated durable immune response," said Michael Engsig, CEO of Nykode Therapeutics.

"Further, our unique targeted vaccine technology has great potential within autoimmune disorders, which affect around every tenth person globally. We have established proof of concept in different autoimmune disease models, and this breakthrough presents a substantial additional potential commercial opportunity for Nykode."

VB10.16: Therapeutic vaccine candidate for human papilloma virus (HPV) 16+ cancers with strong clinical data

- Additional VB-C-02 data supporting a differentiated long-lasting and clinically relevant immune response.
- VB-C-04 trial design: Potentially registrational phase 2 trial in recurrent/metastatic (R/M) cervical cancer progressing on 1st line standard of care (SOC) (pembrolizumab + chemotherapy +/- bevacizumab). IND approval received from FDA and on track to be initiated Q4 2023.
- VB-C-03 trial design: Phase 1/2a trial. Combination treatment of VB10.16+pembrolizumab in 1st line HPV16+ R/M HNSCC. On track to be initiated in Q3 2023.

VB10.16 is Nykode's wholly owned candidate for treatment of HPV16-driven cancer types. Nykode is presenting additional data from the VB-C-02 trial which strongly supports the generation of durable clinically relevant T cell responses. The evidence includes the formation of multiple and enduring T cell clones post-vaccination and significant changes in blood cell composition. A robust correlation observed between HPV16 circulating tumor DNA and clinical outcomes. This correlation is discernible from the first measured post-vaccination timepoint which supports further exploration of HPV16 circulating tumour DNA as an early predictor of clinical outcome.

Nykode has received FDA approval for its potentially registrational VB-C-04 trial, which is on track to initiate in the fourth quarter of the year. The trial builds on the positive data from the VB-C-02 trial indicating differentiated and durable anti-tumor responses. The VB-C-04 trial plans to enroll 130 patients with recurrent or metastatic cervical cancer, who have previously undergone first-line standard of care treatment (comprising pembrolizumab, chemotherapy, and optionally, bevacizumab). Part A of the trial will involve a randomized allocation of 30 patients each to receive either VB10.16 in combination with Atezolizumab or VB10.16 monotherapy. After an interim analysis, the superior treatment arm will be expanded to include an additional 70 patients.

Nykode is expanding into first-line treatment for PD-L1-positive patients with head and neck cancer and has secured all the necessary regulatory approvals to initiate the VB-C-03 trial.

"Taken together, the new data combined with previously presented clinical data reinforces Nykode's confidence in the focused strategy to develop VB10.16 for advanced cancer types and furthermore points to a significant future commercial upside in earlier stages of cancer." said Klaus Edvardsen, Chief Development Officer of Nykode Therapeutics.

VB10.NEO: pioneering neoantigen research

- Vaccine-specific T cells remain functional and immunogenic up to 1-year after last vaccination.
- Multiple vaccinations boost the breadth and magnitude of functional T cell responses.

In-depth analysis of data stemming from Nykode's fully personalized neoantigen trial, VB-N-01, has yielded encouraging results. Enduring immune responses to the vaccine neoantigens have been observed, persisting for at least one year following the administration of the last dose of VB10.NEO. This evidence reaffirms the ability to generate long-lasting T cell responses. VB10.NEO is exclusively outlicensed to Genentech, a member of the Roche Group. The VB-N-01 trial was conducted by Nykode prior to the outlicensing of VB.10.NEO to Genentech.

Future cancer vaccines: De-risked through partnerships

- Regeneron partnership:
    - All five programs initiated and advancing, with multiple preclinical vaccine candidates designed for each program.
    - Nykode vaccine shows potential to induce potent T cell responses against self-antigens with various degrees of central tolerance.
    - Next step involves selecting lead candidates for further development.

Nykode's partnership with Regeneron continues to make significant progress, with the process of lead selection moving forward. In addition to the development of preclinical candidates, Regeneron has explored Nykode's vaccine platform's capacity to elicit T cell responses against germline-encoded tumor-associated antigens (self-antigens). The data demonstrates the possibility of the Nykode vaccine platform to overcome tolerance to various tumor-associated self-antigens that are characterized by low/no thymic expression, which may not be subject to central tolerance. These tumor-associated self-antigens include genes commonly overexpressed in tumor tissues and often prevalent among larger patient populations but with no expression in normal, healthy tissue. These promising findings exemplifies some of the many possibilities in Nykode's future vaccine development endeavors beyond viral and individualized neoantigens.

Advancements in Autoimmunity

- Nykode is leveraging our antigen presenting cells (APC)-targeted technology in a first-in-class approach to pursue treatments for autoimmune diseases.
- New data shows that Nykode vaccines targeting tolerogenic dendritic cells prevents serious disease in a Multiple Sclerosis (MS)-like mouse disease model.
    - Disease-preventing effect demonstrated using different APC-targeting units.
- Additionally, Nykode vaccine targeting tolerogenic DCs shows efficacy in a spontaneous type 1 diabetes mouse model.
- Nykode's 4th Module technology is found to further amplify the effect.

Our results demonstrate the technology's disease modifying potential in autoimmune disorders, as evidenced in models of both multiple sclerosis- and diabetes. This breakthrough presents a substantial additional potential commercial opportunity for Nykode, reinforcing its position as industry frontrunner.

The data showed therapeutic effects with various APC-targeting units and both protein and plasmid DNA delivery methods. Interestingly, the addition of Nykode's proprietary 4th module technology demonstrated potential to further improve the efficacy.

Nykode has made a strategic commitment to intensify its efforts and has established a dedicated autoimmunity research group to drive optimal progress in this new and promising opportunity area.

Looking Ahead

Nykode is financially well capitalized to execute the Company's strategy over the next years with a cash position of USD 174 million at the end of the second quarter.

Nykode has top-tier collaborations within oncology and infectious diseases, valued at potentially more than USD 1.6 billion plus royalties. The Company is continuously looking for value creating partnerships to realize its full commercial potential.

The Company is exploring a potential listing on the Nasdaq Global Market to gain access to a broader shareholder base.

Webcast

The archived webcast and presentation slides are available in the Investors section of the Company's website at: https://nykode.com/investors/financial-reports-and-presentations/.

The live webcast may be accessed at:
https://event.webcasts.com/starthere.jsp?ei=1633969&tp_key=dc0959d03d

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.

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.

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