



Company Announcement

Nykode Therapeutics presents additional efficacy analysis in Phase 2 study of VB10.16 in combination with atezolizumab in advanced cervical cancer

Results show strong signals of clinical responses in patients with advanced cervical cancer who received up to 2 prior lines of therapy

Oslo, Norway, November 7, 2022 – Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced results of additional efficacy analysis of the interim results from its Phase 2 trial of VB10.16 in combination with atezolizumab in advanced cervical cancer.

“This additional analysis confirms our belief in VB10.16’s competitive strength and its potential to improve outcomes in patients with advanced cervical cancer,” said Michael Engsig, Chief Executive Officer of Nykode. “Our C-02 trial enrolled heavily pre-treated patients with about one third having received three or more prior treatments. The additional analysis shows an increased response rate and competitive efficacy in patients receiving up to two prior therapies, which increases our confidence in our vaccine platform’s ability to induce clinically relevant immune responses in patients with recurrent and metastatic diseases. The data will help inform our clinical strategy as we further define the patient population for our next study of VB10.16 in advanced cervical cancer.”

Interim data from 39 patients were announced in [May 2022](#). The trial enrolled patients pre-treated with 1-5 lines of prior systemic therapy in recurrent or metastatic setting and showed a 21% Objective Response Rate (ORR) on average across all lines. This new analysis reviewed patient outcomes based on the number of previous lines of systemic therapy and number of extrapelvic metastases, showing a robust clinical benefit with partial and complete responses in 30% of patients treated with up to two prior lines of therapy. The response rate was similarly higher in patients with lower metastatic burden. A high disease control rate (DCR) was observed across all patient groups. Importantly, the T cell responses continue to show association with clinical outcomes. The data were reviewed as part of the Company’s presentation at the Credit Suisse Annual Healthcare Conference on Tuesday, November 8, 2022. The presentation can be accessed in the Investors section of the Company’s website [here](#).

Results from the analysis showed:

Clinical response by prior systemic treatment line

No. of systemic treatments	Objective Response Rate (ORR)	Disease Control Rate (DCR)
1 (n=12)	17%	75%
2 (n=15)	40%	60%
3 (n=9)	0%	55%
4 (n=1)	0%	100%
5 (n=2)	0%	50%

Clinical response based on number of extrapelvic metastases at baseline

No. of extrapelvic metastases	ORR	DCR
0 (n =4)	25%	100%
1-5 (n=22)	27%	73%
> 5 (n=13)	8%	31%

About Cervical Cancer

Cervical cancer is the fourth leading cause of cancer death in women worldwide and is most frequently diagnosed between the ages of 35 and 44. Each year around 600,000 women are diagnosed with cervical cancer worldwide. Almost all cases are caused by human papillomavirus (HPV) infection and HPV16 accounts for more than half of all cervical cancer cases. Approximately 80% of patients with cervical cancer have squamous cell carcinoma (arising from cells lining the bottom of the cervix) and most other patients have adenocarcinomas (arising from glandular cells in the upper cervix). 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.

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>.

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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.