



**Credit Suisse 31<sup>st</sup>  
Annual Healthcare  
conference**

**November 8, 2022**



# Forward-looking statement

This announcement and any materials distributed in connection with this presentation 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.

# Today's presenters from Nykode management

International management team with solid drug development experience



**MICHAEL ENGSIG**

**Chief Executive  
Officer**

Wide-ranging experience from leading early-stage drug discovery through late-stage and commercial development

- Takeda and Nycomed
- PPD
- KLIFO



**AGNETE FREDRIKSEN**

**Chief Business Officer &  
Co-founder**

More than 20 years experience with APC-targeted vaccines from drug discovery to clinical development in various leadership positions at

- Vaccibody/Nykode

# On our way to build the leading immunotherapy company

## CLINICALLY VALIDATED PLATFORM

- Proven ability to generate broad CD8 killer T cell responses correlating with clinical efficacy
- Broad clinical experience
  - 4 clinical products
  - 5 clinical trials in 8 countries
  - 12 different indications
  - >150 subjects exposed
- Well-tolerated as mono-and combination therapy

## TOP TIER COLLABORATORS

**Genentech**

A Member of the Roche Group

**REGENERON**

**Adaptive**  
biotechnologies

## BUILDING INTERNAL CAPABILITIES

- More than 150 FTEs (>80% in Research and Development)
- Office in Oslo and Copenhagen
- Discovery, bioinformatics, in vivo and GCLP immunomonitoring in house

## BROAD FUTURE POTENTIAL






- Pipeline with clinical products applicable for multiple indications within oncology plus infectious diseases and autoimmunity
- Modular technology platform that can fuel multiple products

## STRONG CASH POSITION

- Total liquidity of \$223 mill end 1H 2022
- Listed on Oslo Stock Exchange



# Pipeline

	Program	Indication	Discovery/ Preclinical	Phase 1	Phase 2	Phase 3	Partnerships
Nykode							
Oncology	VB10.16 (off-the-shelf)	HPV16+ cervical cancer <sup>1</sup>	<div></div>			<sup>1</sup> 	
		HPV16+ head and neck cancer	<div></div>				
		Internal (off-the-shelf)	Undisclosed targets	<div></div>			
Infectious Disease	VB10.CO2	SARS-CoV-2	<div></div>			<sup>2</sup> 	
	Internal	Undisclosed targets	<div></div>				
Partnered							
Oncology	VB10.NEO (individualized)	Melanoma, lung, bladder, renal, head and neck	<div></div>			<sup>3</sup>  <small>A Member of the Roche Group</small>	
	VB10.NEO (individualized)	Locally advanced and metastatic tumors	<div></div>				
		Regeneron (programs 1 – 3) (off-the-shelf)	Undisclosed	<div></div>			<sup>4</sup> 
Infectious Disease	Regeneron (programs 4 – 5)	Undisclosed	<div></div>			<sup>4</sup> 	

1. Roche supplies atezolizumab; 2. Collaboration with Adaptive Biotechnologies on SARS-CoV-2 T cell vaccine; 3. Genentech has an exclusive license to VB10.NEO; 4. Collaboration with Regeneron

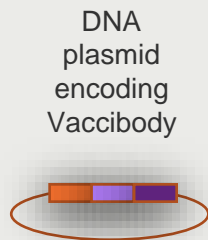
A microscopic image of several cells, likely cancer cells, showing prominent nuclei. A large, solid purple geometric shape, resembling a stylized arrow or a large 'K', is overlaid on the left side of the image. The word 'Technology' is written in white, bold, sans-serif font within this purple shape.

**Technology**

# Unique Antigen Presenting Cell (APC) targeted vaccine technology for cancer and infectious disease

## MODULAR VACCINE INCLUDES THREE DISTINCT COMPONENTS

Vaccibody vaccines can be delivered through DNA, mRNA, viral vectors or as fusion protein







- ▶ **Targeting unit** to attract and bind APCs  
Ability to change the targeting unit enables different immune response profiles that can be tailored to specific diseases\*
- ▶ **Dimerization unit** for crosslinking targeted receptors on the surface of the APC to facilitate strong binding
- ▶ **Antigenic unit** presents globular antigens and T cell epitopes expressed in cancer, viruses, bacteria, parasites and autoimmune disease

\*Targeting unit can consist of natural ligands, including cytokines/chemokines; bacterial proteins; scFv from mAb binding

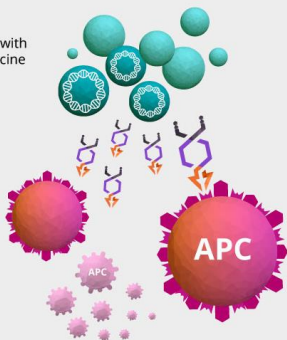
# Vaccine induces a rapid, robust and long-lasting CD8 T cell response against cancer cells

## Mechanism of Action – T Cell Induction

### Nykode's Vaccibody™ Protein

-  Antigenic unit
-  Dimerization unit facilitating the cross linking of target receptors
-  Targeting unit able to attract and bind antigen presenting cells
-  Antigen-Presenting Cell (APC) receptor

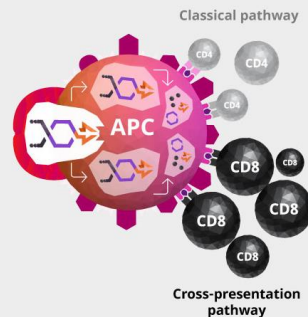
Cells transfected with  
DNA plasmid vaccine



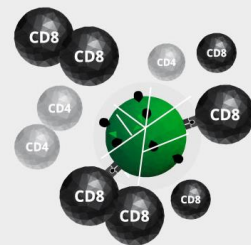
- 1 Cells encode and secrete Vaccibody proteins, which attract a high concentration of APCs.

### T Cell Induction

Nykode's vaccine, once absorbed by the APCs, induces killer T cells (CD8 cells) to attack cancer cells and pathogens. The APCs also enlist CD4 helper cells to boost the tumor-killing power of CD8 cells.



- 2 The APCs process and present the vaccine antigens to T cells and effectively activate CD8 killer T cells via cross-presentation.



- 3 The T cells attack cancer cells or pathogen-infected cells expressing the antigens.



# A clinically proven technology platform with broad future potential

## UNIQUE AND CLINICALLY RELEVANT IMMUNE RESPONSE PROFILE

- Proven ability to generate broad CD8 killer T cell responses
- Link between immune responses and clinical responses (rare and explainable by unique CD8 responses)
- Rapid, strong and long-lasting immune responses aligned with long-lasting clinical responses
- Compatible with homologous boosting

## SAFE AND WELL-TOLERATED

- Allowing several combination therapies, early lines of therapy and continuous boosting

## LOW COMPLEXITY FORMULATION AND MANUFACTURING

- Rapid adaptation and low COGS

## BROAD FUTURE POTENTIAL

- Modular technology platform that can fuel multiple first-in-class and best-in-class products with unique mechanism of actions
- Improvements in progress keeping Nykode ahead of competition
- Broad applicability with ongoing activities in oncology, infectious diseases and autoimmune disorders



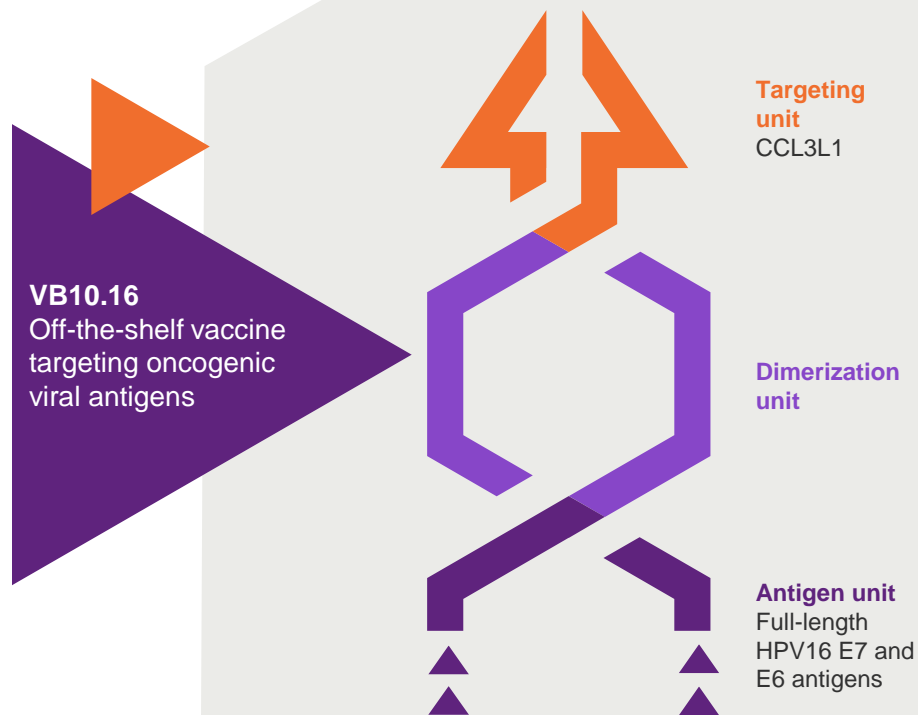
# VB10.16 Overview

Nykode's off the shelf vaccine  
targeting HPV16+ cancers

# VB10.16: Therapeutic HPV vaccine

## Off-the-shelf therapeutic cancer DNA vaccine against HPV16 induced malignancies

- ◆ Finalized VB C-01 Phase 1/2a study investigating VB10.16 monotherapy in HPV16+ precancerous cervical lesions
- ◆ Promising interim clinical data from VB C-02 Phase 2 study investigating VB10.16 in combination with atezolizumab in advanced cervical cancer
- ◆ Nykode is expanding VB10.16 into head and neck cancer
- ◆ Wholly-owned by Nykode



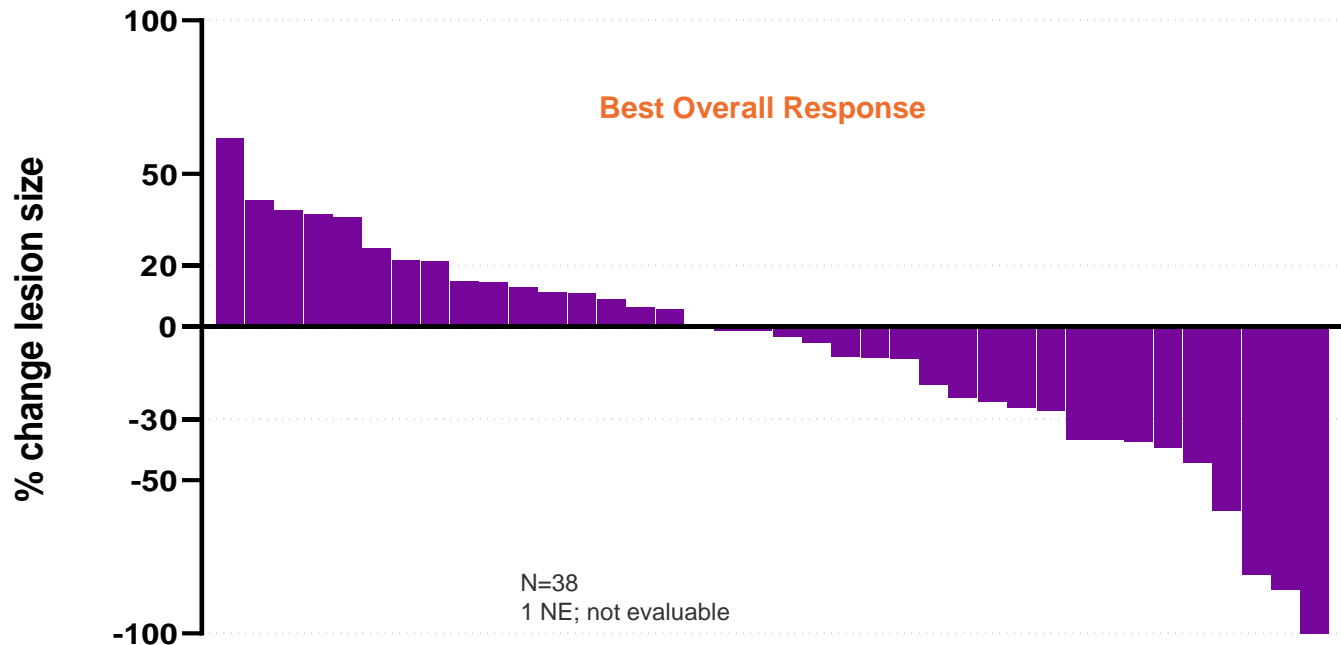
# Baseline characteristics of EAS population

*C-02 included a heavily pre-treated population with advanced cervical cancer*

Characteristic	N (%)
Age (mean)	48.9 yrs
Age (median)	47.0 yrs
Ethnicity (White)	39 (100%)
Prior systemic treatment lines	
1	12 (31%)
2	15 (39%)
3	9 (23%)
4	1 (2%)
5	2 (5%)
Prior surgery	
Y	19 (49%)
N	20 (51%)
Prior radiotherapy	
Y	31 (80%)
N	8 (20%)
Prior chemotherapy	
Y	39 (100%)
N	0 (0%)

Characteristic	N (%)
ECOG	
0	22 (56%)
1	17 (44%)
PD-L1 status at baseline	
TIC 0 (<5%)	12 (31%)
TIC 1 (5-10%)	3 (8%)
TIC 2 (>10%)	19 (49%)
Missing	5 (13%)
Histology	
Squamous cell	28 (72%)
Adenocarcinoma	8 (21%)
Missing/unknown	3 (7%)
Metastases*	
Liver	7 (18%)
Lung	17 (44%)
Other	19 (49%)
Extra-pelvic metastases present	
Yes	35 (90%)
No	4 (10%)

# Anti-tumor activity observed in majority of patients including 9 patients with SD+



**ORR = 21%**  
(8/39 patients)

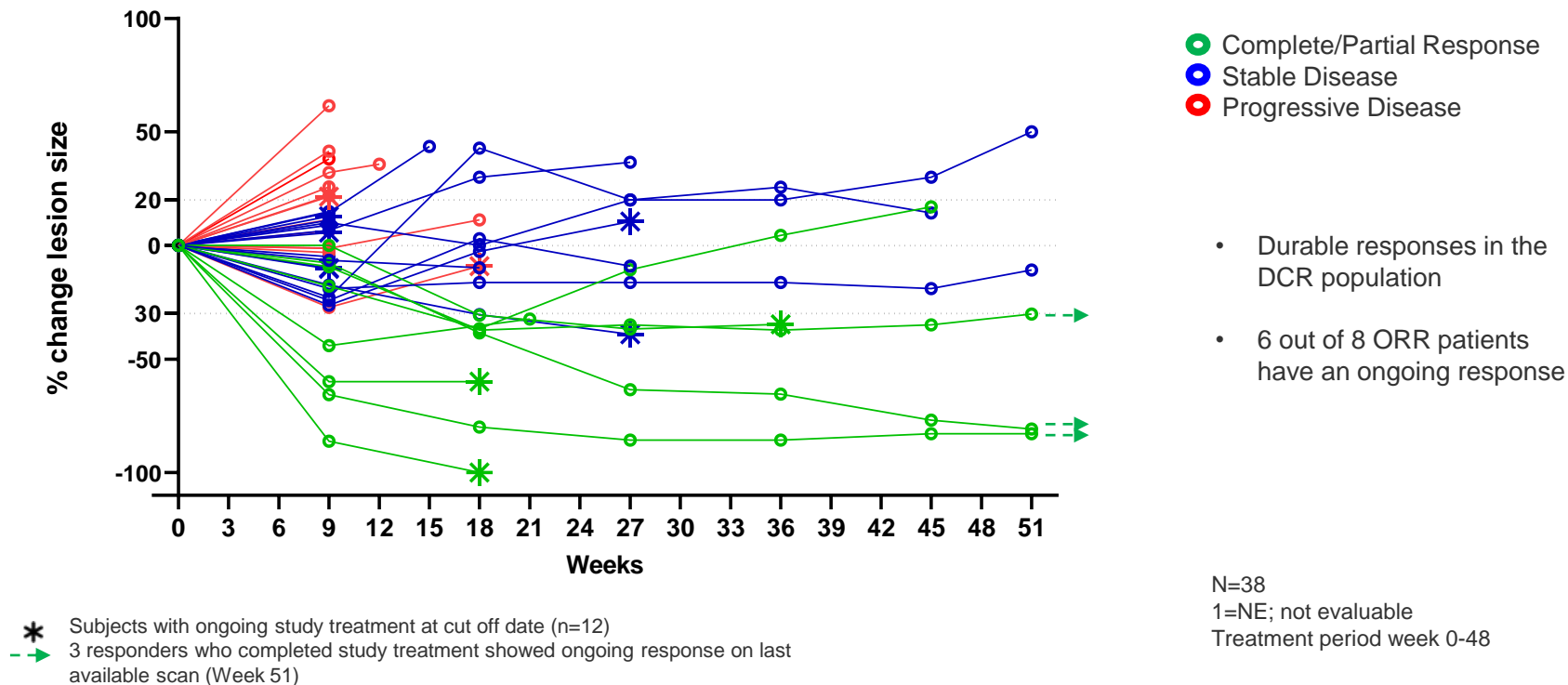
**DCR = 64%**  
(25/39 patients)

**Median follow  
up time (range) =  
6 months (3-20  
months)**

SD+ = SD with shrinkage in target lesion(s)

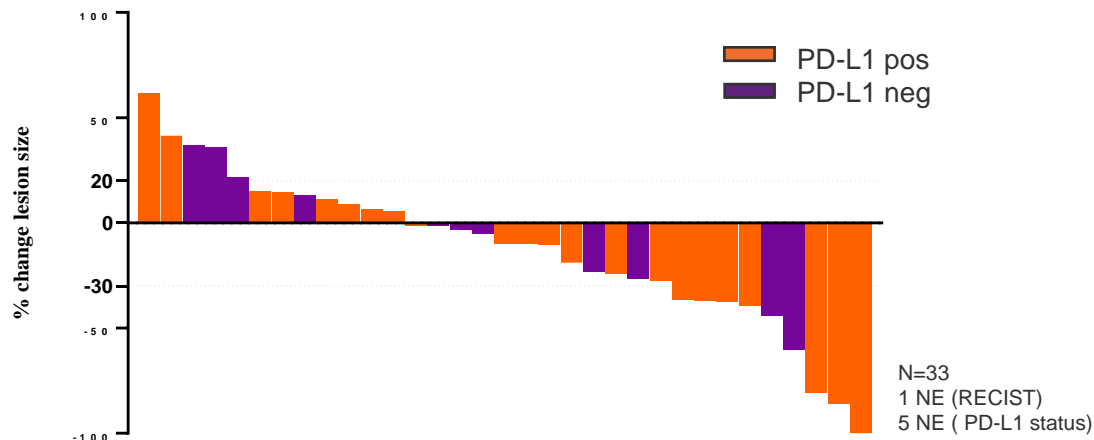


# VB10.16 in combination with atezolizumab showed promising efficacy with durable responses



# Anti-tumor activity was observed both in patients with positive and negative baseline PD-L1 status

## Tumor regression in PD-L1 +/-



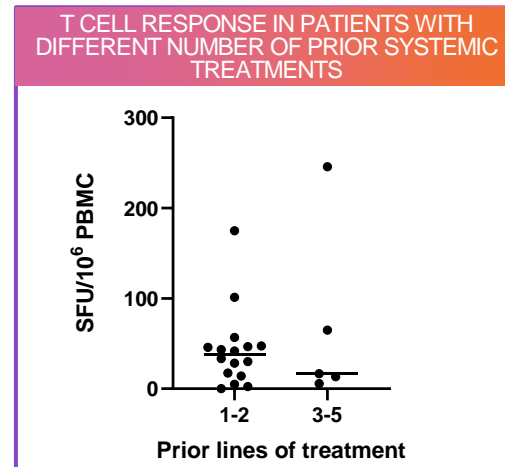
PD-L1 status	ORR (n/N)	DCR (n/N)
Positive (TIC 1-2)	27% (6/22)	77% (17/22)
Negative (TIC 0)	17% (2/12)	58% (7/12)

These findings support that VB10.16 in combination with atezolizumab may enhance clinical responses also in PD-L1 negative patients where CPI monotherapy is not approved

# Clinical response by prior systemic treatment line

High disease control in patients with up to 2 prior lines

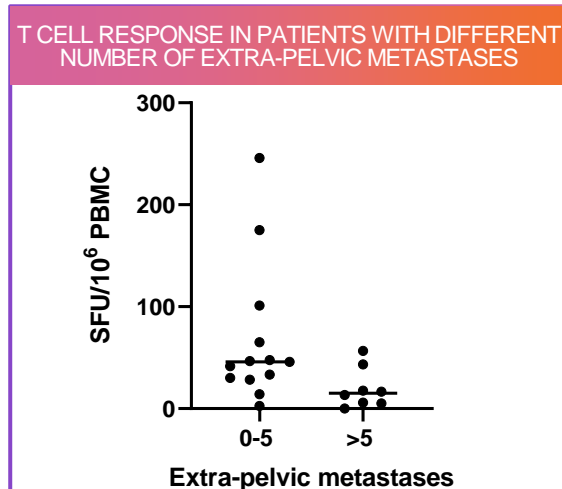
Number of prior systemic treatment lines	ORR	DCR
1 (n=12)	17%	75%
2 (n=15)	40%	60%
3 (n=9)	0%	55%
4 (n=1)	0%	100%
5 (n=2)	0%	50%



- Patients with objective responses have received up to 2 prior lines of systemic treatment
- A stable disease benefit is observed across all lines of prior systemic treatment (up to 5)
  - ORR in 1-2 lines of prior therapy is high (30%)
- HPV16-specific T cell responses were strongest in the patient group that responded best to treatment

# Clinical response by number of extrapelvic metastases at baseline

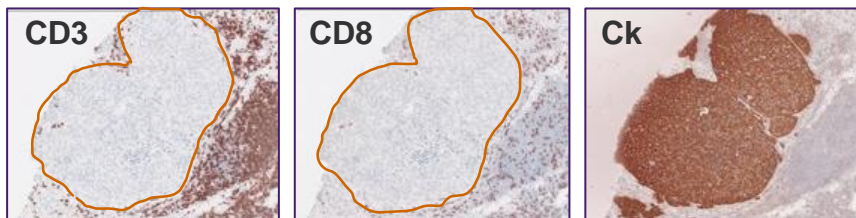
Number of extra-pelvic metastases	ORR	DCR
0 metastases (n=4)	25%	100%
1-5 metastases (n=22)	27%	73%
>5 metastases (n=13)	8%	31%



- Patients with objective responses have up to 10 extra-pelvic metastases.
- A stable disease benefit is observed also in patients with more than 10 extra-pelvic metastases
- HPV16-specific T cell responses were strongest in the patient group that responds best to treatment

# Disease control achieved in patients with non-inflamed tumors at baseline

## T cell excluded tumor



## Immune Desert



10 of 14 patients with non-inflamed tumor immune status at baseline achieved disease control on combination treatment

## DCR

DCR	
Non-inflamed tumors	10 of 14 (71%)
T cell excluded	5 (36%)
Immune desert	5 (36%)

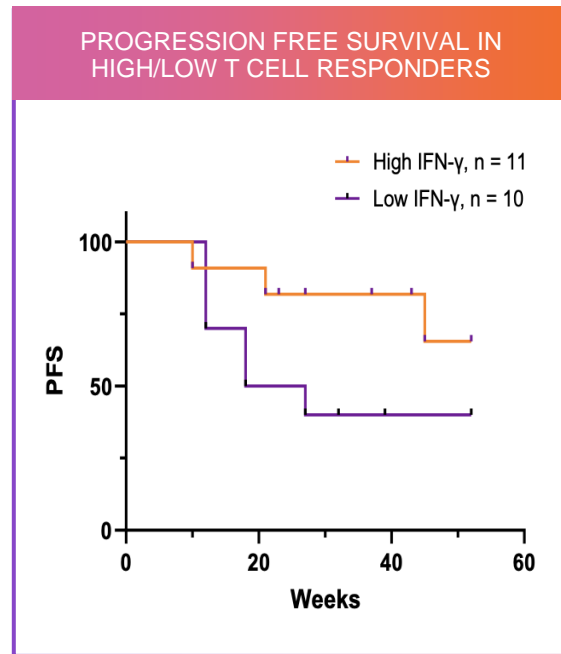
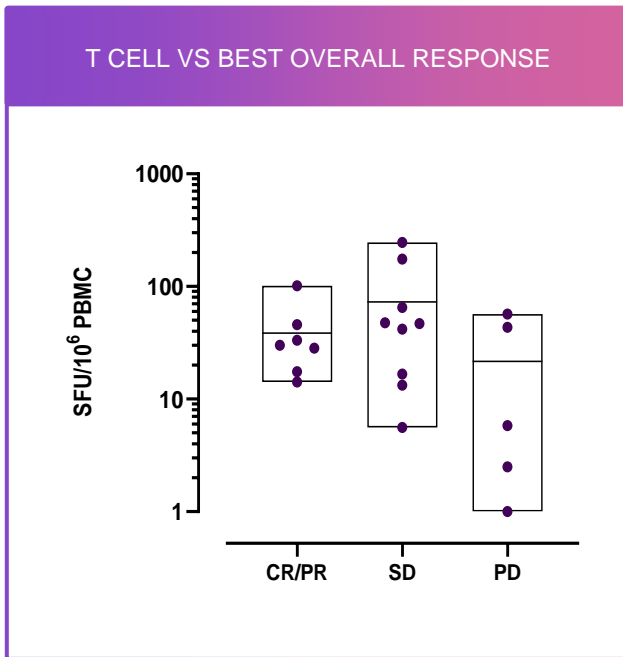
Patients with non-inflamed tumor at baseline, generally unresponsive to CPI monotherapy, show disease control on the combination treatment



# Strong HPV16-specific T cell responses were associated with clinical response in advanced cervical cancer patients

**A strong HPV16-specific IFN- $\gamma$  T cell response was associated with clinical response indicating HPV-specific T cells are important for clinical efficacy in advanced cervical cancer**

Supported by data presented from VB C-01 clinical trial where a strong significant correlation was demonstrated between HPV16-specific T cell responses and clinical responses in a pre-cancerous setting



- IFN- $\gamma$  T cell responses were evaluated in 21 subjects
- T cell responses were evaluated in *ex vivo* ELISpot detecting HPV16 E6 and E7 antigens separately

# Safety and tolerability

*VB10.16 was generally well-tolerated and has a favorable safety profile*

## TRAEs considered related to VB10.16

System Organ Class Preferred Term	Any Grade N=50 (%)	Grade 3 N=50 (%)	Grade 4-5 N=50 (%)
<b>All TRAEs related to VB10.16</b>	15 (30)	1 (2)	-
<b>General disorders and adm. site conditions.</b>	8 (16)	-	-
Administration site pain	2 (4)	-	-
Fatigue	1 (2)	-	-
Injection site bruising	2 (4)	-	-
Injection site discomfort	2 (4)	-	-
Injection site haematoma	1 (2)	-	-
Injection site pain	1 (2)	-	-
<b>Injury, poisoning and procedural complications</b>	1 (2)	-	-
Infusion related reaction	1 (2)	-	-
<b>Metabolism and nutrition disorders</b>	1 (2)	-	-
Decreased appetite	1 (2)	-	-
<b>Musculoskeletal and connective tissue disorders</b>	3 (6)	1 (2)	-
Arthralgia	1 (2)	1 (2)	-
Myalgia	1 (2)	-	-
Pain in extremity	1 (2)	-	-
<b>Skin and subcutaneous tissue disorders</b>	4 (8)	-	-
Erythema	1 (2)	-	-
Pruritus	2 (4)	-	-
Rash	2 (4)	-	-

VB10.16 in combination with atezolizumab was generally well-tolerated

- TRAEs of any grade related to either VB10.16 or atezolizumab was seen in 64% of patients.
- 5 patients (10%) experienced seven TRAEs of grade 3.
  - 1 patient (2%) experienced a TRAE of grade 3 related to VB10.16.
- No TRAEs of grade 4-5 were reported
- No deaths related to either VB10.16 or atezolizumab.

50 patients were included in the safety population for the interim analysis. Median number of VB10.16 doses given was 5 (range 1-11).

AE=adverse event; TRAE=treatment-related adverse event

A microscopic image of a cell, possibly a cancer cell, with a prominent nucleus and complex internal structure. The image is overlaid with a large, solid purple geometric shape on the left side, which serves as a background for the text.

# VB10.NEO Overview

Nykode's individualized  
cancer vaccine

# VB10.NEO: Nykode's individualized cancer vaccine

Targeting antigen presenting cell

Proprietary neoantigen selection method

- ♦ Majority of selected neoepitopes are immunogenic
- ♦ Frequency of high-quality neoepitopes in vaccine and immune responses correlate with responses

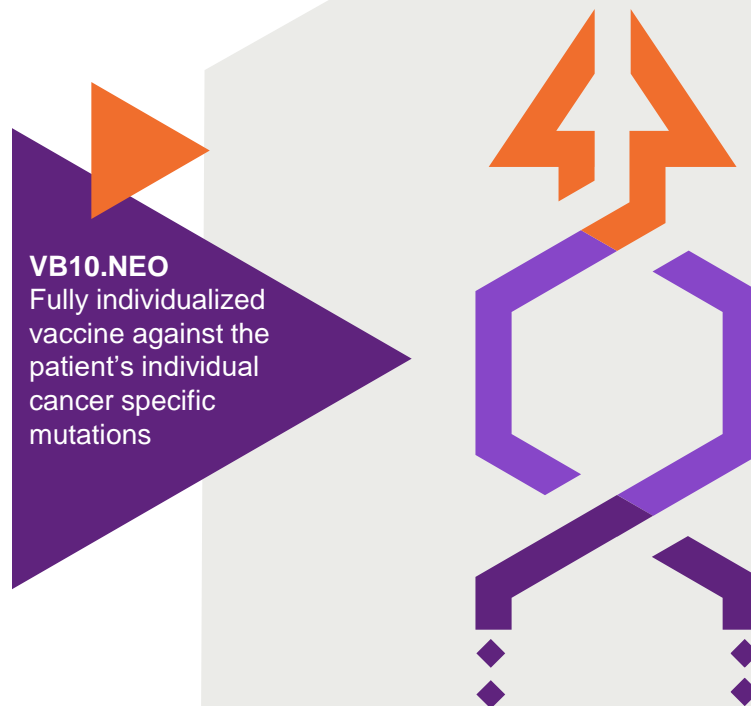
Promising immunogenicity and clinical data

- ♦ Phase I/IIa in >50 patients with melanoma, NSCLC, SCCHN, RCC and urothelial cancer

Delivered as DNA plasmid

- ♦ Flexible, rapid and cost-effective manufacturing.  
100% manufacturing success rate

Exclusively out-licensed to Roche and Genentech, 2020



# VB N-01 – Population and baseline characteristics

*VB N-01 included a population with various pre-treated and advanced cancer types*

Population*	N
VB10.NEO dosed patients (safety population)	41
Completed VB10.NEO treatment	17
Discontinued VB10.NEO treatment	24
Due to Adverse reaction	1
Ongoing VB10.NEO treatment	0

\*Cut off date is 20 May 2022

Median number of vaccines given is 11 (range 1-15)

Median duration in the trial is 54 weeks (range 1-155 weeks)

Characteristic	N (%)
Mean Age (range) Median Age	62.6 yrs (33-81 ys) 62.0 yrs
Ethnicity  White	41 (100%)
Gender  Female Male	16 (39%) 25 (61%)
ECOG  0 1	24 (58.5%) 17 (41.5%)
PD-L1 status at baseline Positive Negative Missing/unknown	7 (21%) 0 (0%) 27 (79%)
Cancer type Head and neck cancer Non-small cell lung cancer Renal cell carcinoma Melanoma Urothelial carcinoma	14 5 10 8 4
Metastatic disease  Y N	37 (90%) 4 (10%)

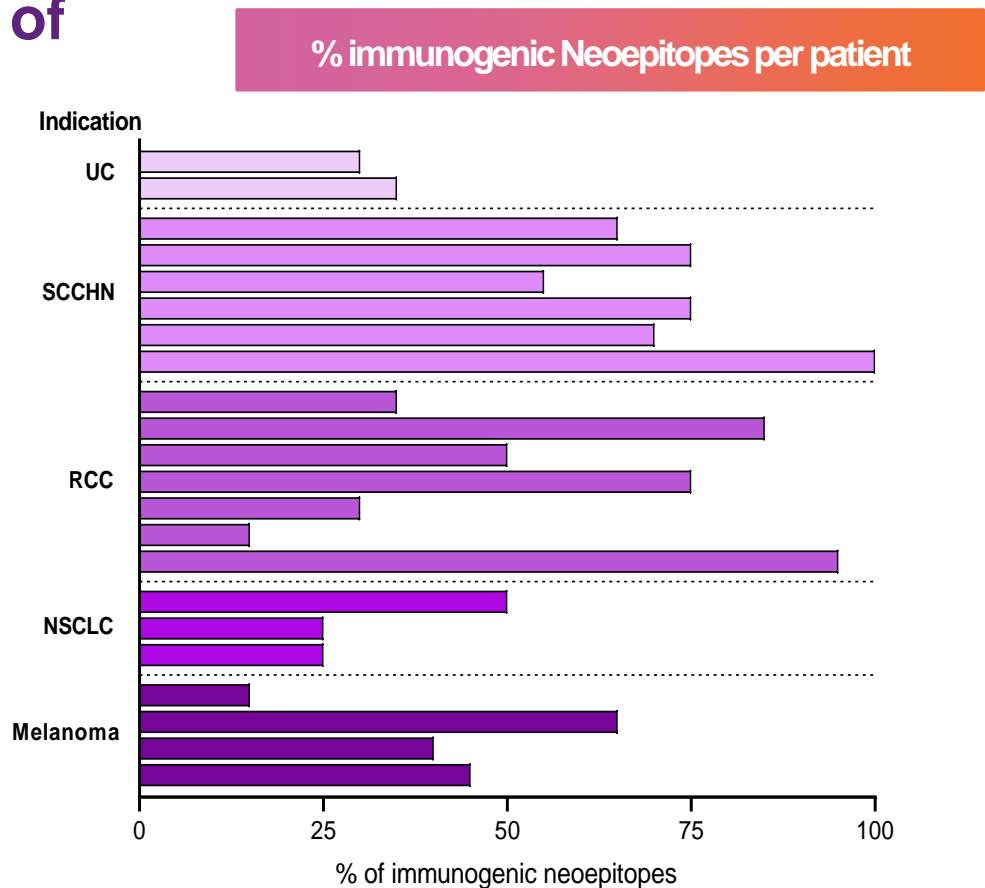
Characteristic	N (%)
Prior systemic treatment lines 1 2 3 4	10 (24%) 20 (49%) 7 (17%) 4 (10%)
Prior surgery  Y N	29 (70%) 12 (30%)
Prior radiotherapy  Prior During trial	23 (56%) 10 (24%)
Chemotherapy  Prior Concomitant	22 (54%) 8 (19.5%)
Other immunotherapy (non-CPI)  Prior Concomitant	3 (7.3%) 0 (0%)
CPI therapy  Prior Concomitant	41 (100%) 33 (80.4%)
Targeted therapy  Prior Concomitant	19 (46%) 10 (24%)



# T-cell responses to majority of selected neopeptides

100% of patients across five indications showed a response to at least one neopeptide

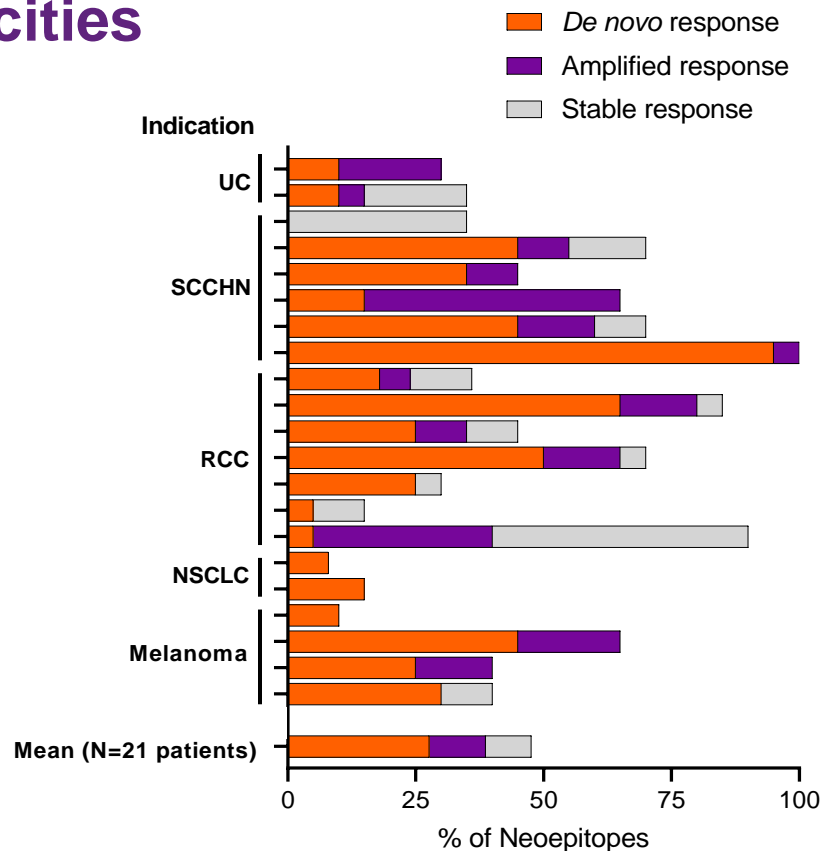
On average, 53% of selected neopeptides were immunogenic, ranging from 3 to all 20 neopeptides in the VB10.NEO vaccine demonstrating a broad response



# VB10.NEO amplify pre-existing T-cell responses and induce novel T-cell specificities

Expansion of both pre-existing and novel T-cell responses in most patients

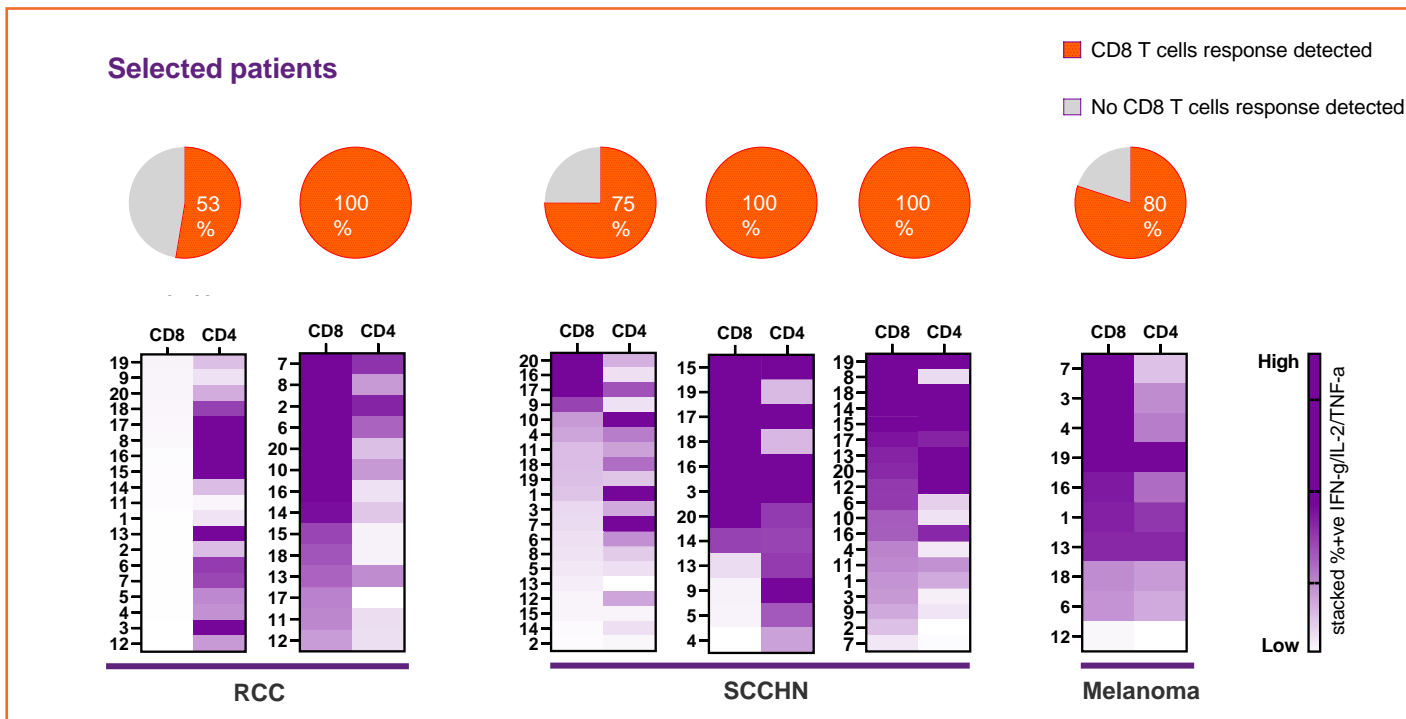
- 20/21 (95%) *de novo* expanded
- 14/21 amplification of pre-existing



# Preliminary immune phenotyping shows that the majority of neopeptides activates CD8 T cells

T cell responses are characterized by both CD8 and CD4 T cells

The majority of tested neopeptides activated functional CD8 T cells in all subjects analyzed

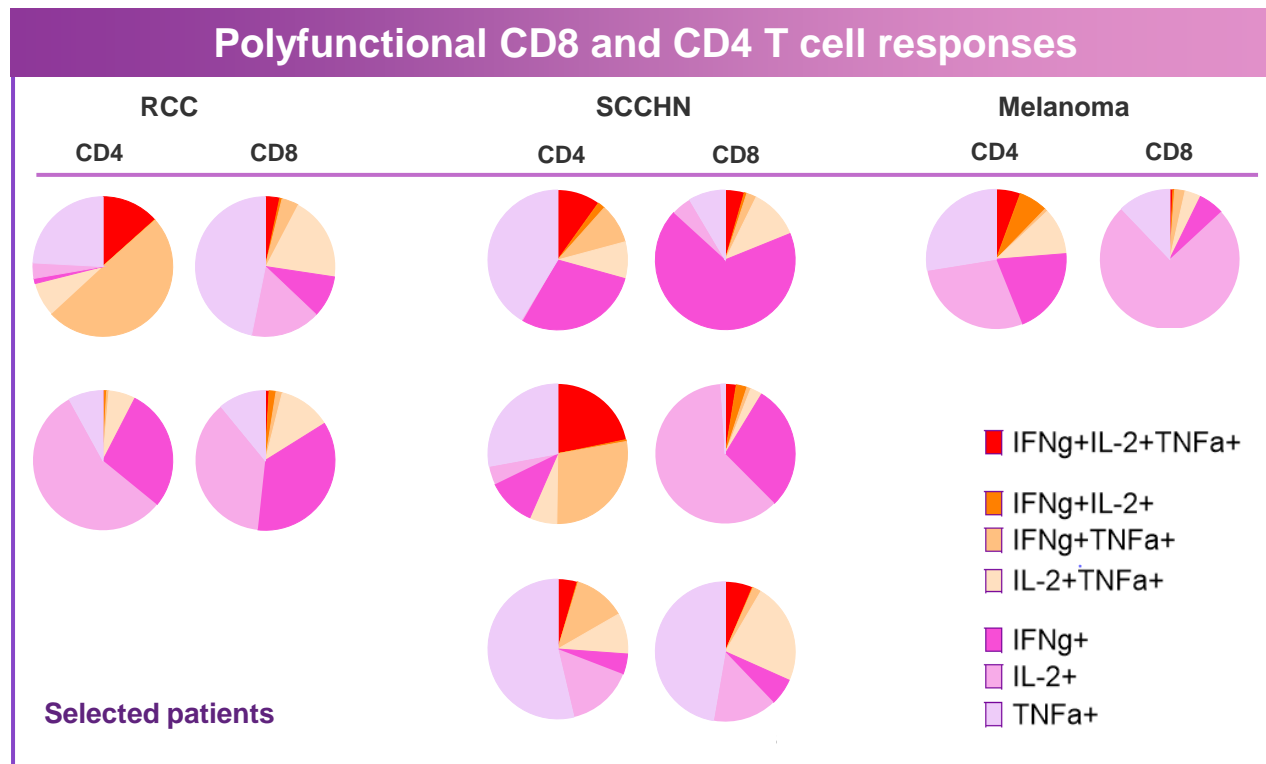


CD8 response defined as  $\geq 0.2\%$  above DMSO background.

Phenotyping was performed by IVS ICS using PBMC from week 22 for 6 subjects. Number indicate neopeptide in VB10.NEO

# Neoepitope-reactive CD8 and CD4 T cells are polyfunctional

The majority of the neoepitopes induced a polyfunctional T cell response characterized by a Th1/Tc1 cytokine profile





# Financial overview




# Strong financial foundation for achieving our vision



- ◆ Financially well positioned to grow and execute the Company's strategy over the next years
- ◆ Strong balance sheet with total liquidity<sup>1)</sup> of \$223 mill on June 30, 2022
- ◆ Successful listing on main list of Oslo Stock Exchange
  - ◆ First day of trading June 16, 2022
  - ◆ To facilitate greater liquidity in the shares and attract new potential shareholders in order to build a more diversified shareholder base

1) Includes cash and cash equivalents of \$213 mill and money market funds of \$10 mill

# Upcoming Catalysts

	Key Priorities	Program	Indication	Partnerships	Milestones
Wholly-Owned Candidates					
Oncology	<ul style="list-style-type: none"> <li>Advance internal oncology programs including cervical cancer program</li> <li>Expand into additional indications for VB10.16, including head and neck cancer</li> </ul>	VB10.16 (off-the-shelf)	HPV16+ cervical cancer		<ul style="list-style-type: none"> <li>✓ Provided updated biomarker data</li> <li>• Present updated Phase 2 data (1H 2023)</li> <li>• Provide updated development strategy</li> <li>• Initiate Phase Ib trial in HNSCC</li> </ul>
		Internal programs	Undisclosed		
Infectious Disease	<ul style="list-style-type: none"> <li>Advance COVID-19 vaccines</li> <li>Expand into additional high-priority disease areas</li> </ul>	VB10.COVID	SARS-CoV-2		<ul style="list-style-type: none"> <li>✓ Presented Phase 1 key results measuring immune responses in previously vaccinated subjects (2H 2022)</li> </ul>
		Internal programs	Undisclosed		
Technology	<ul style="list-style-type: none"> <li>Leverage technology platform</li> </ul>				<ul style="list-style-type: none"> <li>• Announce further preclinical data from Ag-specific immune tolerance platform</li> </ul>
Manufacturing	<ul style="list-style-type: none"> <li>Enhance control of manufacturing capacity and capability</li> </ul>				<ul style="list-style-type: none"> <li>• Provide update on manufacturing strategy</li> </ul>

# UNLOCKING THE FUTURE OF MEDICINE

Contact:  
**Agnete Fredriksen**  
**CBO**  
[IR@nykode.com](mailto:IR@nykode.com)