



## Q4 Presentation

February 28, 2023

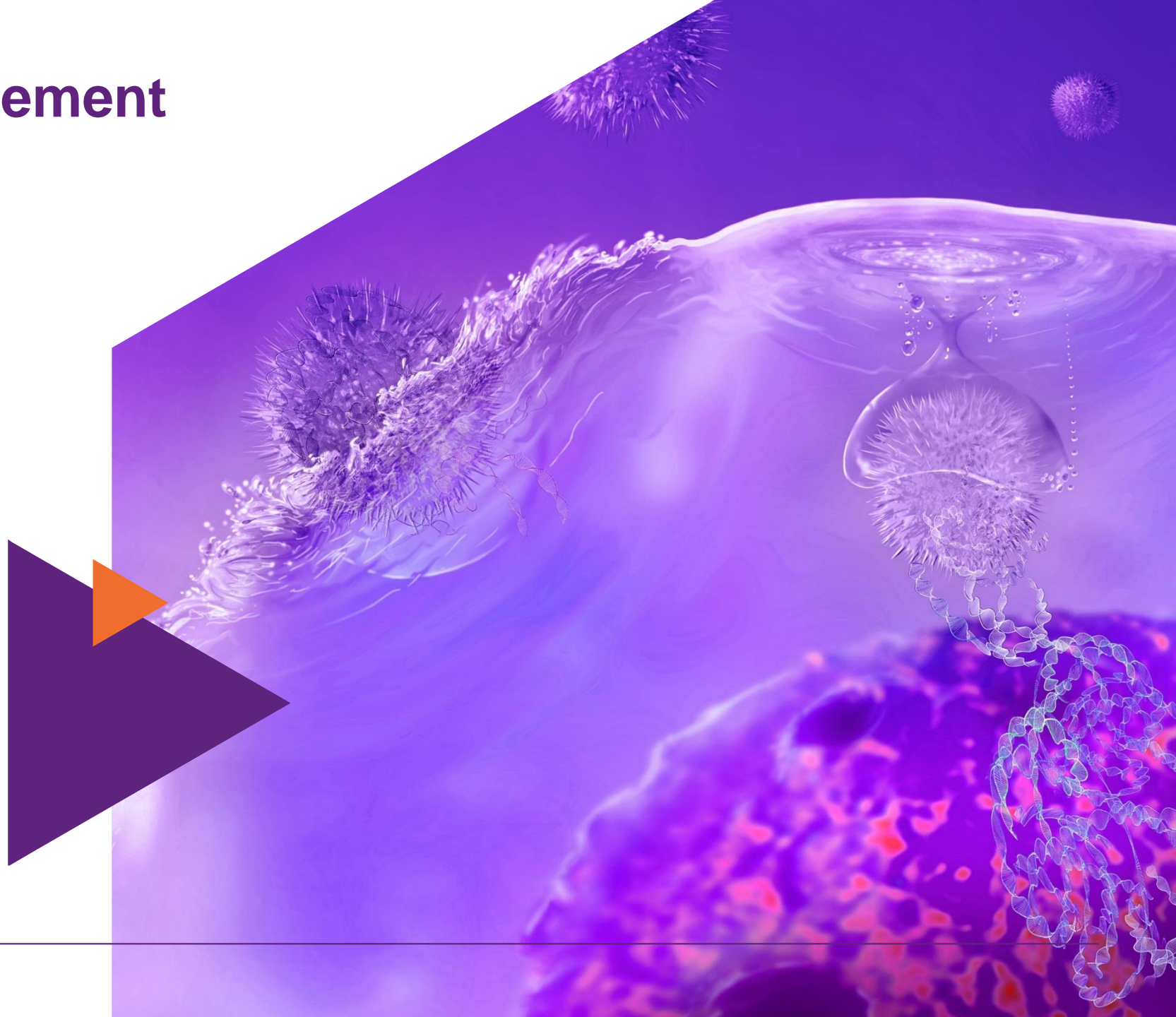




# Forward-looking statement

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



**AGNETE FREDRIKSEN**

Chief Business Officer &  
Co-founder



**HARALD GURVIN**

Chief Financial  
Officer



# Global leader in APC-targeted immunotherapy technology



## NYKODE THERAPEUTICS (NYKD-OL, MKT CAP ~\$800M)



Proprietary immunotherapies targeting antigens to Antigen-Presenting Cell (APC) and generating strong CD8 killer T cell responses correlated with clinical responses in solid tumors



Modular, versatile platform

- ◆ Easily incorporate new antigens and adapt to new diseases across oncology, infectious diseases and autoimmunity



Rapidly advancing wholly owned lead asset, VB10.16, immunotherapy for HPV16+ cancers

- ◆ Reporting final data from C-02 with focus on durability in 1H 2023
- ◆ Potentially registrational study in advanced cervical cancer to initiate 2023
- ◆ Dose escalation study with KEYTRUDA<sup>®1</sup> in head and neck cancer to initiate 1H2023



Strategic partnerships to advance clinical programs and commercialize assets worldwide<sup>2</sup>

**Genentech**  
A Member of the Roche Group

**REGENERON**

**Adaptive**  
biotechnologies



Well-capitalized with a cash position of \$206m at December 31, 2022

1. Note: KEYTRUDA<sup>®</sup> is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

2. Note: Genentech has an exclusive license to VB10.NEO. Collaboration and license to 5 programs with Regeneron. Collaboration and license with Adaptive Biotechnologies on SARS-CoV-2 T cell vaccine. Roche supplies atezolizumab; . Merck (MSD) supplies pembrolizumab

# 4Q highlights

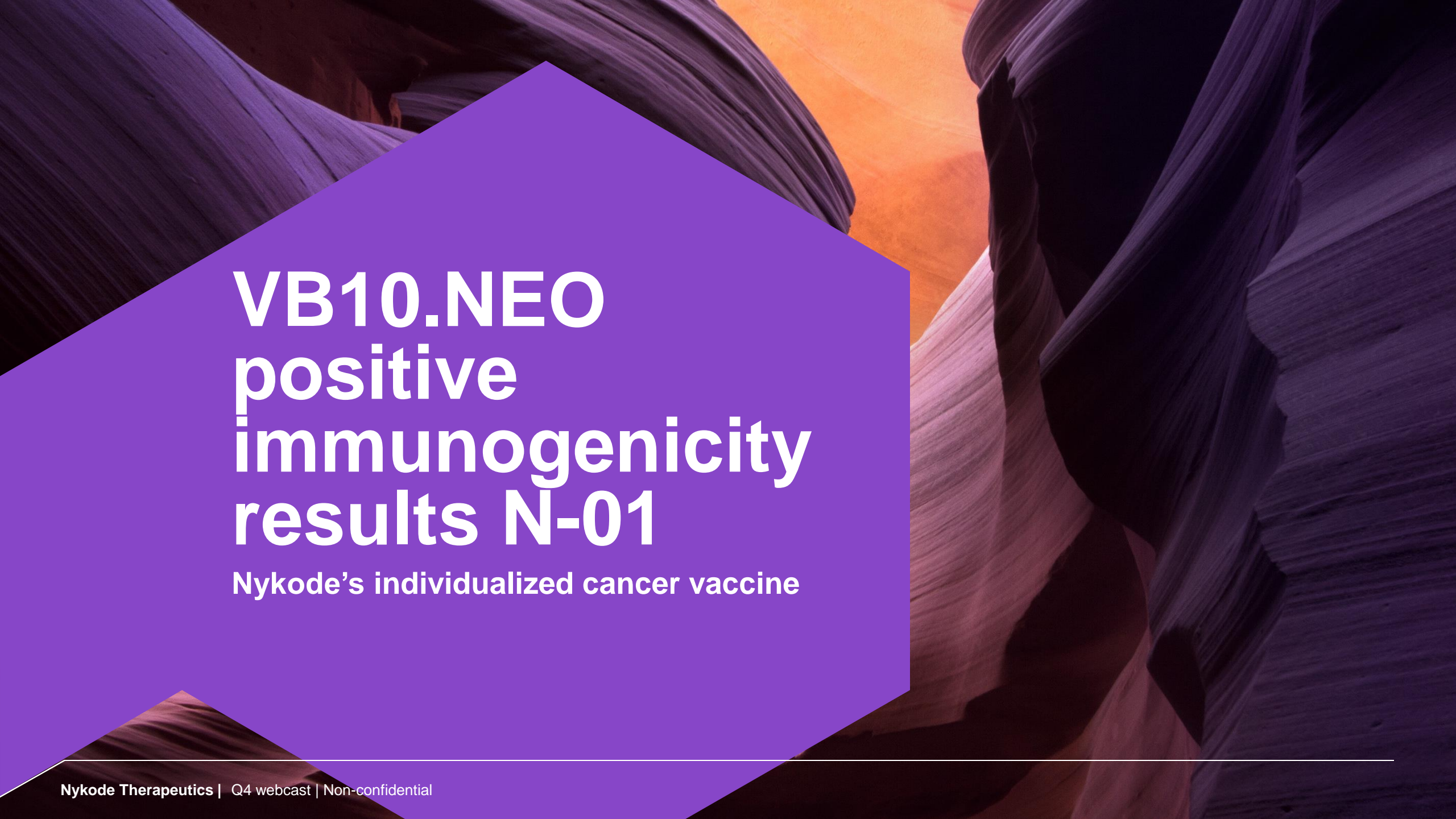
## Clinical programs

- Announced positive immunogenicity results from a Phase 1/2a trial of VB10.NEO in multiple indications
- Presented additional efficacy analysis from a Phase 2 trial of VB10.16 in advanced cervical cancer
- Announced clinical collaboration and drug supply of KEYTRUDA® with MSD for the VB C-03 trial
- Entered into strategic manufacturing partnership with Richter-Helm BioLogics
- Announced expanded clinical development plan for VB10.16 in HPV16-positive cancers, including a potentially registrational trial in advanced cervical cancer (VB C-04).

### Post Q4:

- Announced collaboration with gynecologic study group GOG Foundation to conduct the VB C-04 trial in advanced cervical cancer.





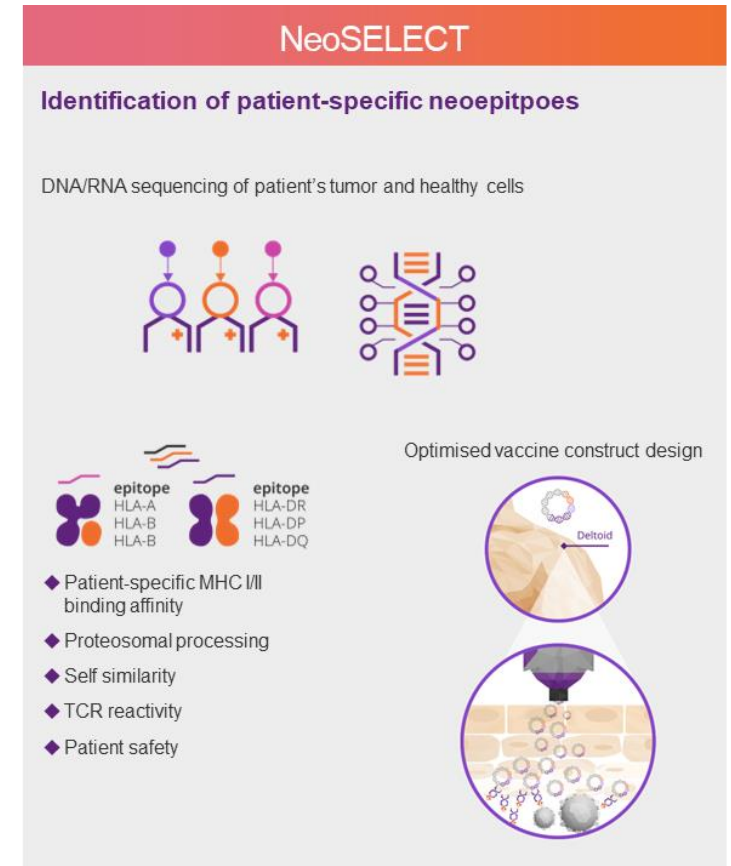
# **VB10.NEO positive immunogenicity results N-01**

**Nykode's individualized cancer vaccine**

# Nykode is a key player in the field of individualized cancer vaccines

**Individualized neoantigen-specific vaccines custom-design and manufacture one vaccine per patient based on each patient's cancer-specific mutations**

- Recent positive data announced by Moderna and Merck for their individualized neoantigen-specific cancer vaccine in adjuvant setting
  - Generated new enthusiasm for the promise of cancer vaccines in early stage disease
- Nykode was one of the first companies in the clinic with an individualized cancer vaccine (VB N-01 trial, FPFD 2018)
- Nykode has presented positive data in multiple indications in CPI-experienced advanced, metastatic setting
  - Recently presented updated positive immunogenicity data confirming a broad and strong CD8 skewed immune response
  - 100% manufacturing success rate
  - Safe and well tolerated



# VB10.NEO: Individualized neoantigen immunotherapy for the treatment of broad range of solid tumor indications

ONGOING. REPORTED POSITIVE INTERIM DATA.

N-01

- ◆ VB10.NEO in combination with CPI
- ◆ Melanoma, lung, bladder, renal, head and neck
- ◆ Recruitment finalized
- ◆ Positive interim data: broad and long-lasting polyfunctional CD8 T cell responses in advanced cancer patients on prior CPI

ONGOING IN >10 INDICATIONS, COLLABORATION WITH GENENTECH

N-02

- ◆ Dose escalation 3-9 mg VB10.NEO in combination with atezolizumab (Tecentriq®)
- ◆ >10 indications
- ◆ Initiated 2021. Planned enrollment up to 40 patients

Exclusively out-licensed to Roche and Genentech, 2020



# VB10.NEO: leading technology applicable for individualized cancer neoantigen immunotherapy

## Strong in-house bioinformatic competences and proprietary neoantigen selection method

- ◆ Trained on Nykode's data and unique broad CD8 dominated immune response
- ◆ Focus on clonal and clinically relevant epitopes
- ◆ High quality immunogenic neoepitopes shown to correlate with clinical responses
- ◆ Data in advanced cancer patients (1-4 prior lines of systemic treatment) and CPI-experienced

## Optimal manufacturing for individualized

- ◆ DNA plasmid manufacturing is an intermediate in mRNA and viral vector productions and thus will be more rapid, cost-effective and robust
- ◆ 100% manufacturing success rate to date

## Safe and well tolerated platform

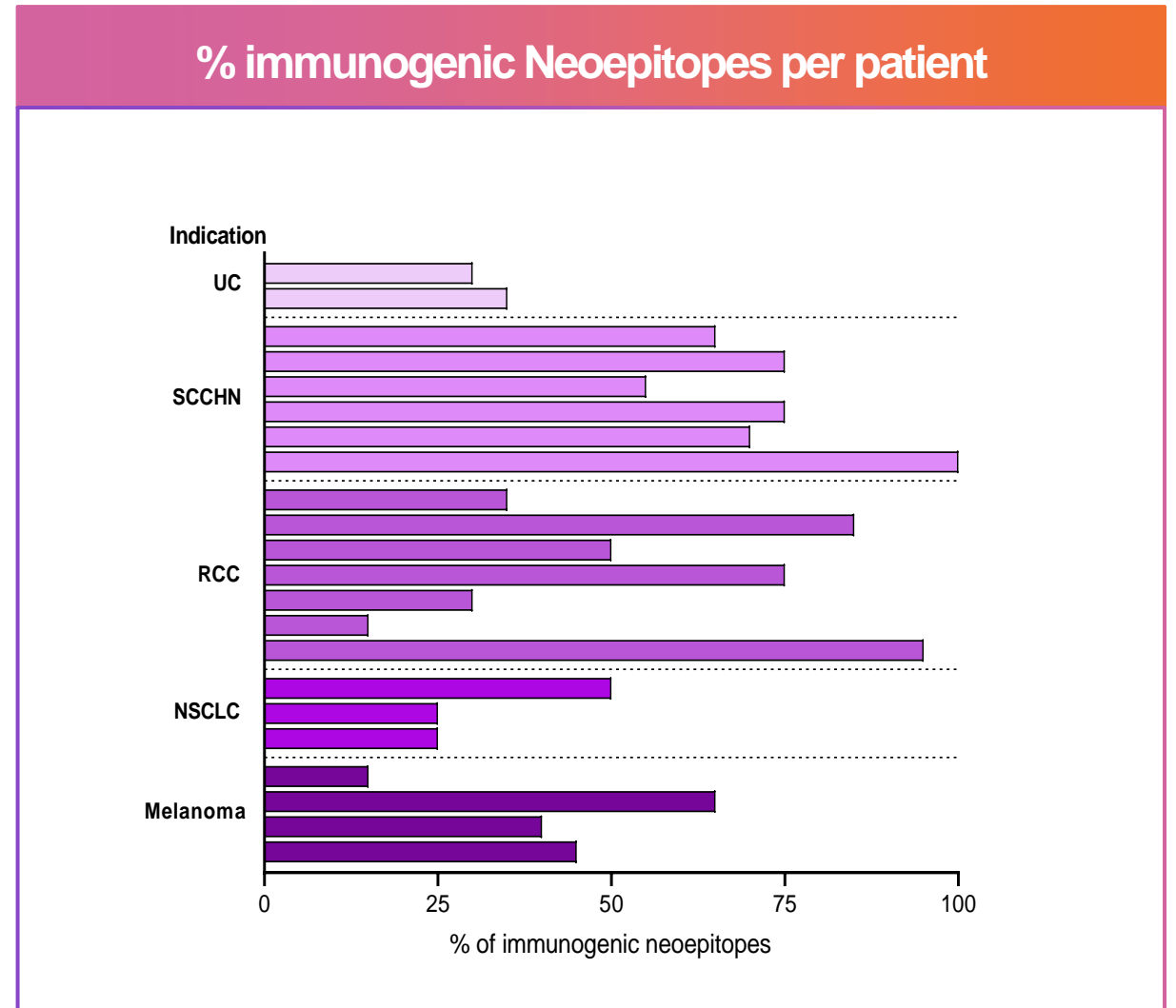
### VB10.NEO

Fully individualized immunotherapy against the patient's individual cancer specific mutations

# T-cell responses to the majority of selected neopeptopes

100% of patients across five indications showed a response to at least three neopeptopes (at least one time point)

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

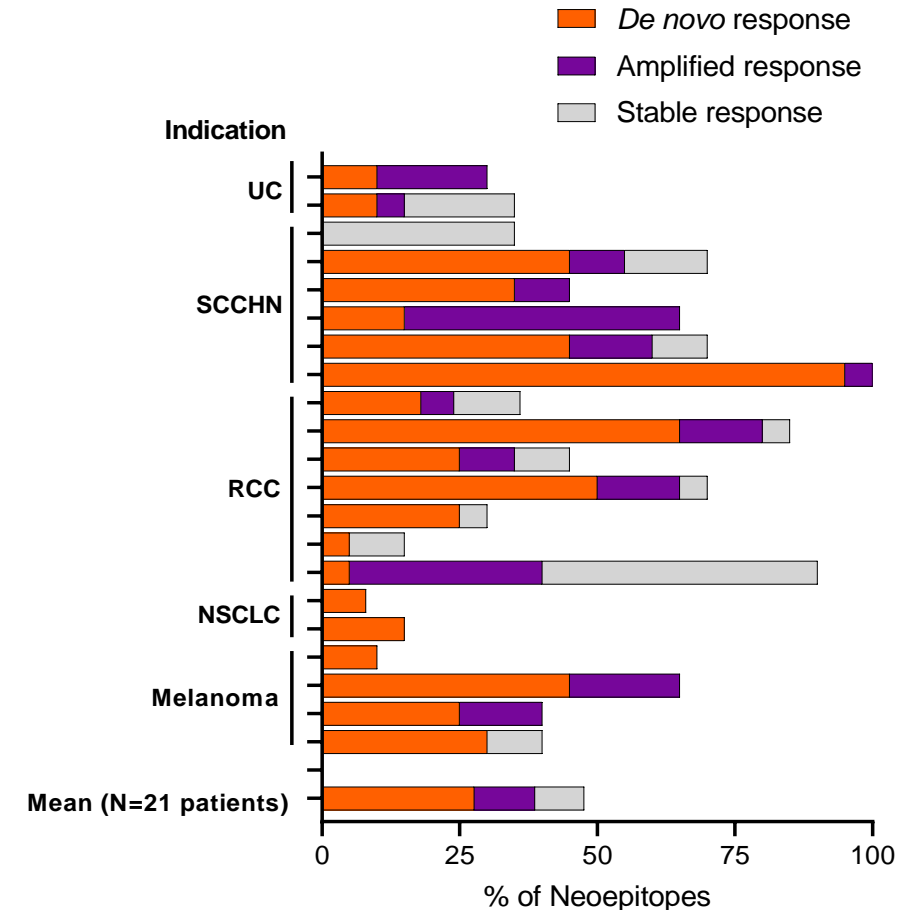


# VB10.NEO amplifies pre-existing T-cell responses and induces multiple novel T-cell specificities

Expansion of both pre-existing and novel T-cell responses in most patients (at least one time point post vaccination)

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

## Expansion of pre-existing and induction of novel T cells

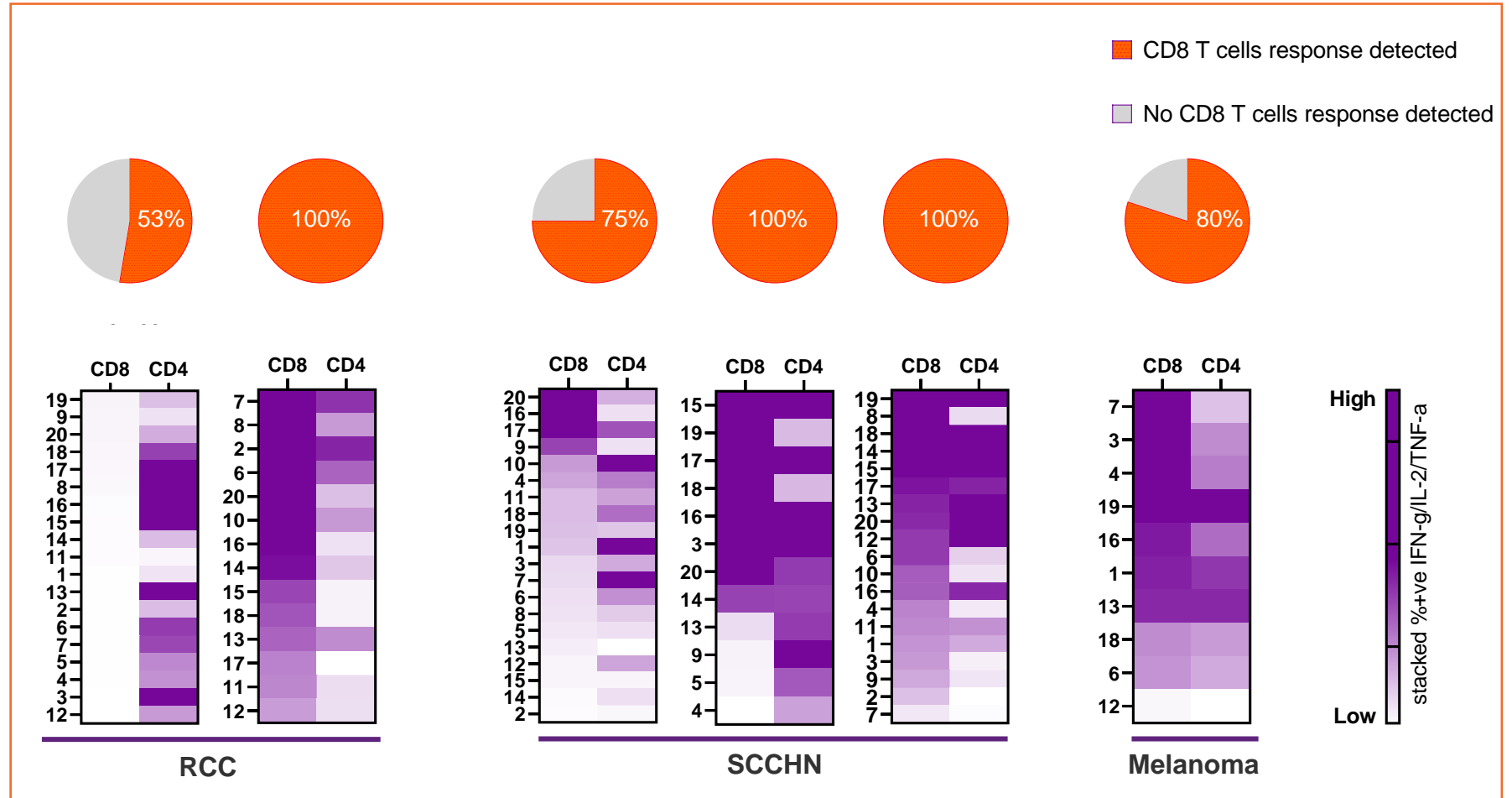




# Preliminary immune phenotyping shows that the majority of neoepitopes activate CD8 T cells

T cell responses are characterized by both CD8 and CD4 T cells (at week 22)

The majority of tested neoepitopes activated functional and strong CD8 T cell responses 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 neoepitope in VB10.NEO



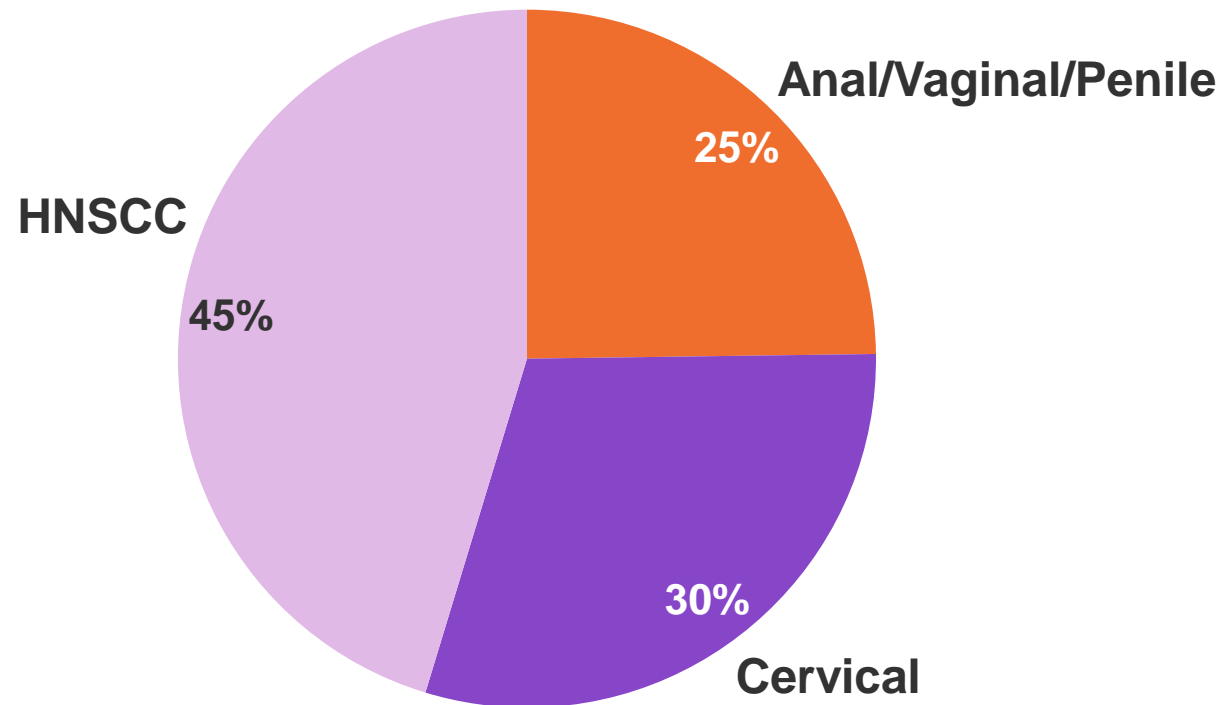
# **VB10.16** **rapidly advancing** **wholly owned asset**

**Nykode's off the shelf vaccine  
targeting HPV16+ cancers**

# HPV16+ cancers represent significant unmet need

Prophylactic HPV vaccination program coverages suggest a continued need

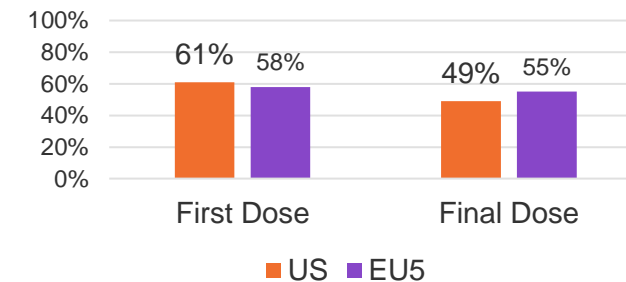
Approximately 58,500 new HPV16+ cancer cases per year in the U.S. and EU5<sup>1</sup>



HPV vaccination program is not expected to impact the rate of HPV related cancer incidence for the next decades<sup>3</sup>

- The HPV vaccination program has seen low coverage and completion of ~ 50% in US and EU5
- It takes 15-20 years for the HPV infection to develop into cervical cancer

**2019 HPV Vaccination Program Coverages Estimates for Females, %<sup>2</sup>**



Source:1 Goldman Sachs analyst report; Datamonitor; GlobalData; Secondary- and internal analysis.

2:American Cancer Society; <https://www.sciencedirect.com/science/article/pii/S0091743520304308>; [https://www.who.int/data/gho/data/indicators/indicator-details/GHO/coverage-of-national-cervical-cancer-screening-program\(-\)](https://www.who.int/data/gho/data/indicators/indicator-details/GHO/coverage-of-national-cervical-cancer-screening-program(-)); <https://hpvcentre.net/statistics/reports/>; KOLs

3: Projected Association of Human Papillomavirus Vaccination with Oropharynx Cancer in the US 2020-2045, JAMA Oncology, September 2021; [Cervical cancer \(who.int\)](https://www.who.int/cancer/cervical)



# VB10.16: HPV16-targeted immunotherapy with broad potential across HPV-driven cancers

## FINALIZED. REPORTED POSITIVE DATA

## ONGOING. REPORTED POSITIVE INTERIM DATA

## EXPANSION PLANNED FOR 2023

## FURTHER POTENTIAL

### C-01 Pre-cancerous Cervical Lesions

- ◆ Monotherapy of VB10.16, 3 mg
- ◆ CIN2/3 (HSIL) patients
- ◆ Well tolerated and strong antigen specific immune responses correlating with clinical efficacy

### C-02 Cervical Cancer

- ◆ VB10.16, 3 mg in combination with atezolizumab (Tecentriq®)
- ◆ Advanced cervical cancer
- ◆ Positive interim analysis, Q2 2022
- ◆ Updated results expected 1H2023

### C-03 Head and Neck Cancer

- ◆ VB10.16, 9 mg in combination with pembrolizumab (Keytruda®)
- ◆ Unresectable recurrent or metastatic head and neck cancer (HNSCC)
- ◆ CTA submitted Q4, 2022
- ◆ First patient dosed, expected 1H2023

### C-04 Cervical Cancer

- ◆ VB10.16 in combination with check point inhibitor
- ◆ Potentially **registrational trial** in the U.S.
- ◆ Collaboration with GOG
- ◆ Recurrent/ metastatic cervical cancer and PD-L1 positive tumors
- ◆ First patient dosed, expected 4Q 2023

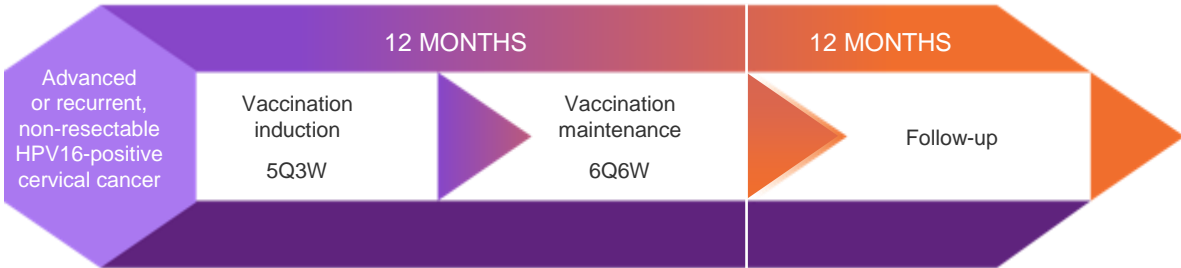
### Other HPV+ driven cancers

- ◆ VB10.16 in combination with checkpoint inhibitor
- ◆ Investigator-sponsored basket trial
- ◆ Additional HPV16+ cancers and PD-L1 negative tumors

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

## Study design

- ◆ Fully enrolled with 52 patients
- ◆ Conducted in Europe in 6 countries
- ◆ Enrolled patients received treatment with 3 mg VB10.16 in combination with 1200 mg TECENTRIQ® for up to 48 weeks



52 patients received 3 mg VB10.16 with 1200 mg TECENTRIQ® for up to 48 weeks

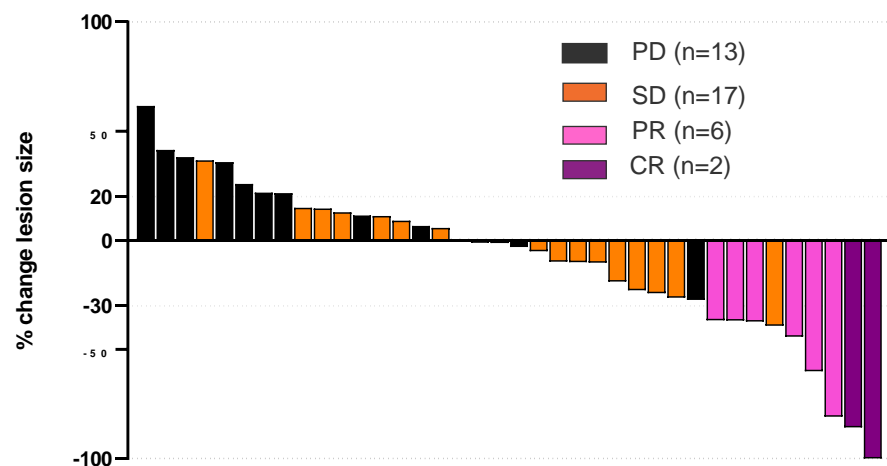
Characteristic	N (%)
Age (mean)	48.9 yrs
Age (median)	47.0 yrs
Prior systemic treatment lines	
1	12 (31%)
2	15 (39%)
3	9 (23%)
4	1 (2%)
5	2 (5%)
PD-L1 status at baseline	
TIC 0 (<5%)	12 (31%)
TIC 1 (5-10%)	3 (8%)
TIC 2 (>10%)	19 (49%)
Missing	5 (13%)
Extra-pelvic metastases present	
Yes	35 (90%)
No	4 (10%)

# Positive interim results from Phase 2 study of VB10.16 in combination with TECENTRIQ® in advanced cervical cancer

► Heavily pre-treated (1-5 lines of prior systemic therapy) recurrent/metastatic cervical cancer patient population

Anti-tumor activity observed in majority of patients including 2 CRs and 6 PRs

## Best Overall Response

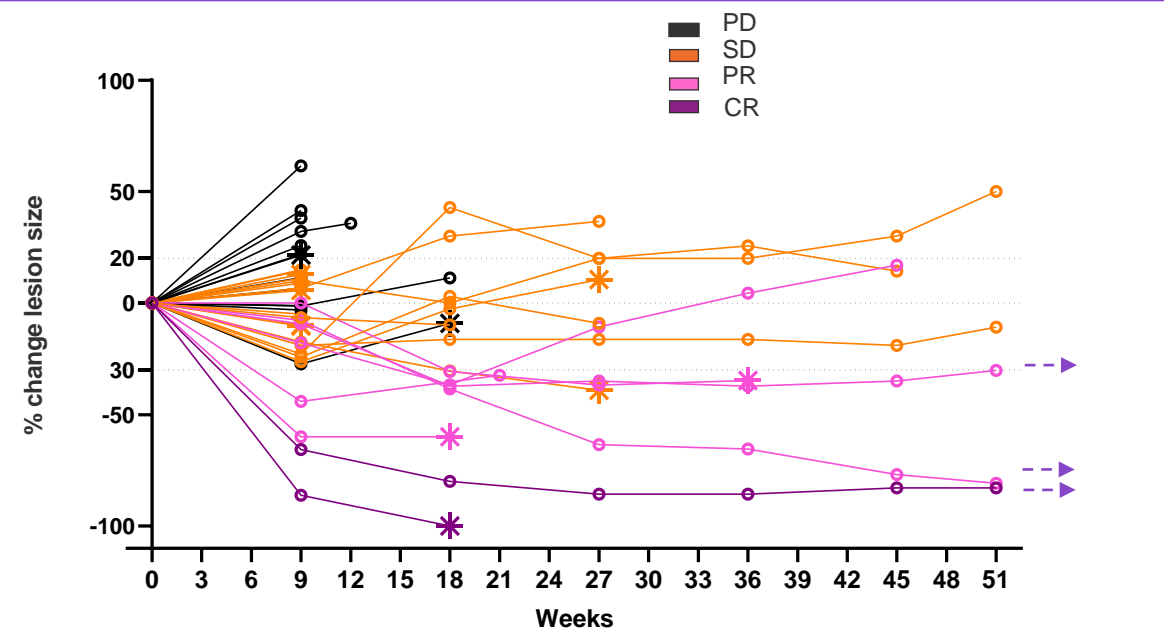


N=38; 1 NE; not evaluable

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

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

**ORR=30% in max  
2 prior lines**



**Durable responses in  
the DCR population**

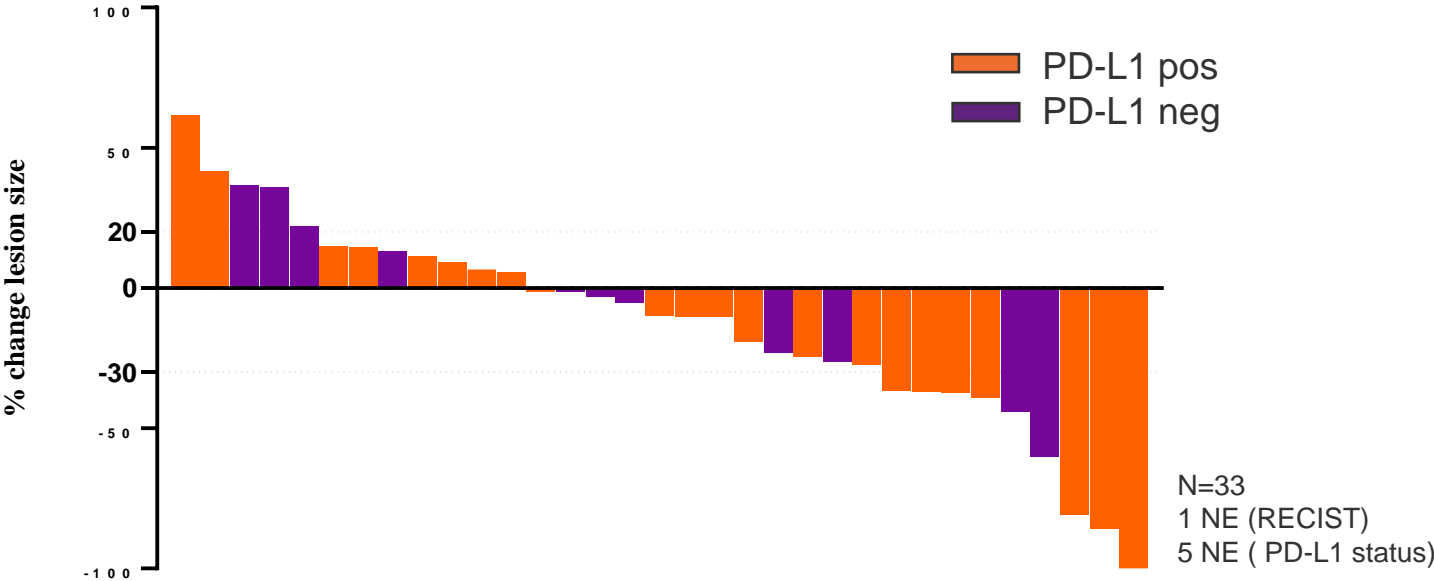
**6 out of 8 ORR patients  
have an ongoing response**

**Deepening of  
responses post w9**



# 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)

- CPI monotherapy published ~15% ORR in PD-L1 positive and 0% ORR in PD-L1 negative
- These findings support that VB10.16 in combination with atezolizumab may enhance clinical responses in both PD-L1 positive and PD-L1 negative patients

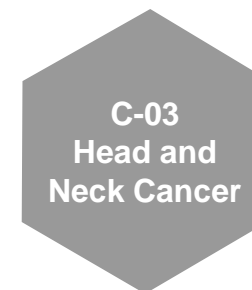
# Near term key inflection points in 1H 2023

Long-term follow up including durability and survival readouts C-02, start of C-03



## Updated durability results from Phase 2 study

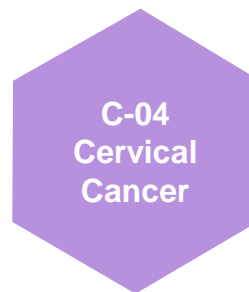
- minimum 12 month follow-up
- PD-L1+ and PD-L1- patients
- 1 or more prior systemic treatment lines
- Updated ORR and DCR
- DOR
- OS



## FPPD in dose escalation (3-9 mg VB10.16)

- PD-L1+ patients
- 1st line
- Combination with pembrolizumab (Keytruda®)
  - Collaboration and supply agreement with Merck announced in December 2022

# Preparing for FPFD in a potential registrational trial in cervical cancer in collaboration with GOG



## To be initiated in Q4

- ◆ HPV16+, recurrent or metastatic cervical cancer
- ◆ Refractory to first line treatment with CPI
- ◆ High unmet medical need
- ◆ Potential for fast to market
- ◆ VB10.16 in combination with a selected CPI
- ◆ In tight collaboration with the Gynecological Oncology Group (GOG) Foundation.
  - ◆ GOG Foundation is a U.S. based expert group focused on gynecological cancer and has a 50-year history of designing and executing successful clinical trials in cervical cancer in partnerships



# Strategic partnership with Richter Helm to secure and optimize manufacturing

- Highly reputable plasmid DNA manufacturer with a proven track record
- Highly comparable COG's
- Flexible forecasting model to secure capacity for entire portfolio
- Potential Tech Transfer to partners supported by RHB, including Nykode IP

Manufacturing capacity  
(1000L Bovenau, 200L Hannover)

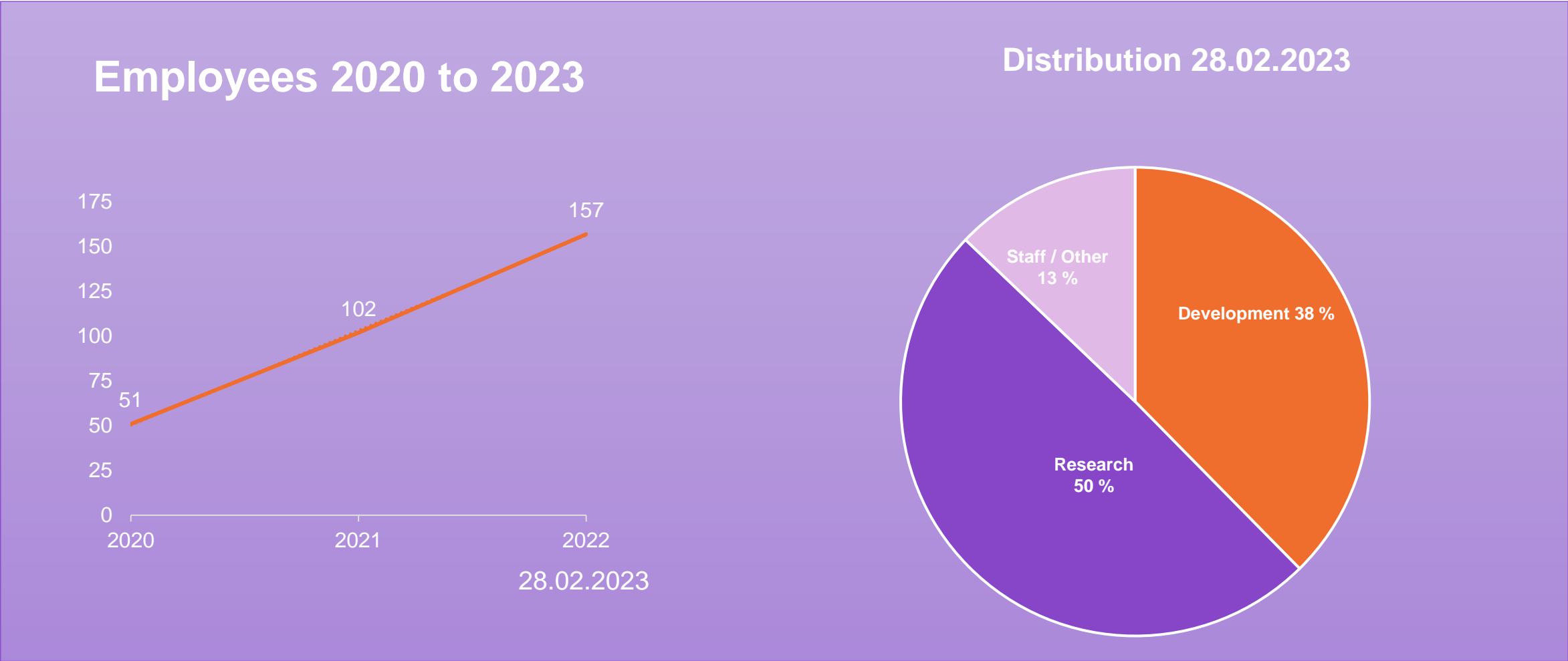


Process Development (Hamburg)



# Organization

# Continued strong growth across the organization (Current Employees)





# Financials



# Strong financial foundation for achieving our vision

## Cash position of \$206m year-end 2022

- ◆ Financially well positioned to grow and execute the Company's strategy over the next years

- ◆ Successful listing on main list of Oslo Stock Exchange in June 2022
- ◆ Included in Oslo Børs Benchmark Index (OSEBX) and Oslo Børs Mutual Fund Index (OSEFX)

Nykode continues to explore a potential listing on the Nasdaq Global Market in the United States

# Income Statement

Amounts in USD '000	Q4 2022	Q4 2021	FY 2022	FY 2021
Revenue from contracts with customers	2,690	30,908	7,168	33,963
Other income	610	865	1,861	1,803
<b>Total revenue and other income</b>	<b>3,300</b>	<b>31,773</b>	<b>9,030</b>	<b>35,766</b>
Employee benefit expenses	7,427	7,267	18,047	16,846
Other operating expenses	9,815	9,377	42,325	28,960
Depreciation	441	424	1,813	735
<b>Operating profit (loss)</b>	<b>(14,382)</b>	<b>14,705</b>	<b>(53,156)</b>	<b>(10,775)</b>
Finance income	3,146	2,640	8,461	4,133
Finance costs	1,070	2,061	6,288	4,475
<b>Profit (loss) before tax</b>	<b>(12,307)</b>	<b>15,283</b>	<b>(50,983)</b>	<b>(11,117)</b>
Income tax expense	(101)	4,514	(8,240)	(1,704)
<b>Profit (loss) for the period</b>	<b>(12,206)</b>	<b>10,769</b>	<b>(42,743)</b>	<b>(9,413)</b>

## Revenue from contracts with customers

- R&D activities under Genentech and Regeneron agreements
- \$2.5m (Q4 2022) and \$6.3m (FY 2022) under Genentech agreement
- \$0.2m (Q4 2022) and \$0.9m (FY 2022) under Regeneron agreement

## Other income

- Government grants from SkatteFUNN and Research Council of Norway

## Employee benefit expenses

- Increase due to growth in organization

## Other operating expenses

- Increase in 2022 mainly due to increased R&D activities



# Balance Sheet

Amounts in USD '000	31/12/2022	31/12/2021
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	3,518	1,884
Right-of-use assets	6,009	7,281
Intangible assets	32	32
Other long-term receivables	46	501
<b>Total non-current assets</b>	<b>9,604</b>	<b>9,698</b>
<b>Current assets</b>		
Trade receivables	2,544	23,750
Other receivables	2,943	3,708
Other current financial assets	-	12,169
Cash and cash equivalents	206,386	216,231
<b>Total current assets</b>	<b>211,873</b>	<b>255,858</b>
<b>TOTAL ASSETS</b>	<b>221,477</b>	<b>265,556</b>

## Cash and cash equivalents

- Strong cash position of \$206m at December 31, 2022

## Other current financial assets

- Sale of money market funds in 2022

## Trade receivables

- Amounts invoiced under Genentech and Regeneron agreements
- \$20m milestone payment from Genentech invoiced 4Q 2021, received 1Q 2022.

# Balance Sheet - contd.

Amounts in USD '000	31/12/2022	31/12/2021
<b>EQUITY AND LIABILITIES</b>		
Equity		
Share capital	338	333
Share premium	83,318	81,526
Other capital reserves	11,695	7,863
Other components of equity	(3,044)	(3,122)
Retained earnings	64,713	107,455
<b>Total equity</b>	<b>157,019</b>	<b>194,055</b>
<b>Non-current liabilities</b>		
Non-current lease liabilities	4,365	5,820
Non-current provisions	30	4,915
Deferred tax liabilities	21,159	29,400
<b>Total non-current liabilities</b>	<b>25,554</b>	<b>40,134</b>
<b>Current liabilities</b>		
Government grants	133	219
Current lease liabilities	1,147	1,350
Trade and other payables	10,175	8,494
Current provisions	7,714	5,234
Current contract liabilities	19,736	16,044
Income tax payable	-	26
<b>Total current liabilities</b>	<b>38,904</b>	<b>31,367</b>
<b>Total liabilities</b>	<b>64,458</b>	<b>71,501</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>221,477</b>	<b>265,556</b>











## Equity

- Total equity of \$157m as per December 31, 2022
- Equity ratio of 71%







## Contract liabilities

- Payments received/due for services not rendered under the Genentech agreement
- Invoicing follows milestone payments
- Revenues recognized as services are delivered
- Contract liability of \$19.7m per December 31, 2022, mainly due to invoicing of \$20m milestone in 4Q 2021

# 2022 Achievements

VB10.16	VB10.2210	VB10.NEO	All	
 <b>Cervical Cancer</b>  Reported positive interim results from Ph 2 study of VB10.16 in combination with TECENTRIQ® in advanced cervical cancer  	 <b>Head and Neck Cancer</b>  Entered into an agreement with MSD/Merck to evaluate VB10.16 with KEYTRUDA® in a Ph 1/2a study in unresectable recurrent or metastatic disease  	 <b>COVID</b>  Reported positive results from Ph 1/2 study of T cell focused pan-SARS-CoV-2 booster vaccine candidate VB10.2210  	 <b>Individualized Cancer Vaccine</b>  Reported positive immunogenicity results from Ph 1/2a study of VB10.NEO in multiple solid tumors  	 <b>Manufacturing</b>  Entered into strategic manufacturing partnership with Richter-Helm BioLogics to supply plasmid DNA for Nykode's wholly owned and partnered product portfolio  

# Upcoming milestones for Nykode's wholly owned programs

1H 2023		<b>VB10.16 Cervical Cancer</b>	Updated durability results from Phase 2 study; minimum 12 month follow-up	
1H 2023		<b>VB10.16 Head and Neck Cancer</b>	First patient dosed in C-03 trial with KEYTRUDA® in patients with unresectable recurrent or metastatic disease	
4Q 2023		<b>VB10.16 Cervical Cancer</b>	Initiate potentially registrational C-04 trial in the U.S. in patients with recurrent/ metastatic disease and PD-L1 positive tumors	
3Q 2023		<b>Autoimmunity and Allergy</b>	Update on Nykode's Ag-specific immune tolerance platform	

Note. The news flow from the collaboration with Genentech and Regeneron is at their discretion, respectively.



# UNLOCKING THE FUTURE OF MEDICINE

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