nykode therapeutics

# Q3 Presentation

**November 23, 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

**HARALD GURVIN**

**Chief Financial Officer**

Long career in the field of finance including:

- Flex LNG
- SFL Corporation

# On our way to build the leading immunotherapy company

## CLINICALLY VALIDATED PLATFORM

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

## TOP TIER COLLABORATORS

Genentech
A Member of the Roche Group

REGENERON

Adaptive

## BUILDING INTERNAL CAPABILITIES

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

## BROAD FUTURE POTENTIAL

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

## STRONG CASH POSITION

- Cash position of $212 mill at September 30, 2022
- Listed on Oslo Stock Exchange

# 3Q highlights

## Clinical programs

•Nykode announced positive results from its Phase 1/2 trial with the T-cell focused SARS-CoV-2 vaccine

•Nykode Therapeutics announced positive immunogenicity results from its Phase 1/2a trial with VB10.NEO, an individualized therapeutic cancer vaccine

•Nykode presented additional efficacy analysis from its Phase 2 trial of VB10.16 in advanced cervical cancer

# 3Q highlights

## Finance

•Nykode included in the Oslo Børs Index (OSEBX) and the Oslo Børs Mutual Fund Index (OSEFX)

• Strong cash position of USD 212 million

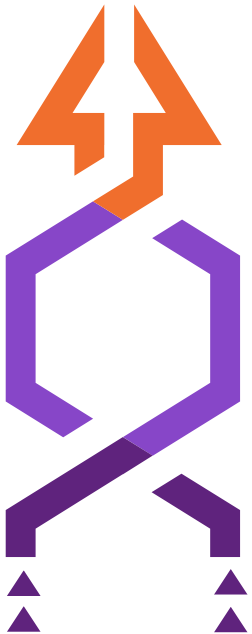
## Organization

• Company continued onboarding of new talent reaching 153 employees by November 15, 2022

# VB10.COV2 positive results D-01

## Nykode’s Covid-19 vaccine

# VB10.2210 includes a large set of 96 validated and conserved viral T cell epitopes



Targeting unit:
CCL3L1

Dimerization unit

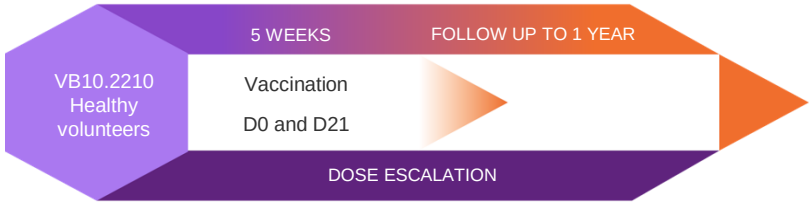
Antigenic unit: contains epitopes against majority (colored) of SARS-CoV-2 antigens


- High mutational drift in Spike are likely to affect both Spike-specific antibody and T cell responses
- VB10.2210 is designed to induce T cell responses against Spike and seven additional antigens less affected by mutational drift
- VB10.2210 epitopes from non-Spike antigens are thus highly conserved across previous and existing SARS-CoV-2 variants, including Omicron

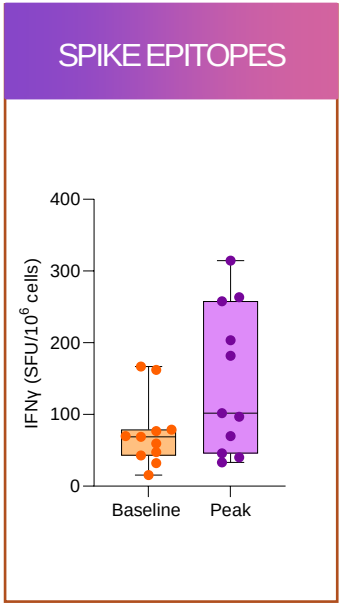
# First-in-human trial investigating VB10.2210 as booster in previously vaccinated subjects

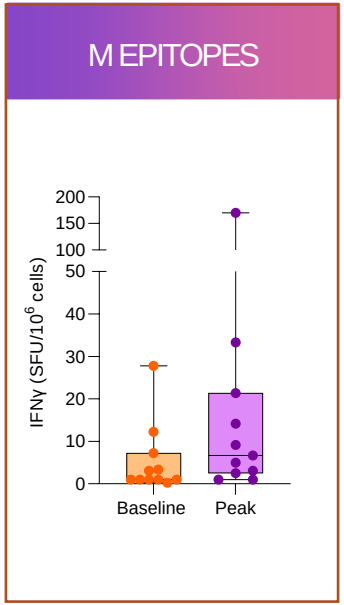
**A Phase 1/2, open label, dose escalation trial to determine safety and of the T-cell candidate (VB10.2210) (NCT05069623)**

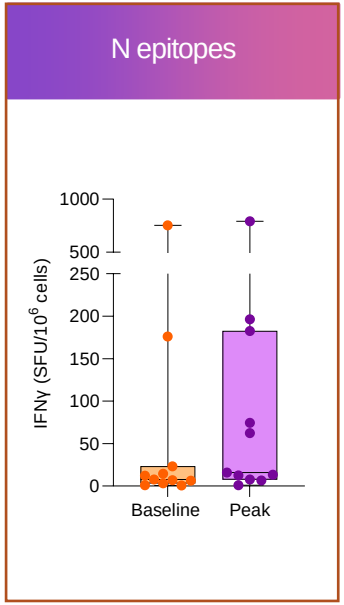
- Booster in Covid-19 naïve healthy adults (18-60y)
- Vaccinated with at least 2 doses mRNA vaccine >8 weeks since last dose
- 2 sites in Norway (Oslo University Hospital Ullevål, and Haukeland University Hospital, Bergen)
- Primary objective: Safety and reactogenicity
- Secondary objective: Cellular immunogenicity
- 34 subjects enrolled to 3 dose levels

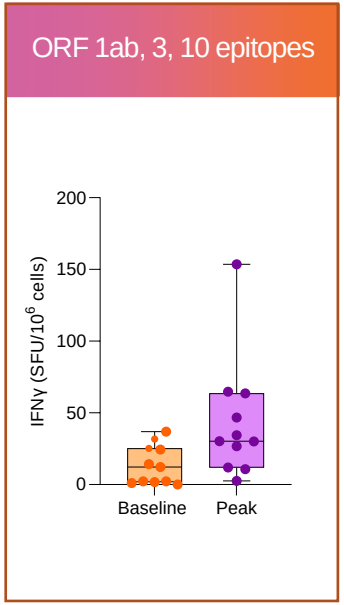


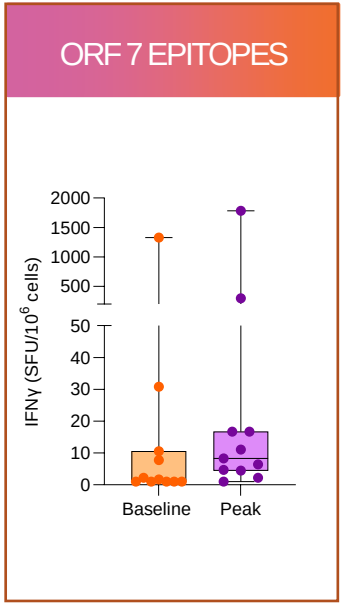

# VB10.2210 induced de novo T cell responses to all four non-Spike antigens conserved across SARS-CoV-2 variants




- VB10.2210 amplified responses to Spike and induced novel T cell responses towards epitopes in Non-Spike Antigens

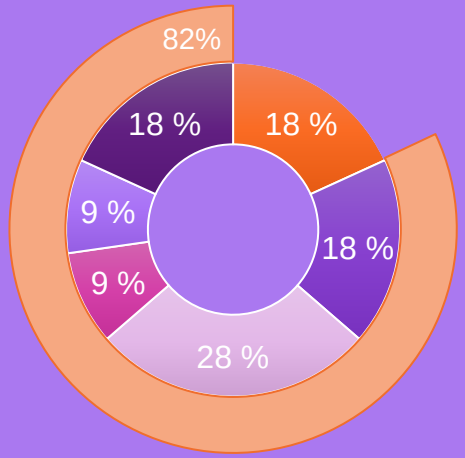


T cell responses were analyzed by ex vivo ELISpot up until day 35

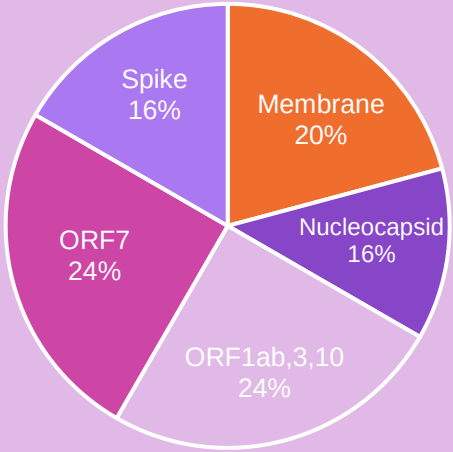
Box plots show median; whiskers show min and max values

# VB10.2210 induces response to all 5 peptide pools from Spike and Non-spike

Response > 1 peptide pool




No response | 1 pool | 2 pools | 3 pools | 4 pools | 5 pools




Number of responders to each peptide pool

- 82 % (9/11) of the subjects vaccinated with VB10.2210 responded to at least 1 peptide pool
- All peptide pools in VB10.2210 vaccine induced a response
- 2 subjects responded to all 5 peptide pools

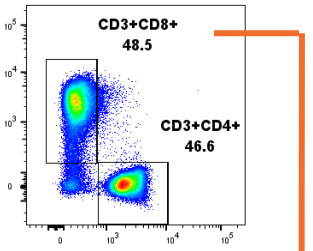
**Confirming induction of a broad response to the selected vaccine epitopes**

> 2-fold increase from baseline was defined as response

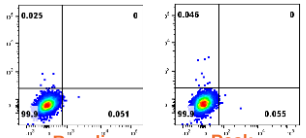
# Preliminary data indicates that the T cell responses are dominated by polyfunctional CD8+ T cells

- CD4/CD8 distribution determined in 5 patients
- A dominant CD8 response observed in all 5 patients

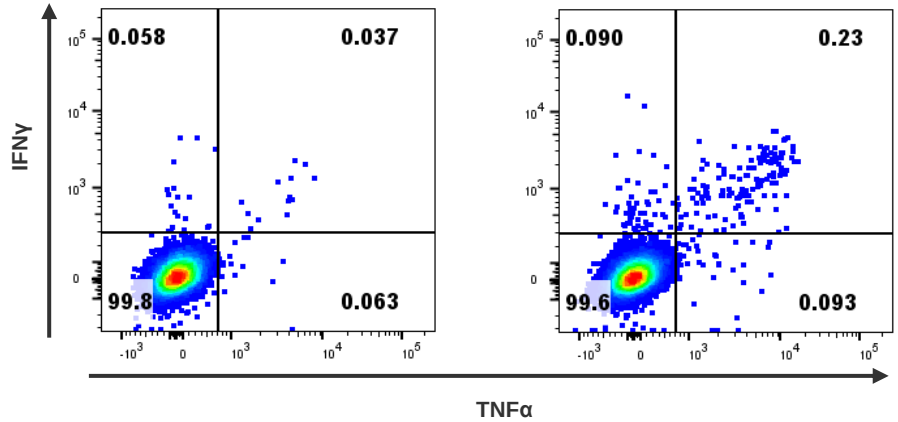
**Responses to VB10.2210 were dominated by CD8+ T cells expressing IFNγ and TNFα**




Negative control



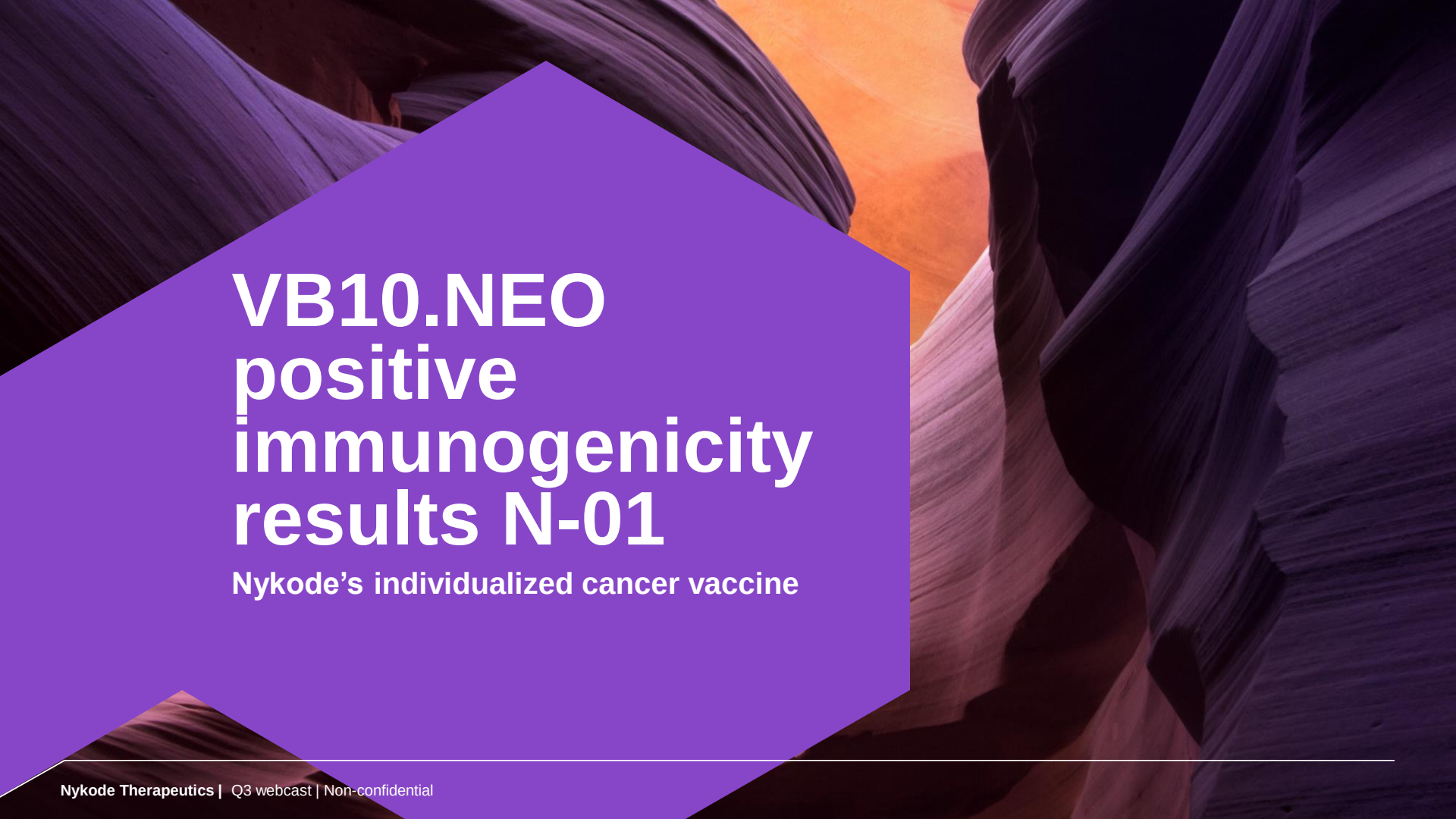

Non-Spike epitopes in N, M, ORFs




Ex vivo stimulated PBMC in ICS flow

# Conclusions and next steps

- Successful proof of concept for the combination of Nykode's APC-targeted Vaccibody technology with T cell epitopes from SARS-CoV-2 selected by Adaptive Biotechnologies
- Confirms the ability of Nykode's platform to generate broad T cell responses dominated by CD8 T cells, which recognize viral peptides on the cell surface and has the potential to eliminate infected cells
- Substantiates the favorable safety profile of our Vaccibody platform
- Nykode will guide on further development strategy 1H 2023



# VB10.NEO positive immunogenicity results N-01

## 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

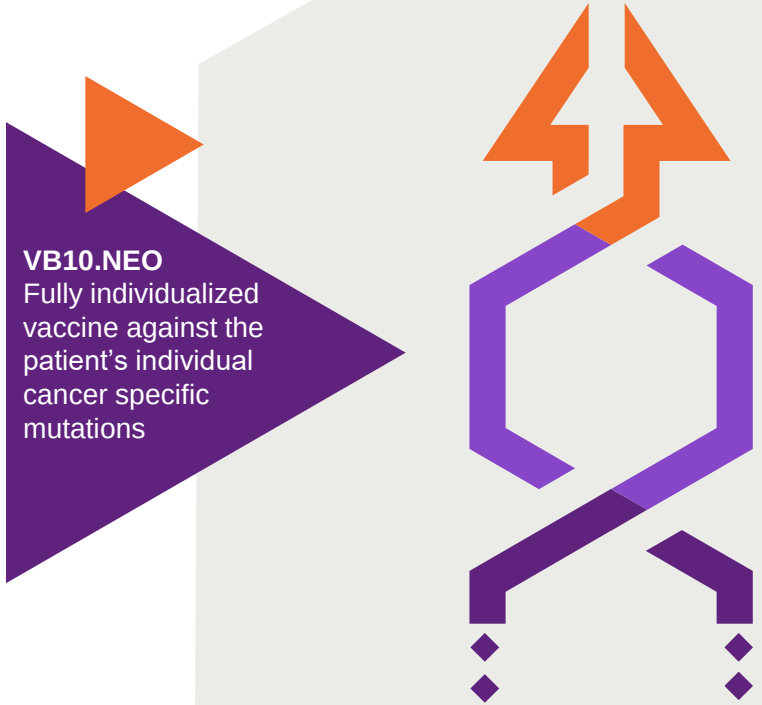
Promising immunogenicity and clinical data

- 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)*

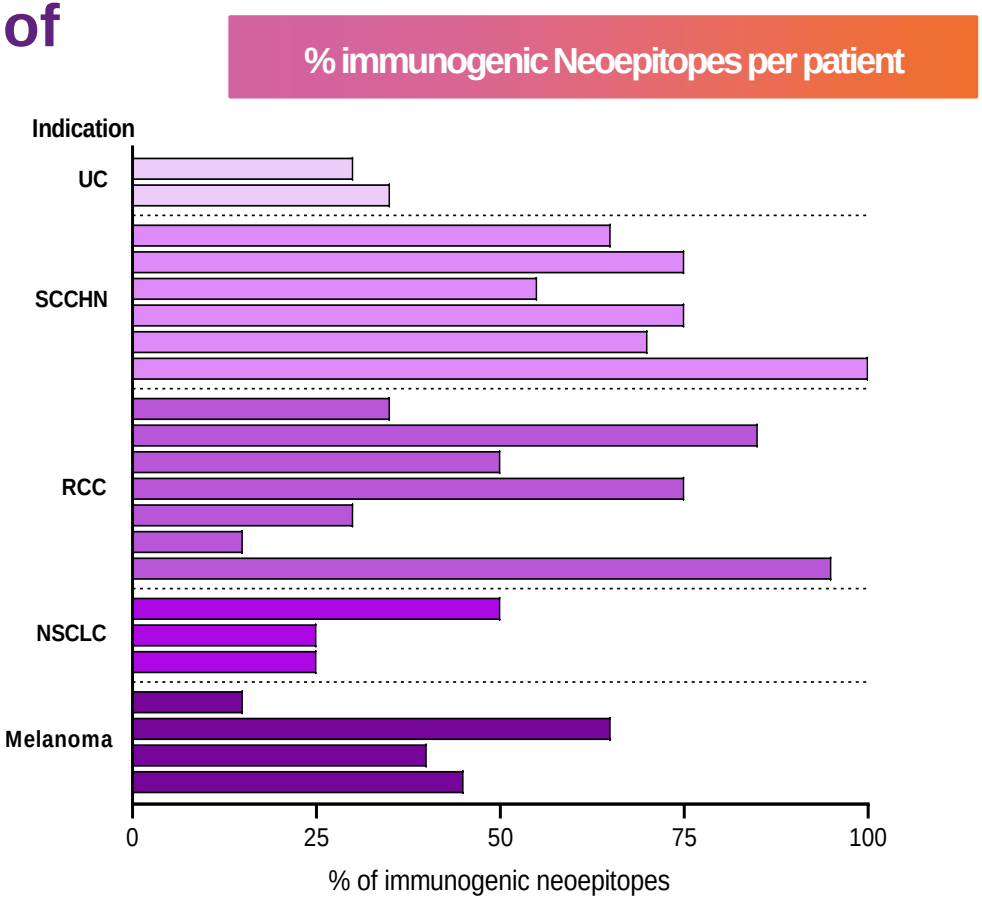
| Characteristic | N (%) |
|---|---|
| Mean Age (range) | 62.6 yrs (33-81 ys) |
| Median Age | 62.0 yrs |
| Ethnicity | |
| White | 41 (100%) |
| Gender | |
| Female | 16 (39%) |
| Male | 25 (61%) |
| ECOG | |
| 0 | 24 (58.5%) |
| 1 | 17 (41.5%) |
| PD-L1 status at baseline | |
| Positive | 7 (21%) |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

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

# T-cell responses to majority of selected neoepitopes

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

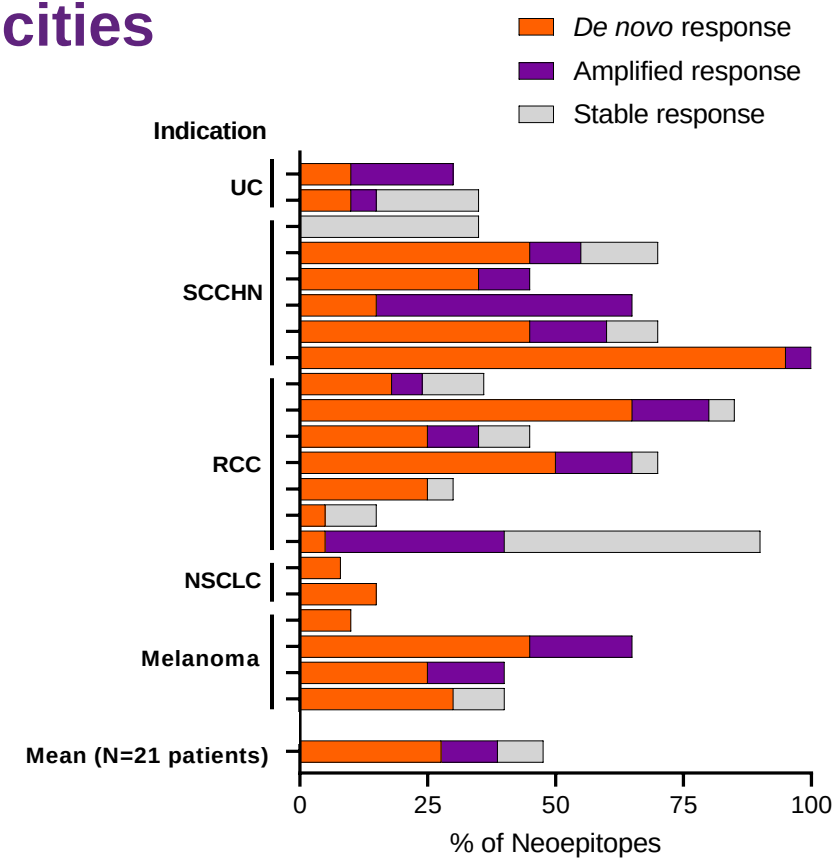
On average, 53% of selected neoepitopes were immunogenic, ranging from 3 to all 20 neoepitopes in the VB10.NEO vaccine demonstrating a broad response



# 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



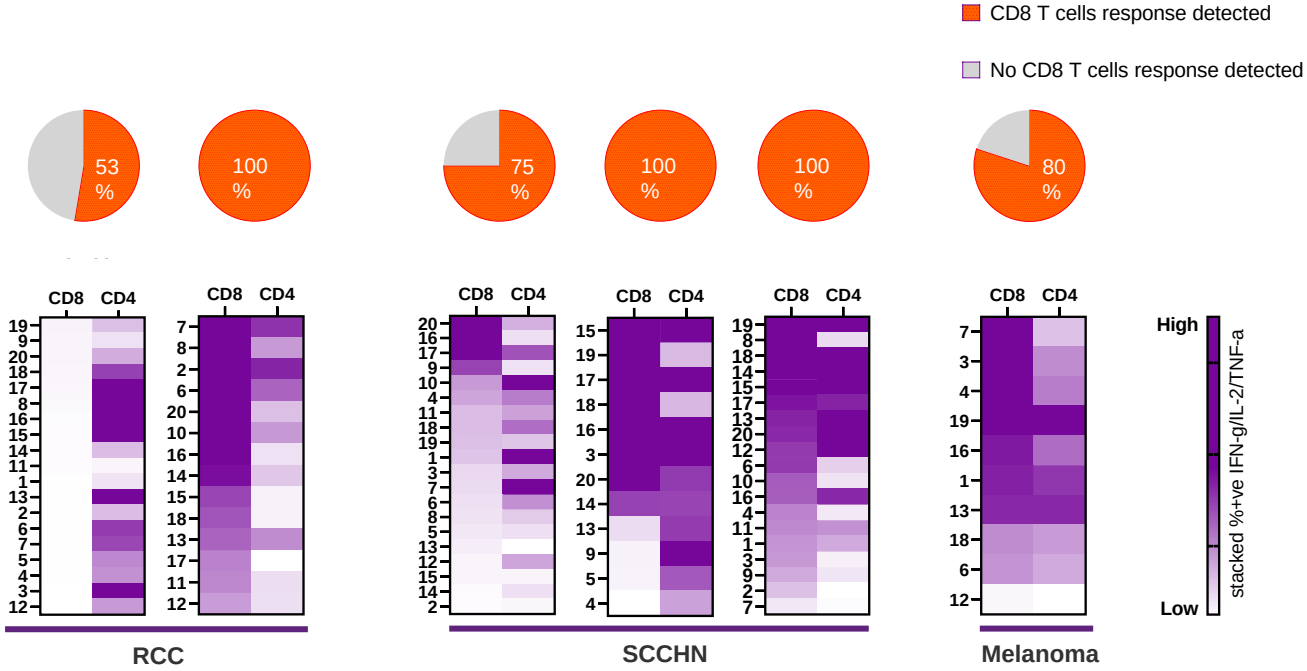



Analysis reported for patients with available PBMC, data missing for 1 or more neoepitopes for 1 patient (N=21)

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

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

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

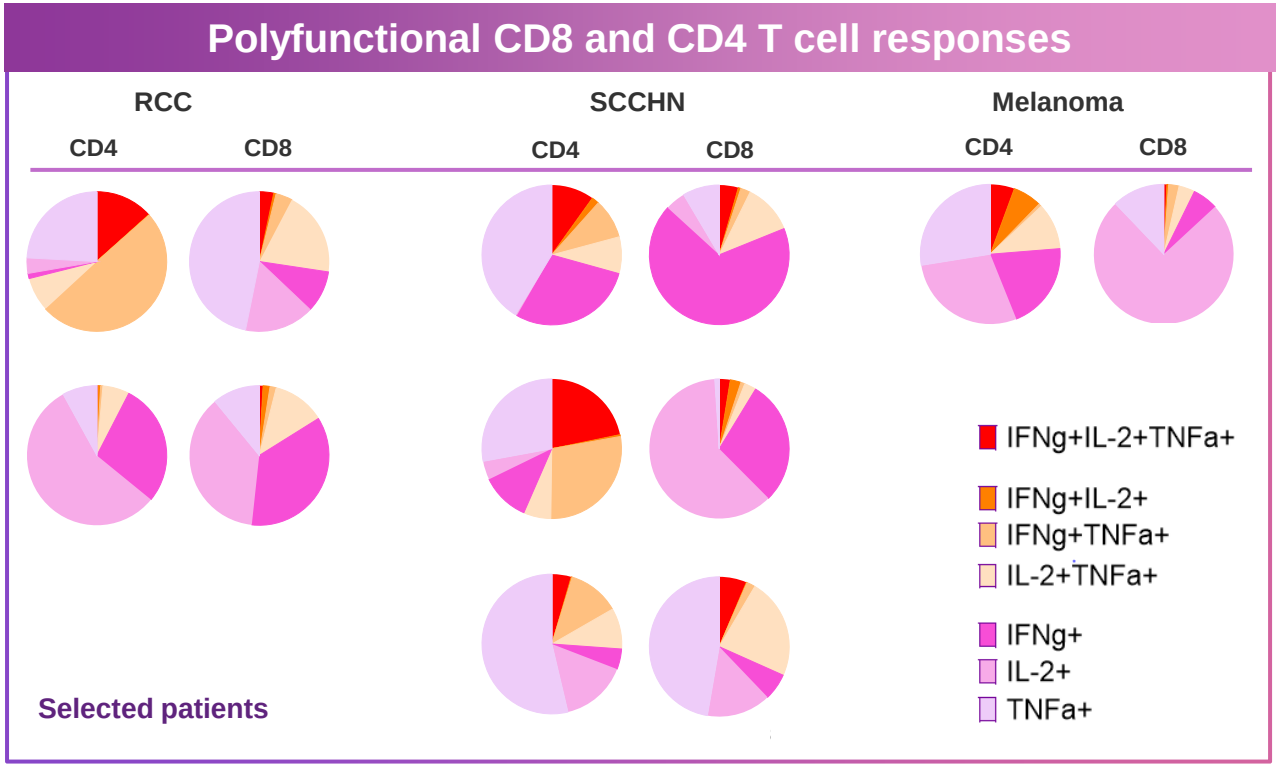





CD8 response defined as ≥ 0.2% above DMSO background.
Phenotyping was performed by IVS ICS using PBMC from week 22 for 6 subjects. Number indicate neoepitope in VB10.NEO

# 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

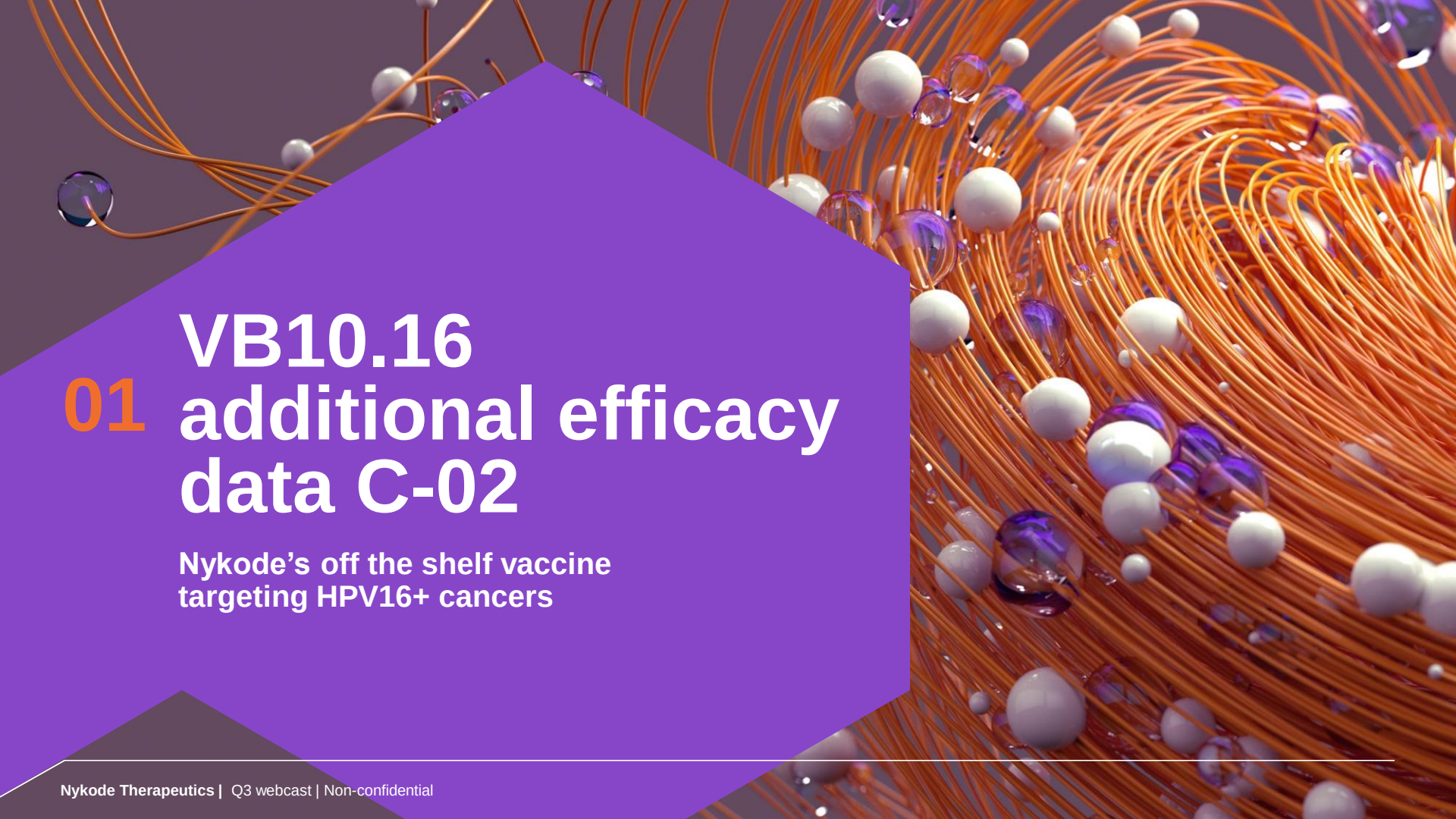





Preliminary data from 7 subjects analysed by IVS ICS using PBMC from week 22

# VB N-01:  Summary

- **VB10.NEO was generally safe and well-tolerated in patients with solid tumors**
- **A broad T cell response was observed in the majority of patients, inducing expansion of both novel and pre-existing T cells**
- **Breadth and magnitude of immune response increased upon multiple vaccinations**
- **Most T cell responses detected at week 22 were maintained for at least one year**
- **VB10.NEO induced polyfunctional CD8 and CD4 T cells**



01

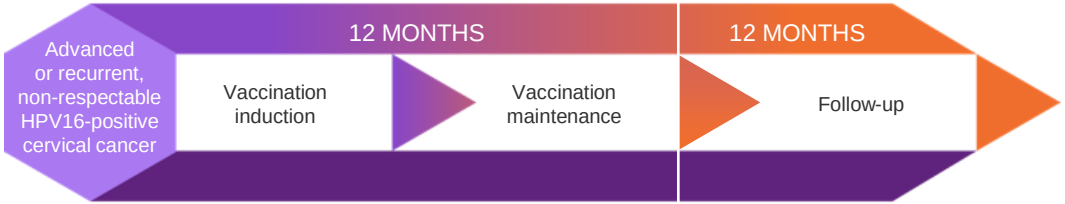
# VB10.16 additional efficacy data C-02

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

# **VB C-02:** VB10.16 in combination with atezolizumab in advanced cervical cancer

## A Multi-Centre, Single Arm, Open-label Phase 2a Trial of the Combination of VB10.16 and atezolizumab in Patients with Advanced or Recurrent, Non-resectable HPV16 Positive Cervical Cancer (NCT04405349)

- Objectives: safety/tolerability, immunogenicity and efficacy
- Primary endpoints: incidence/severity of AEs, ORR (based on RECIST 1.1 by blinded independent central review)
- Fully enrolled with 52 patients
- Conducted in Europe in 6 countries (Germany, Belgium, Bulgaria, Czech Republic, Poland and Norway)
- Enrolled patients received treatment with 3 mg VB10.16 in combination with 1200 mg atezolizumab for up to 48 weeks.



# Baseline characteristics of EAS population

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

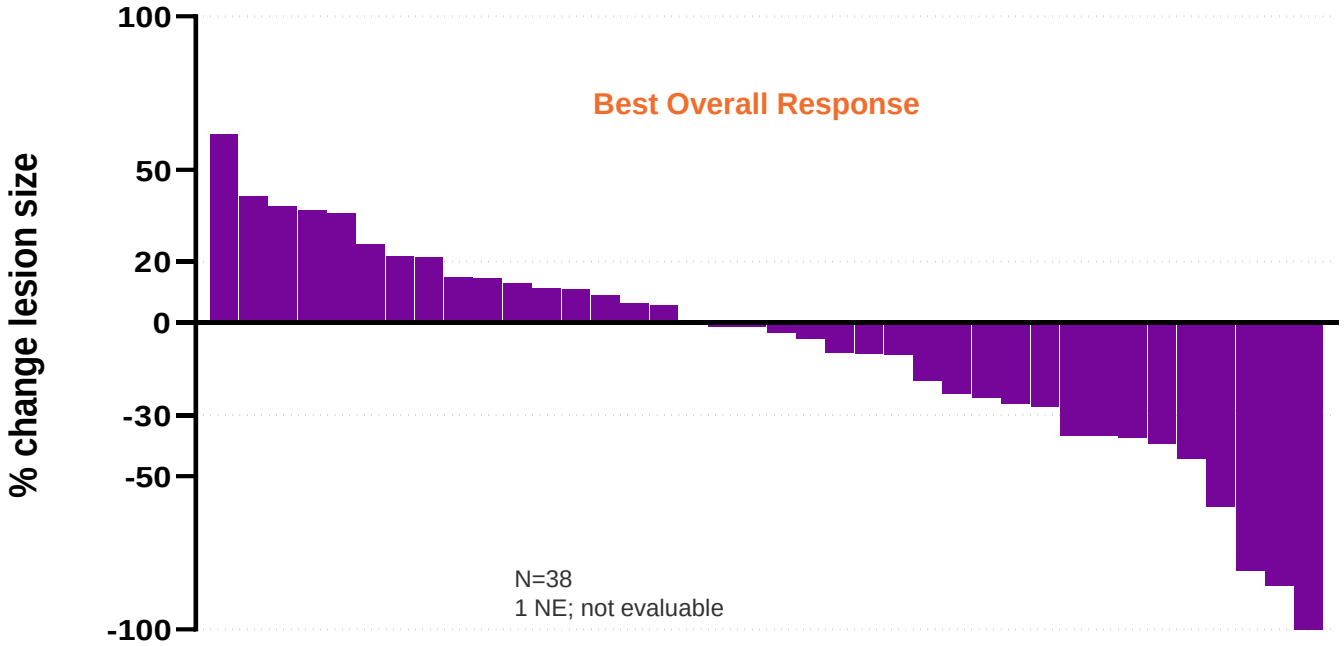
| Characteristic | N (%) |
|---|---|
| **Age (mean)** | 48.9 yrs |
| **Age (median)** | 47.0 yrs |
| **Ethnicity (White)** | 39 (100%) |
| **Prior systemic treatment lines** | |
| **1** | 12 (31%) |
| **2** | 15 (39%) |
| **3** | 9 (23%) |
| **4** | 1 (2%) |
| **5** | 2 (5%) |
| **Prior surgery** | |
| **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%) |



*Sum >100% as 4 patients had both liver and lung metastases

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




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

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

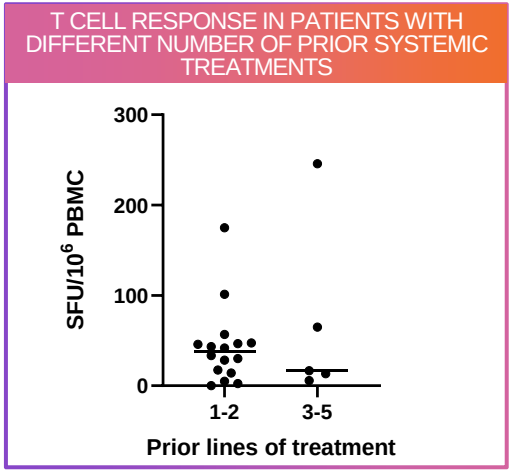
**DCR = 64%**
(25/39 patients)

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

# Clinical response by prior systemic treatment line

## High disease control in patients with up to 2 prior lines

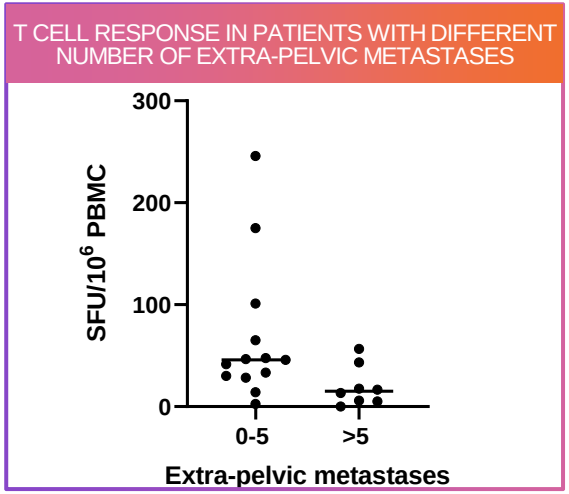
| Number of prior systemic treatment lines | ORR | DCR |
|---|---|---|
| 1 (n=12) | 17% | 75% |
| 2 (n=15) | 40% | 60% |
| 3 (n=9) | 0% | 55% |
| 4 (n=1) | 0% | 100% |
| 5 (n=2) | 0% | 50% |




- Patients with objective responses have received up to 2 prior lines of systemic treamtent
- 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

# VB C-02: Positive interim results from VB C-02 May 2022

*Conclusions*

- VB10.16 in combination with atezolizumab showed durable responses with a very high disease control rate (DCR) of 64% in heavily pre-treated advanced cervical cancer patients
- Anti-tumor efficacy was observed in both PD-L1 positive and negative patients, with 27% overall response rate (ORR) and 77% DCR in PD-L1 positive patients and 17% ORR and DCR 58% in PD-L1 negative patients
- HPV16-specific IFN-γ T cell responses were associated with clinical efficacy
- DCR of 71% was observed in patients with non-inflamed tumors, including both immune desert and T cell excluded tumors
- Biomarkers including complete clearance of HPV16 ctDNA and inflammation markers were significantly correlated with clinical outcomes
- VB10.16 in combination with atezolizumab is well-tolerated and has a safety profile comparable to CPI monotherapy

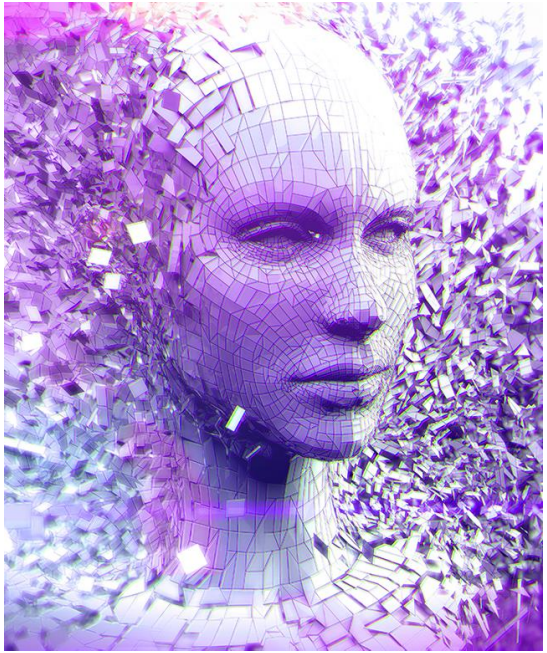
**Further updates on the VB10.16 development plan is planned in 2022 and 1 year data 1H 2023**

# Organization

# Continued strong growth across the organization (Current Employees)


# Financials

# Highlights



- Financially well positioned to grow and execute the Company's strategy over the next years
- Strong balance sheet with cash position of $212 mill at September 30, 2022

- Successful listing on main list of Oslo Stock Exchange in June 2022
  - To facilitate greater liquidity in the shares and attract new potential shareholders in order to build a more diversified shareholder base
  - Included in Oslo Børs Benchmark Index (OSEBX) and Oslo Børs Mutual Fund Index (OSEFX) in mid-September
- Nykode continues to explore a potential listing on the Nasdaq Global Market in the United States

# Income Statement

| Amounts in USD '000 | Q3 2022 | Q3 2021 | YTD 2022 | YTD 2021 |
|---|---|---|---|---|
| Revenue from contracts with customers | 648 | 1,001 | 4,478 | 3,055 |
| Other income | 634 | 313 | 1,251 | 938 |
| **Total revenue and other income** | **1,282** | **1,314** | **5,729** | **3,993** |
| Employee benefit expenses | 5,897 | 3,003 | 10,620 | 9,579 |
| Other operating expenses | 14,831 | 8,529 | 32,511 | 19,583 |
| Depreciation | 458 | 106 | 1,372 | 311 |
| **Operating profit (loss)** | **(19,905)** | **(10,324)** | **(38,774)** | **(25,480)** |
| Finance income | 3,073 | 865 | 6,096 | 1,493 |
| Finance costs | 2,364 | 1,157 | 5,998 | 2,414 |
| **Profit (loss) before tax** | **(19,196)** | **(10,616)** | **(38,676)** | **(26,401)** |
| Income tax expense | (4,306) | (3,169) | (8,139) | (6,218) |
| **Profit (loss) for the period** | **(14,889)** | **(7,447)** | **(30,537)** | **(20,183)** |

**Revenue from contracts with customers**

- R&D activities under Genentech and Regeneron agreements
- $0.4m (Q3 2022) and $3.8m (YTD 2022) under Genentech agreement
- $0.3m (Q3 2022) and $0.7m (YTD 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
- Non-recurring cost of $6.3m in Q3 2022

# Balance Sheet

| Amounts in USD '000 | 30/09/2022 | 31/12/2021 |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| Property, plant and equipment | 2,873 | 1,884 |
| Right-of-use assets | 6,341 | 7,281 |
| Intangible assets | 32 | 32 |
| Other long-term receivables | 450 | 501 |
| **Total non-current assets** | **9,695** | **9,698** |
| | | |
| **Current assets** | | |
| Trade receivables | 2,544 | 23,750 |
| Other receivables | 4,054 | 3,708 |
| Other current financial assets | - | 12,169 |
| Cash and cash equivalents | 212,021 | 216,231 |
| **Total current assets** | **218,619** | **255,858** |
| **TOTAL ASSETS** | **228,314** | **265,556** |

**Cash and cash equivalents**

- Strong cash position of $212m at September 30, 2022

**Other current financial assets**

- Sale of money market funds in Q3 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 | 30/09/2022 | 31/12/2021 |
|---|---|---|
| **EQUITY AND LIABILITIES** | | |
| Equity | | |
| Share capital | 334 | 333 |
| Share premium | 82,314 | 81,526 |
| Other capital reserves | 10,620 | 7,863 |
| Other components of equity | (3,075) | (3,122) |
| Retained earnings | 76,918 | 107,455 |
| **Total equity** | **167,111** | **194,055** |
| | | |
| **Non-current liabilities** | | |
| Non-current lease liabilities | 4,126 | 5,820 |
| Non-current provisions | 252 | 4,915 |
| Deferred tax liabilities | 21,259 | 29,400 |
| **Total non-current liabilities** | **25,637** | **40,134** |
| | | |
| **Current liabilities** | | |
| Government grants | 346 | 219 |
| Current lease liabilities | 1,045 | 1,350 |
| Trade and other payables | 5,274 | 8,494 |
| Current provisions | 9,138 | 5,234 |
| Current contract liabilities | 19,739 | 16,044 |
| Income tax payable | 23 | 26 |
| **Total current liabilities** | **35,566** | **31,367** |
| **Total liabilities** | **61,203** | **71,501** |
| | | |
| **TOTAL EQUITY AND LIABILITIES** | **228,314** | **265,556** |

**Equity**

- Total equity of $167m as per September 30, 2022
- Equity ratio of 73%

**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 September 30, 2022, mainly due to invoicing of $20m milestone in 4Q 2021

# Recent Achievements and Upcoming Catalysts

| Key Priorities | Program | Indication | Partnerships | Milestones |
|---|---|---|---|---|
| **Wholly-Owned Candidates** | | | | |
| **Oncology**<br>• Advance internal oncology programs including cervical cancer program<br>• Expand into additional indications for VB10.16, including head and neck cancer | VB10.16 (off-the-shelf) | HPV16+ cervical cancer | | ✓ Provided additional data from interim analysis Ph2<br>• Present updated Phase 2 data (1H 2023)<br>• Provide updated development strategy<br>• Initiate Phase Ib trial in HNSCC |
| | VB10.NEO (individualized) | Melanoma, lung, bladder, renal, head and neck | Genentech | ✓ Provided positive immunogenicity data Ph1/2 |
| | Internal programs | Undisclosed | | |
| **Infectious Disease**<br>• Advance COVID-19 vaccines<br>• Expand into additional high-priority disease areas | VB10.COV2 | SARS-CoV-2 | Adaptive | ✓ Presented Phase 1 key results measuring immune responses in previously vaccinated subjects (2H 2022)<br>• Guide on further development strategy |
| | Internal programs | Undisclosed | | |
| **Technology**<br>• Leverage technology platform | | | | • Announce further preclinical data from Ag-specific immune tolerance platform |
| **Manufacturing**<br>• Enhance control of manufacturing capacity and capability | | | | • Provide update on manufacturing strategy |

# UNLOCKING THE FUTURE OF MEDICINE

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