nykode therapeutics

VB10.16

Outline of further clinical development in HPV16-positive malignancies

December 20, 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

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

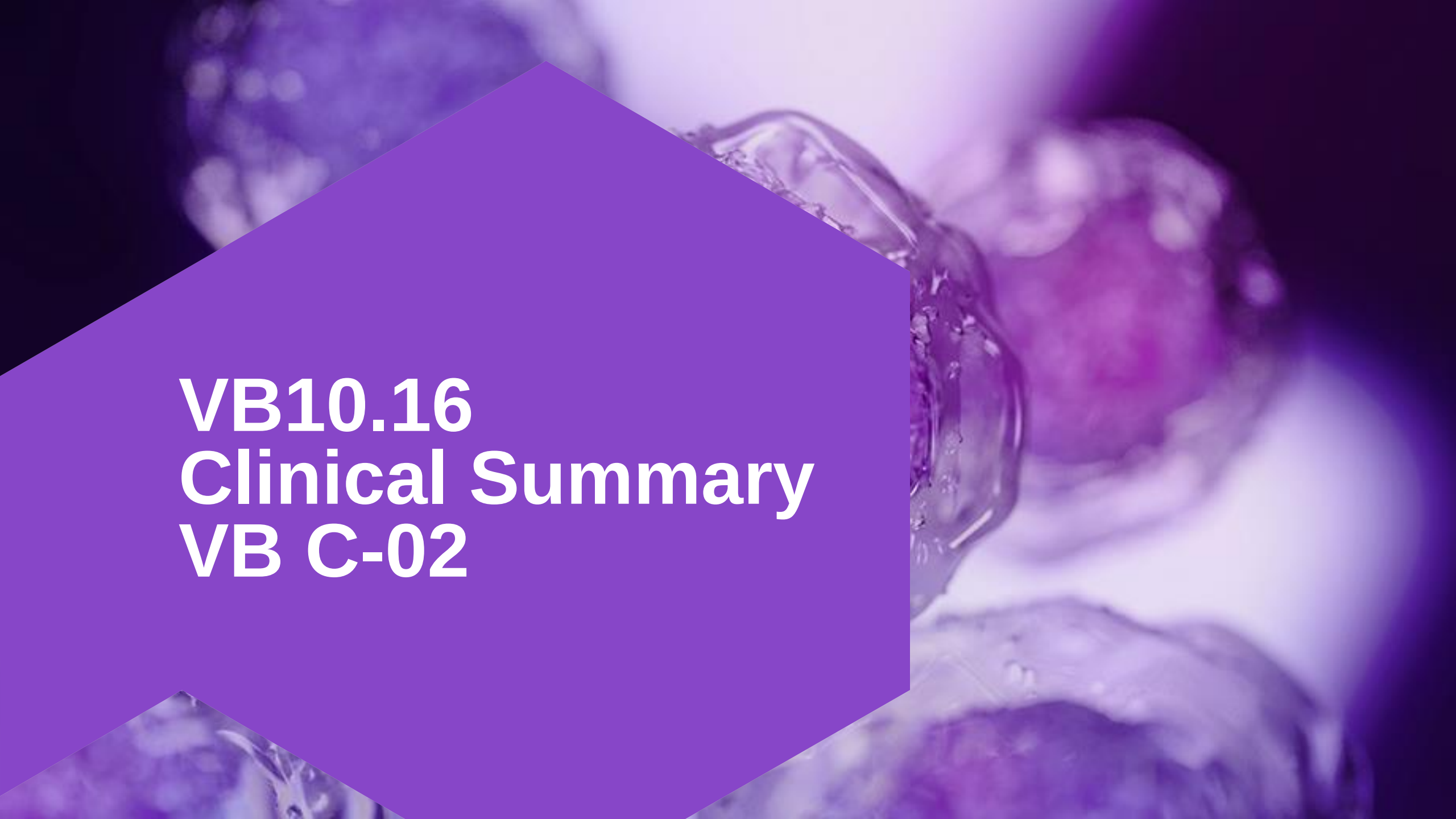
- Vaccibody/Nykode

KLAUS EDVARDSEN

Chief Development Officer

Extensive experience from leading drug development programs within oncology, hematology and infectious diseases in both biotech and pharma companies:

- CureVac (as CDO)
- Merck KGaA
- AstraZeneca

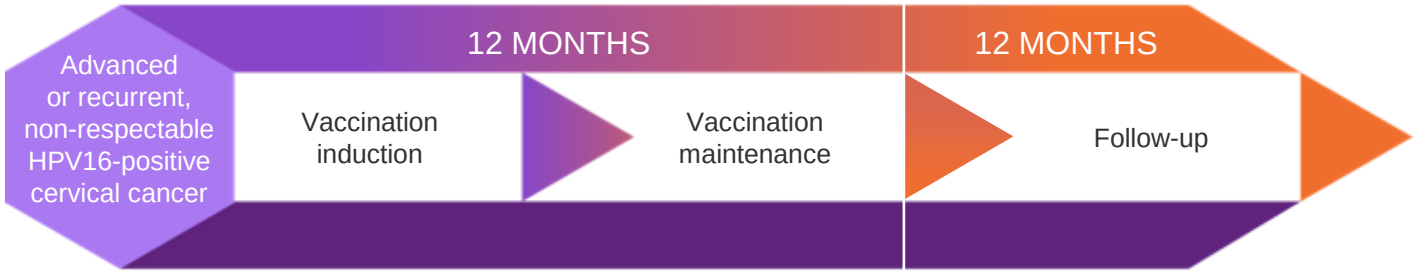


VB10.16
Clinical Summary
VB C-02

VB C-02: VB10.16 + Atezolizumab (Tecentriq®) in advanced Cervical Cancer – Study on track

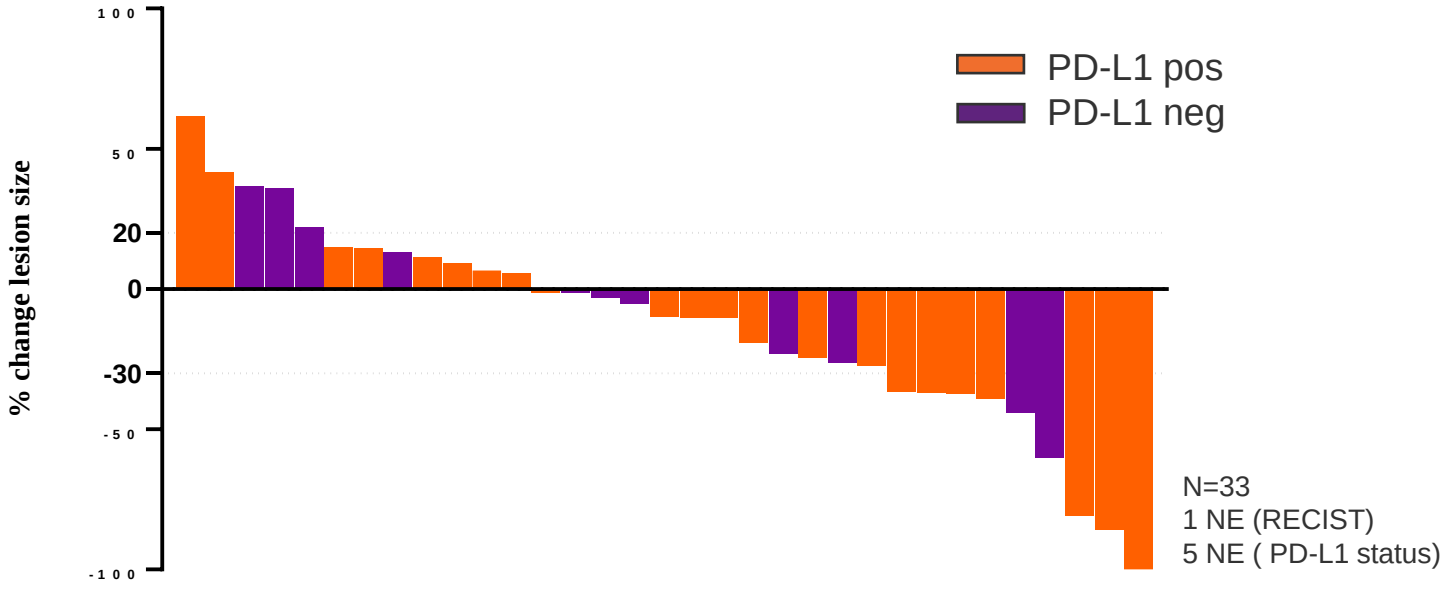
A Multi-Centre, Single Arm, Open-label Phase 2a Trial of the Combination of VB10.16 and atezolizumab in Patients with Advanced or Recurrent, Non-resectable HPV16 Positive Cervical Cancer (NCT04405349)

- 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



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)

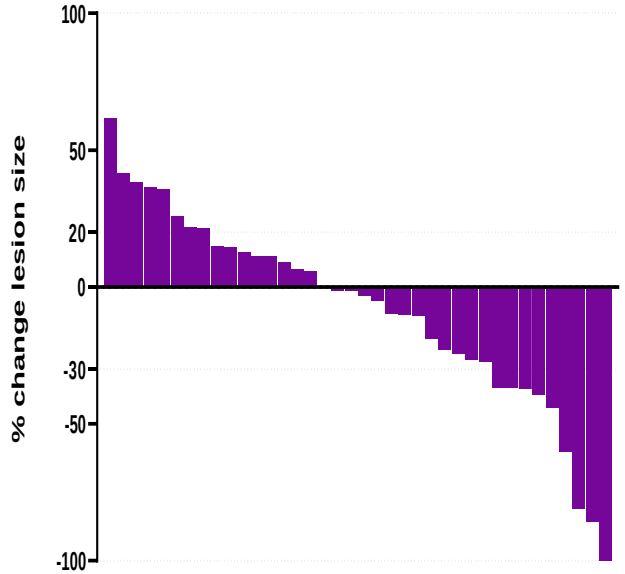
- **These findings support that VB10.16 in combination with atezolizumab may enhance clinical responses also in PD-L1 negative patients where CPI monotherapy has limited effect**

- PD-L1 was scored by TIC (Tumor and immune cell) scoring using Ventana SP263 platform (Roche Diagnostics)
- PD-L1 status at baseline was available in 34 patients, 1 PD-L1 negative patient was NE according to RECIST

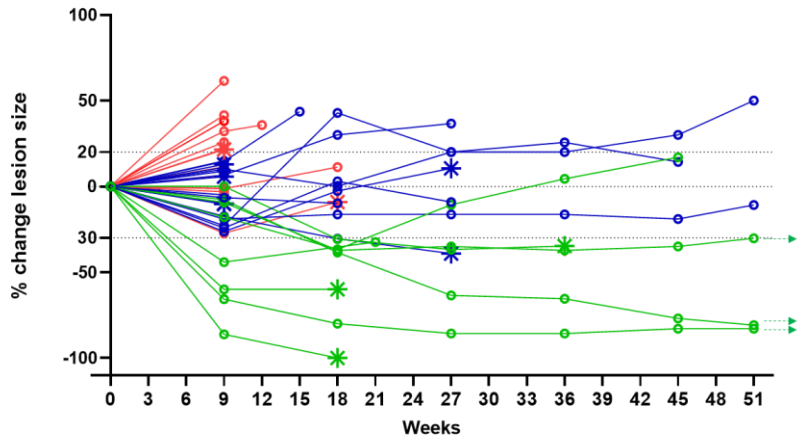
Link between vaccine-induced immune responses and clinical efficacy in advanced cervical cancer

VB10.16: HPV16 vaccine (VB C-02)

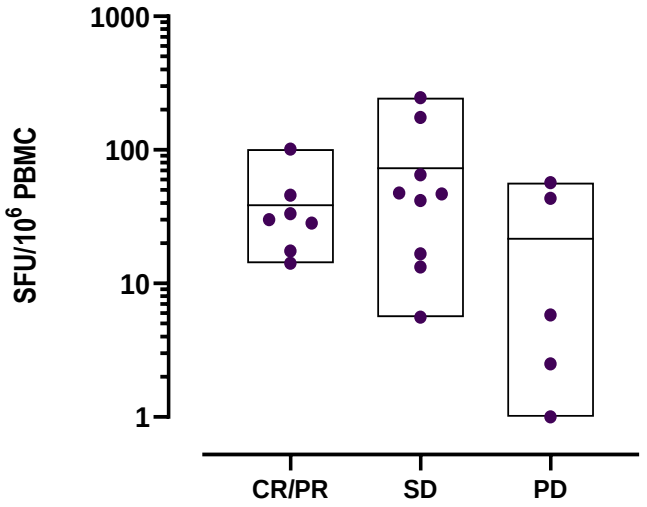
DEEP CLINICAL RESPONSES



LONG-LASTING CLINICAL RESPONSES



T CELL VS BEST OVERALL RESPONSE



VB10.16 - Safety summary

VB10.16 is generally well tolerated and safe – both as monotherapy and in combination with a PD-L1 inhibitor

VB-C-01 trial

- No SAEs occurred in 34 female subjects with HPV16+ CIN 2/3 receiving 3 or 4 vaccinations of 3 mg dose.
- 2 subjects experienced grade 3 events within the 24 weeks follow-up period - injection site hyperaesthesia and injection site pain was considered related to VB10.16.
- The most frequently reported adverse events were transient mild to moderate reactions at the injection site.

VB-C-02 trial

- In women with advanced or recurrent, non-resectable HPV16+ cervical cancer, 50 females had received 3 mg dose in combination with atezolizumab at the time of the interim analysis (cut-off date 14 February 2022)
- No unexpected safety risks have been observed.
- Well-known side effects linked to immunotherapy such us anemia, and fatigue were reported - these were considered related to atezolizumab or the underlying disease.
- 15 subjects (30%) had adverse events considered related to VB10.16 - these were primarily mild injection site reactions.

VB10.16 Clinical development

Incidence of various HPV16+ cancers

Prophylactic HPV vaccination program coverages suggest a continued unmet need

The addressable market for VB10.16 represents a significant opportunity with additional market expansion potential from the unmet need represented by the PD-L1 negative patient population[1]

HNSCC[2]

- Estimated 9 500 HPV16+ new cases per year in the U.S.
- Estimated 17 000 HPV16+ new cases per year in EU5

- US/EU5 HPV16+ Local/Locally advanced – 19 000
- US/EU5 HPV16+ Recurrent/Metastatic – 12 500

Cervical[2]

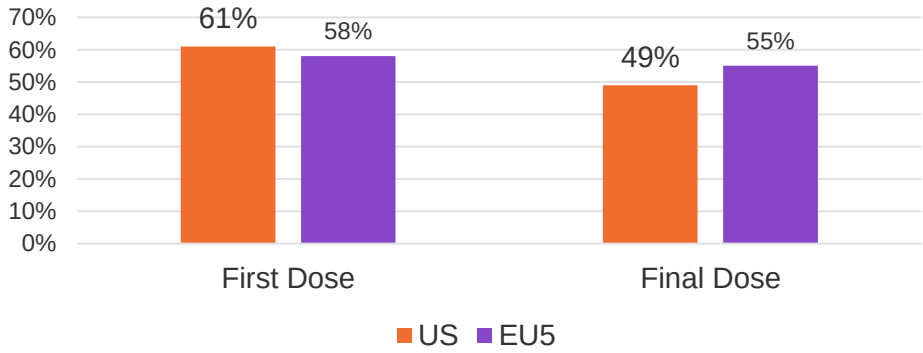
- Estimated 7 500 HPV16+ new cases per year in the U.S.
- Estimated 10 000 HPV16+ new cases per year in EU5

- US/EU5 HPV16+ Local/Locally advanced – 14 000
- US/EU5 HPV16+ Recurrent/Metastatic – 9 000

Anal/Vaginal/ Penile[2]

- Estimated 8 200 HPV16+ new cases per year in the U.S.
- Estimated 6300 HPV16+ new cases per year in EU5

2019 HPV Vaccination Program Coverages Estimates for Females, %[2]



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://hpvcentre.net/statistics/reports/; KOLs

VB10.16 – Planned clinical development in HPV16-positive related cancer types

Improving patient outcomes in various HPV16-positive related cancer types with high unmet needs by combining VB10.16 with a PD-(L)1 inhibitor

Cervical cancer

- Study VB10.16 in combination with PD-(L)1 inhibitor in recurrent/metastatic disease in patients who failed first line treatment including checkpoint inhibitors

Head and neck cancer

- Study VB10.16 in combination with PD-(L)1 inhibitor in first line recurrent/metastatic disease

Other HPV16-positive cancer types

- Plan investigator-initiated basket trial of VB10.16 in combination with PD-(L)1 inhibitor in anal, penile, vaginal and/or vulvar cancer

PD-L1 negative patient population

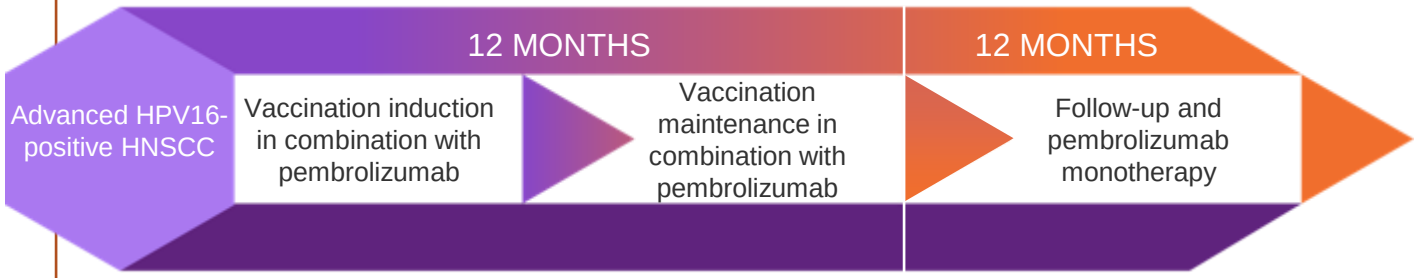
- Expand program to study VB10.16 in patients with hard-to-treat PD-L1 negative tumours aiming to further improve clinical outcomes

VB-C-03 trial in advanced HPV16-positive Head and Neck cancer in combination with pembrolizumab

Single arm phase Ib/IIa dose escalation trial in patients with first line recurrent or metastatic squamous cell head and neck cancer (HNSCC)

- **Key eligibility criteria**
  - HPV16+, recurrent or metastatic HNSCC
  - Patients eligible for standard of care treatment with pembrolizumab monotherapy
- **Approximately 40 patients will be enrolled**
- **Key endpoints**
  - Overall response rate (RECIST 1.1 criteria)
  - Safety/tolerability
  - Antigen specific immune response
- **Exploratory endpoints**
  - Biomarkers (e.g. ctDNA)
  - Changes in tumor micro-environment
- **To be initiated in 1H 2023**

- **Dosing schedule VB10.16**
  - Dose levels between 3 mg and 9 mg will be studied
  - Combination treatment administered for up to 1 year
- **Dosing schedule pembrolizumab**
  - Treatment with approved dose for up to 2 years
- **Combination treatment until progression or unacceptable toxicity**



Pembrolizumab will be supplied by MSD

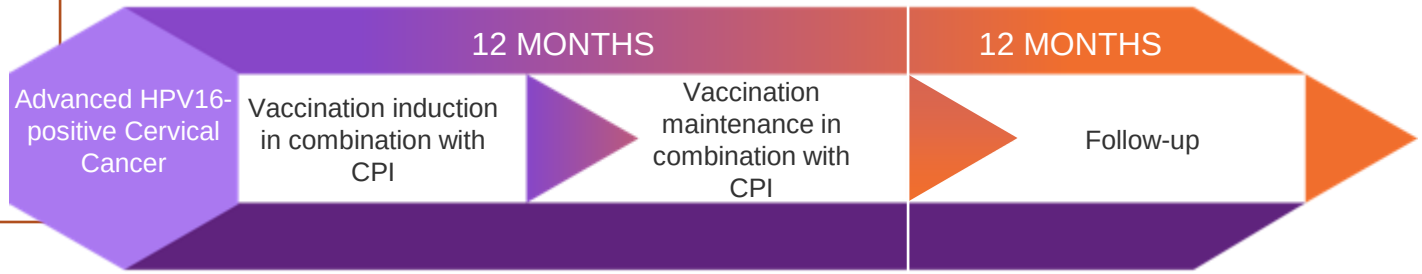
MSD

VB-C-04 trial with potential registrational intent in advanced HPV16-positive cervical cancer

Single arm phase II trial in patients refractory to chemotherapy + pembrolizumab +/- bevacizumab

- **Key eligibility criteria**
  - HPV16+, recurrent or metastatic cervical cancer
  - Progression on chemotherapy + pembrolizumab +/- bevacizumab as first line treatment
- **Key endpoints**
  - Overall response rate (RECIST 1.1 criteria)
  - Safety/tolerability
  - Antigen specific immune response
- **Exploratory endpoints**
  - Biomarkers (e.g. ctDNA)
- **To be initiated in 4Q 2023**

- **Combination treatment until progression or unacceptable toxicity for up to 1 year**
- **Dosing schedule VB10.16**
  - Treatment with 3 mg, administered for up to 1 year
- **Dosing schedule CPI**
  - Treatment with approved dose for up to 2 years

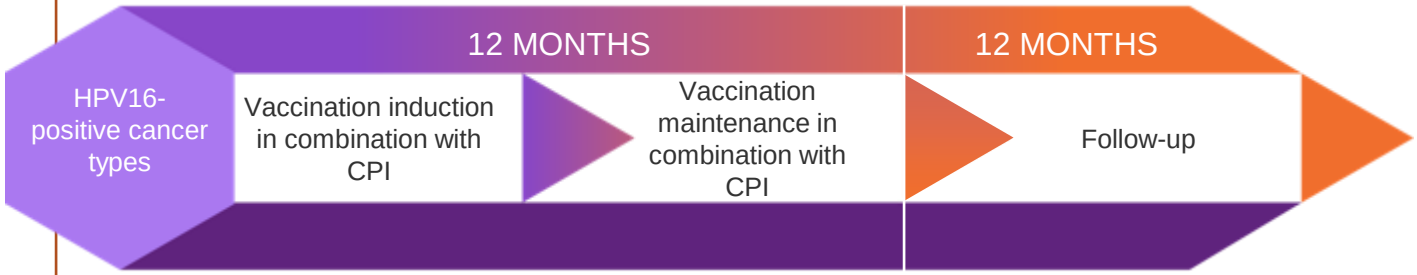


Basket trial in other HPV16-positive cancer types

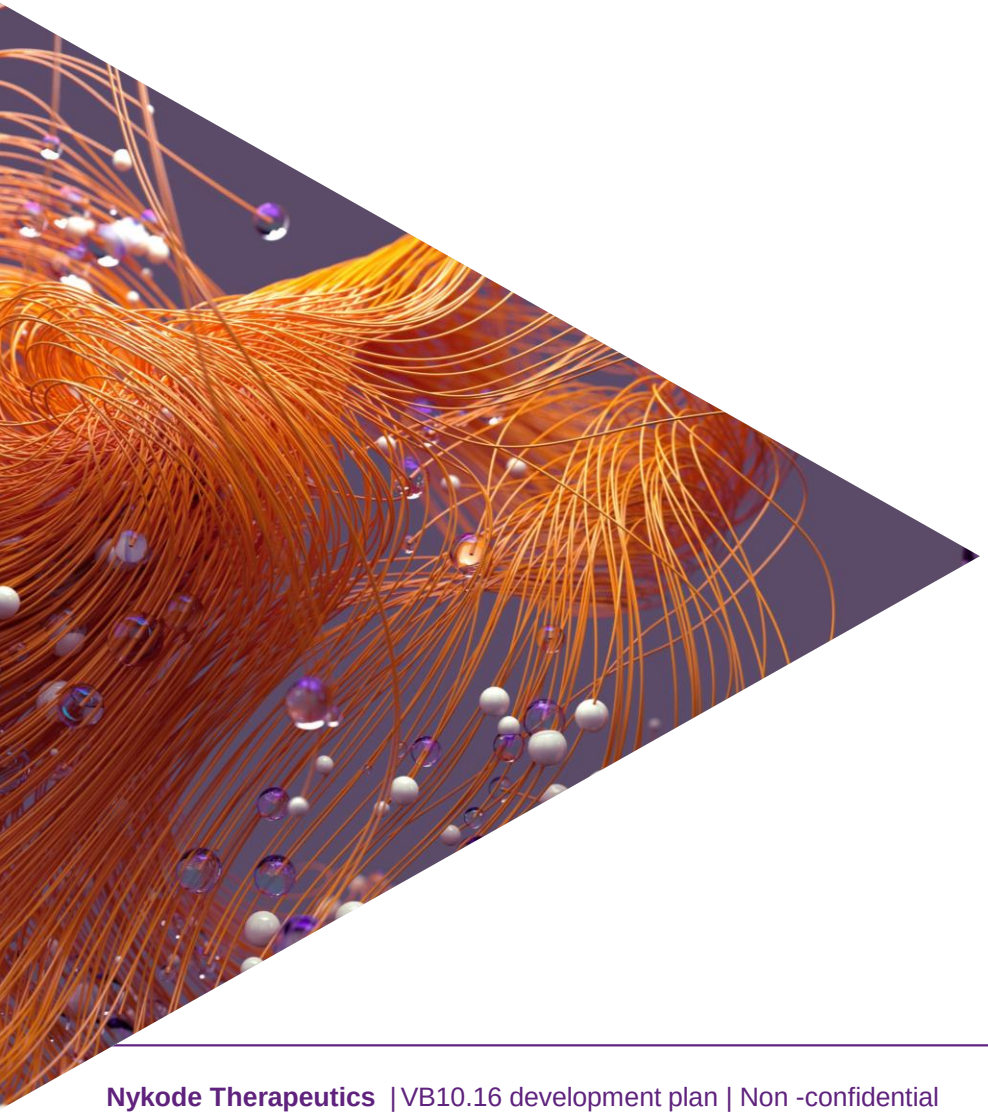
Potential investigator initiated basket trial with option for expansion

- **Key eligibility criteria**
  - HPV16+ anal, penile, vaginal and/or vulvar cancer
  - Patients who are no longer eligible for curative treatment (e.g. surgery)
  - Include both patients with PD-L1 positive and PD-L1 negative tumors
- **Key endpoints**
  - Overall response rate (RECIST 1.1 criteria)
  - Safety/tolerability
  - Antigen specific immune response
- **Exploratory endpoints**
  - Biomarkers (e.g. ctDNA)
  - Changes in tumor micro-environment

- **Dosing schedule VB10.16**
  - Combination treatment administered for up to 1 year
- **Dosing schedule CPI**
  - Treatment with approved dose for up to 2 years
- **Initial enrolment of approximately 10-15 patients per cohort with potential for expansion cohort(s) in case of positive signals**



Current treatment landscape for PD-L1 negative patient population

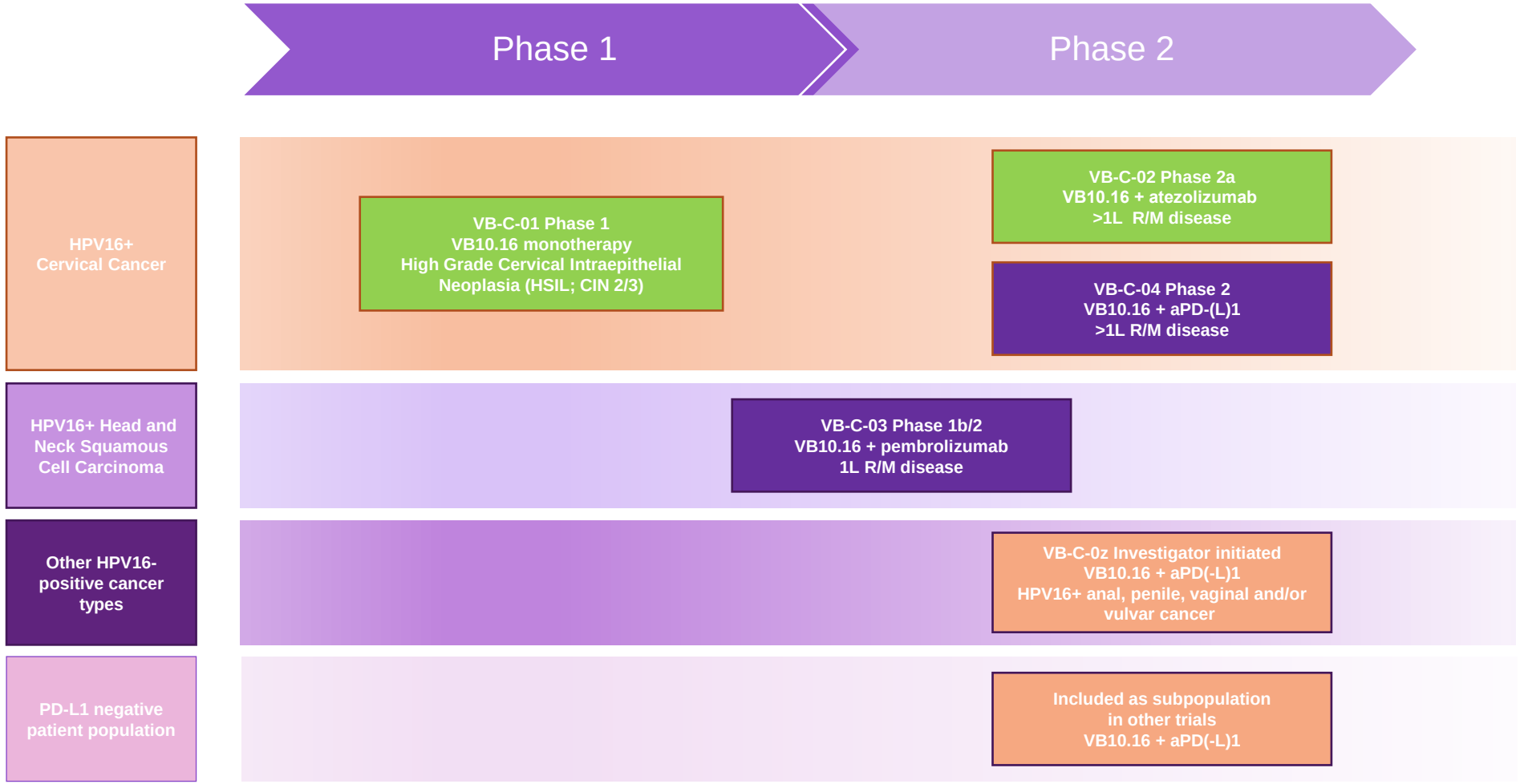


- **Chemotherapy-based regimens are current standard of care in US and EU for PD-L1 negative patients with recurrent or metastatic HPV16+ cancer**
- **Around 15-20% of patients with recurrent or metastatic HPV16+ cancers are PD-L1 negative**
- **Treatment options in PD-L1 negative patients who progress on or after treatment with chemotherapy are currently limited to salvage chemotherapy with poor outcomes (ORR 5-10%) or clinical trials* - urgent need for better treatment regimens in this setting**

***Cemiplimab recently approved in PD-L1 pos/neg R/M cervical cancer after progression on chemotherapy in EU only**

VB10.16 - Clinical Development

Overview of completed, ongoing and planned clinical trials



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 cash position of $212 mill at September 30, 2022
- Successful listing on main list of Oslo Stock Exchange
  - 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

Recent Achievements and Upcoming Catalysts

Key Priorities	Program	Indication	Partnerships	Milestones
Oncology • Advance internal oncology programs including cervical cancer program • Expand into additional indications for VB10.16, including head and neck cancer	VB10.16 (off-the-shelf)	HPV16+ cervical cancer	1 Roche 2 MSD	✓ Provided additional interim data ✓ Provide updated development strategy • Present updated Phase 2 data (1H 2023) • Initiate Phase Ib/2 trial in HNSCC • Initiate Phase 2 in cervical cancer
	VB10.NEO (individualized)	Melanoma, lung, bladder, renal, head and neck	3 Genentech	✓ Provided positive immunogenicity data Ph1/2
	Internal programs	Undisclosed		
Infectious Disease • Advance COVID-19 vaccines • Expand into additional high-priority disease areas	VB10.COV2	SARS-CoV-2	4 Adaptive	✓ Presented Phase 1 key results measuring immune responses in previously vaccinated subjects (2H 2022) • Guide on further development strategy
	Internal programs	Undisclosed		
Technology • Leverage technology platform				• Announce further preclinical data from Ag-specific immune tolerance platform
Manufacturing • Enhance control of manufacturing capacity and capability				✓ Provided update on manufacturing strategy

1. Roche supplies atezolizumab; 2. Merck (MSD) supplies pembrolizumab for HNSCC trial with VB10.16; 3. Genentech has an exclusive license to VB10.NEO; 4. Collaboration with Adaptive Biotechnologies on SARS-CoV-2 T cell vaccine

UNLOCKING THE FUTURE OF MEDICINE

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