



# HCW Global Investment Conference

September 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.

# Global leader in APC-targeted immunotherapy technology



## NYKODE THERAPEUTICS (NYKD-OL, MKT CAP ~\$700M)



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

- ◆ Final data from phase 2 VB-C-02- unprecedented long lasting survival benefit in advanced cervical cancer
- ◆ 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>



Well-capitalized with a cash position of \$174m at June 30, 2023

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

# Nykode executive management

## Experienced and international management team



**MICHAEL ENGSIG**

Chief Executive Officer



**AGNETE FREDRIKSEN**

Chief Business Officer & Co-founder



**MIKKEL W. PEDERSEN**

Chief Scientific Officer



**KLAUS EDVARDSEN**

Chief Development Officer



**HARALD GURVIN**

Chief Financial Officer



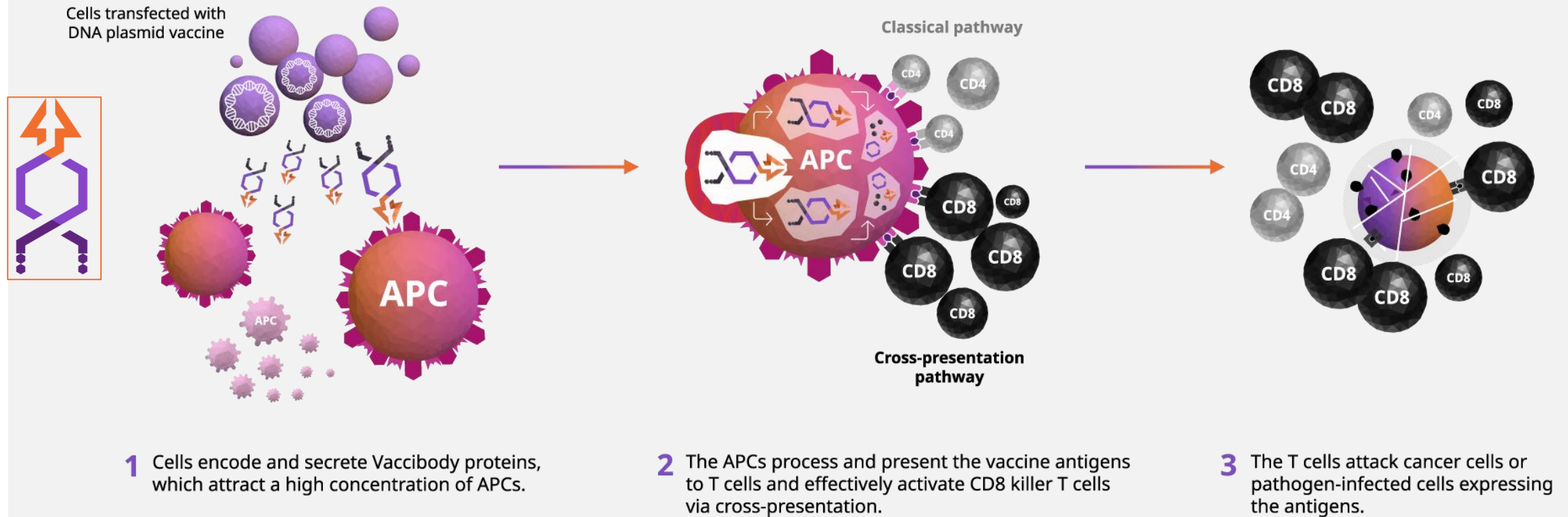
# Rich and diversified pipeline

	Asset	Indication	Rights	Preclinical	Phase 1	Phase 2	Phase 3	Upcoming Catalyst
<b>Oncology</b>								
Off-the-shelf	VB10.16	HPV16+ cervical cancer	1	[Progress bar: ~85%]				Initiate trial (Q4 2023)
		HPV16+ head and neck cancer	2	[Progress bar: ~60%]				FPPD (Q3 2023)
	Regeneron programs	Undisclosed	3	[Progress bar: ~30%]				
	Internal	Undisclosed	4	[Progress bar: ~30%]				Update (Q4 2023)
Individualized	VB10.NEO	Melanoma, lung, bladder, renal, head and neck cancer; locally advanced and metastatic tumors	4	[Progress bar: ~85%]				
		Locally advanced and metastatic tumors	4	[Progress bar: ~60%]				
<b>Infectious Disease</b>								
Regeneron programs		Undisclosed	3	[Progress bar: ~30%]				
Internal		Undisclosed	4	[Progress bar: ~30%]				
<b>Autoimmune</b>								
Internal		Undisclosed	4	[Progress bar: ~30%]				Update (Q3 2023)

1. Wholly-owned by Nykode. Potentially registrational. Roche supplies atezolizumab; 2. Wholly-owned by Nykode. Merck (MSD) supplies pembrolizumab; 3. Collaboration with Regeneron; 4. Genentech has an exclusive license to VB10.NEO.

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

## MECHANISM OF ACTION – T CELL INDUCTION



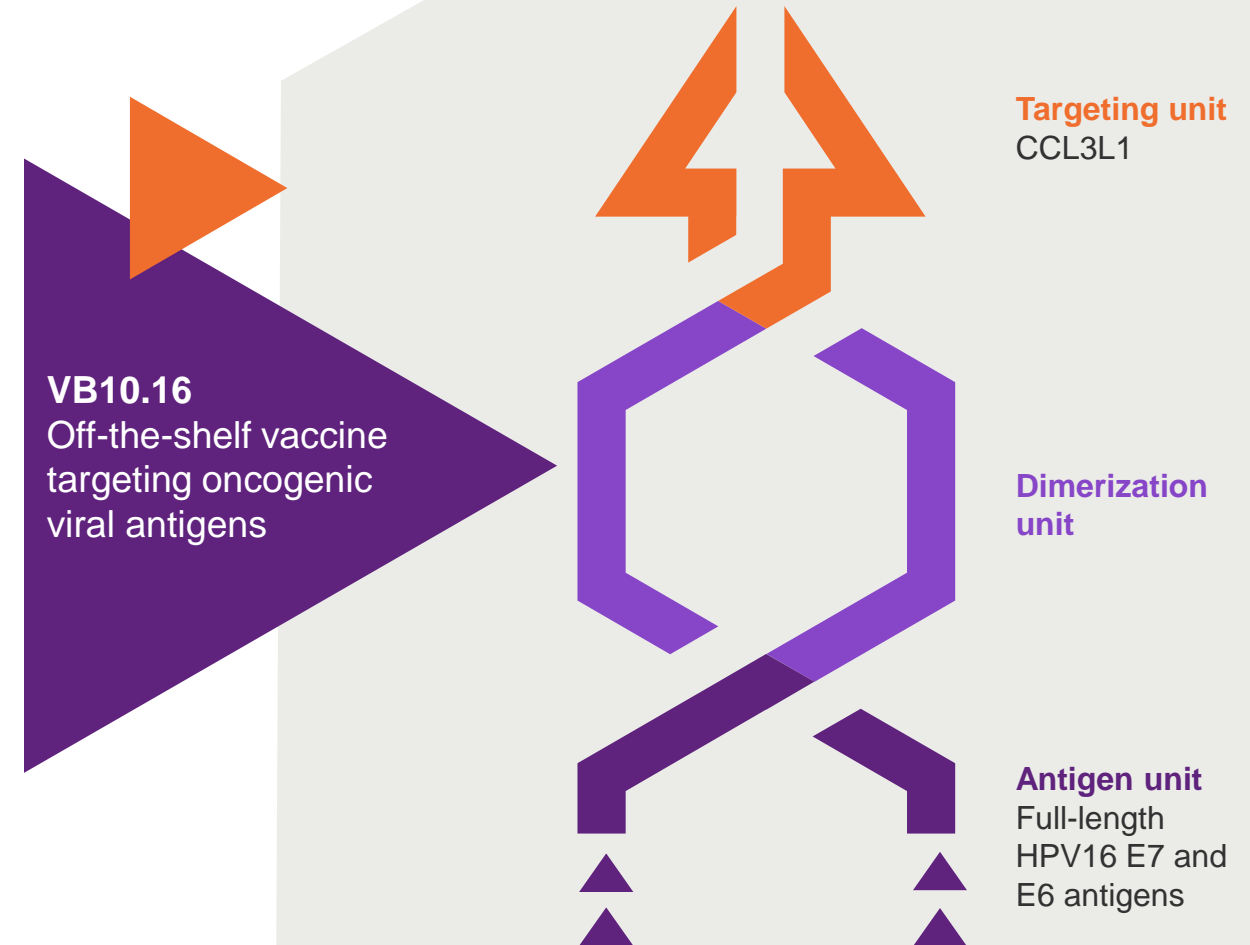


# **VB10.16 in HPV16+ cancers**

# VB10.16: Therapeutic vaccine candidate for HPV16+ cancers

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

- ◆ HPV16 is the most prevalent oncogenic HPV strain
- ◆ Targeting the cancer-specific full-length HPV16 E7 and E6 antigens
- ◆ Wholly-owned by Nykode





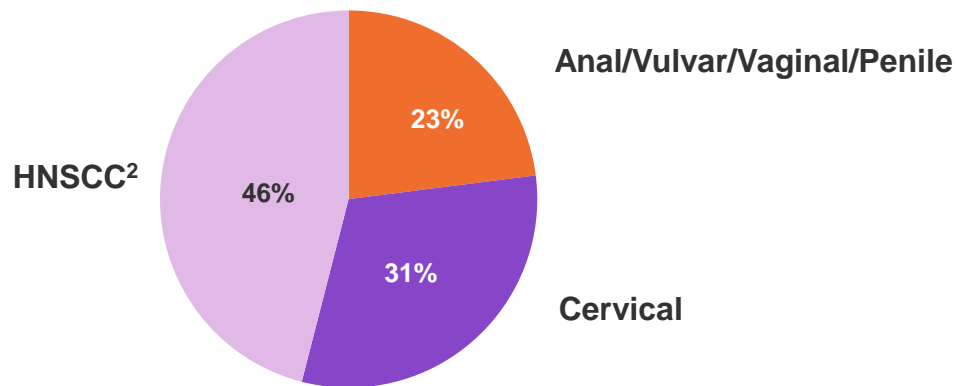
# HPV16+ cancers are a significant unmet need

Despite prophylactic HPV vaccination, HPV+ cancer incidence is expected to increase

## HPV+ cervical cancer

- 4<sup>th</sup> most common cancer in women worldwide
- 4<sup>th</sup> leading cause of cancer-related death
- Prognosis is poor for recurrent and/or metastatic (R/M) cervical cancers, 5-year survival <5%

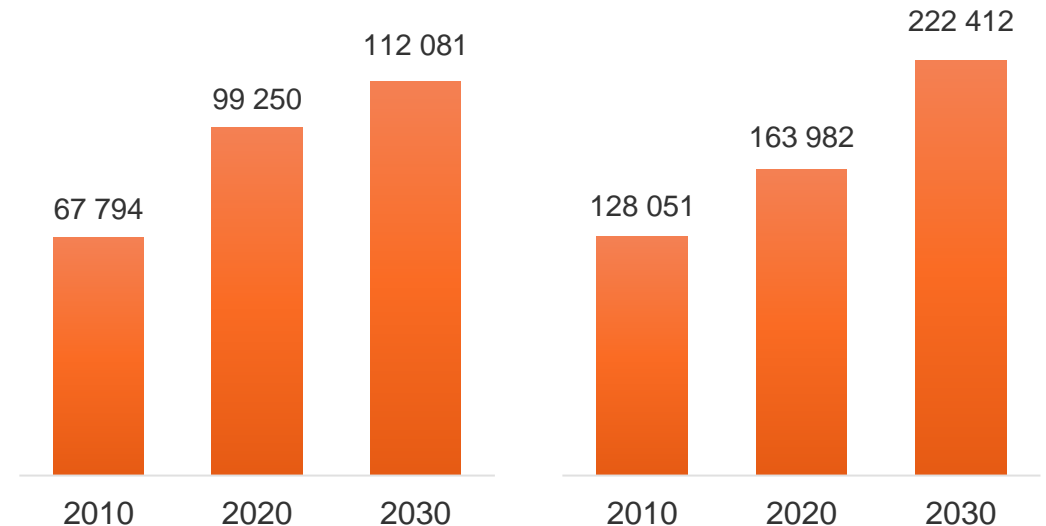
~130,000 new HPV16+ cancer cases per year (U.S. and Europe<sup>1</sup>)



## HPV-related cancer incidence is expected to grow

HPV+ cervical cancer diagnosed incident cases<sup>3</sup> (U.S. + EU5 + China + Japan)

HPV+ HNSCC diagnosed incident cases<sup>4</sup> (U.S. + EU5 + China + Japan)

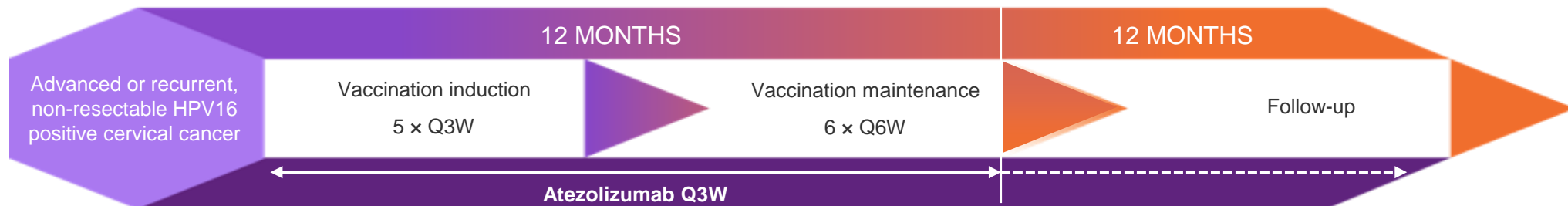


Sources and notes: <sup>1</sup> HPV information centre <https://hpcvcentre.net/statistics/reports/XEX.pdf?t=1680531103948>; American Cancer Society, Cancer Facts & Figures 2020 <https://www.cancer.org/>; Head Neck Pathol. 2012; 6:55; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3394159/>; J Natl Cancer Inst. 2015 Jun; 107(6): djv086 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838063/>; Internal analysis; <sup>2</sup> Head and neck squamous cell carcinoma; <sup>3</sup> GlobalData Cervical Cancer. 8 main markets (U.S., France, Germany, UK, Italy, Spain, Japan, China); <sup>4</sup> GlobalData HNSCC. 8 main markets (U.S., France, Germany, UK, Italy, Spain, Japan, China). Head Neck Pathol. 2012; 6:55; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3394159/>

# VB C-02: VB10.16 plus atezolizumab (Tecentriq®) 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, overall response rate (ORR) as per RECIST 1.1 by blinded independent central review (BICR)
- ◆ **Secondary endpoints:**
  - ◆ Duration of response (DOR)
  - ◆ Progression-free survival (PFS)
  - ◆ Overall survival (OS)
  - ◆ Evaluate immunogenicity of VB10.16 in combination with atezolizumab by analysing HPV16 E6/E7-specific cellular immune responses
- ◆ Conducted in Europe in 6 countries (Germany, Belgium, Bulgaria, Czech Republic, Poland and Norway)
- ◆ Fully enrolled with 52 patients
- ◆ Enrolled patients received treatment with 3 mg VB10.16 in combination with 1200 mg atezolizumab up to 48 weeks, with atezolizumab monotherapy dosed every 3 weeks, and a follow up period of up to 12 months



# Recent clinical progress has increased survival outcomes in advanced cervical cancer patients, but room for significant improvement remains

Patients that have failed 1 or more line of systemic treatment have limited Progression Free Survival and Overall Survival with current approved treatments



**mPFS of >4 months and mOS of >14 months combination with a favourable safety profile regarded as highly competitive / best-in-class**

Notes: <sup>1</sup> Tewari et al. Survival with cemiplimab in recurrent cervical cancer. N Engl J Med 2022. Chemotherapy at investigator choice as control arm; <sup>2</sup> Keynote-158 study update (Chung et al. Efficacy and safety of pembrolizumab in previously treated advanced cervical cancer: Results from the phase II KEYNOTE-158 study. J Clin Oncol 2019; Chung et al. Pembrolizumab treatment of advanced cervical cancer: Updated results from the phase II KEYNOTE-158 study. Gynecol Oncol 2021); <sup>3</sup> Coleman et al. Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): A multicentre, open-label, single-arm, phase 2 study. Lancet Oncol 2021. (Tabernero et al. Phase II multicohort study of atezolizumab monotherapy in multiple advanced solid cancers. ESMO Open. 2022 did not report PD-L1+ patient data).

# VB10.16 evaluated in pretreated advanced cervical cancer patients, with ~40% PD-L1 negative

## Baseline characteristics

PATIENT CHARACTERISTICS <sup>1</sup>		SAF <sup>2</sup> (n = 52)
Median age, years (range)		47.5 (27-83)
Histology	◆ Squamous cell carcinoma	81% (42/52)
	◆ Adenocarcinoma	15% (8/52)
	◆ Adenosquamous carcinoma	2% (1/52)
	◆ Unknown	2% (1/52)
Prior lines of SACT (range 0-5) <sup>3</sup>	◆ 0	4% (2/52)
	◆ 1	50% (26/52)
	◆ ≥ 2	46% (24/52)
ECOG PS	◆ 0	56% (29/52)
	◆ 1	44% (23/52)
PD-L1 expression <sup>4</sup>	◆ PD-L1+	48% (25/52)
	◆ PD-L1-	39% (20/52)
	◆ Unknown	14% (7/52)

ECOG PS: Eastern Cooperative Oncology Group performance status; SACT: systemic anticancer therapy.

Note: <sup>1</sup> Total may not sum to 100% due to rounding; <sup>2</sup> Safety analysis set; <sup>3</sup>Prior lines of therapy did not include CPI. <sup>4</sup>PD-L1 expression was evaluated using Ventana clone SP263 .

# VB10.16 was generally well-tolerated

VB10.16 plus atezolizumab tolerability profile was consistent with checkpoint inhibitor monotherapy<sup>1</sup>

Treatment-related Adverse Events assessed as related to VB10.16 (n = 52)

System Organ Class Preferred Term	Grade 1-2 n (%)	Grade 3-4 n (%)
<b>All AEs related to VB10.16</b>	<b>15 (31%)</b>	<b>1 (2%)</b>
<b>General disorders and adm. site conditions.</b>	<b>10 (19%)</b>	–
♦ Administration site pain	2 (4%)	–
♦ Fatigue	1 (2%)	–
♦ Injection site bruising	2 (4%)	–
♦ Injection site discomfort	3 (6%)	–
♦ Injection site haematoma	1 (2%)	–
♦ Injection site pain	2 (4%)	–
<b>Injury, poisoning and procedural complications</b>	<b>1 (2%)</b>	–
♦ Infusion related reaction	1 (2%)	–
<b>Metabolism and nutrition disorders</b>	<b>1 (2%)</b>	–
♦ Decreased appetite	1 (2%)	–
<b>Musculoskeletal and connective tissue disorders</b>	<b>2 (4%)</b>	<b>1 (2%)</b>
♦ Arthralgia	–	1 (2%)
♦ Myalgia	2 (4%)	–
<b>Skin and subcutaneous tissue disorders</b>	<b>4 (8%)</b>	–
♦ Erythema	1 (2%)	–
♦ Pruritus	2 (4%)	–
♦ Rash	2 (4%)	–

VB10.16 in combination with atezolizumab was generally well-tolerated and showed a favourable tolerability profile

- ♦ Treatment-related AEs of any grade related to either VB10.16 or atezolizumab were seen in 67% of patients
- ♦ Most treatment-related AEs were mild or moderate (gr. 1-2)
  - ♦ Five patients (10%) experienced treatment-related AEs of gr. 3 related to atezolizumab
  - ♦ Of these, 1 event of gr. 3 arthralgia was additionally reported as related to VB10.16
- ♦ **No serious AEs were reported related to VB10.16**
- ♦ No deaths were related to either VB10.16 or atezolizumab

Note: 52 patients were included in the safety population; Median number of VB10.16 doses given was 5 (range 1-11); AE = adverse event; <sup>1</sup> Taberero et al. Phase II multicohort study of atezolizumab monotherapy in multiple advanced solid cancers. ESMO Open. 2022.

# Strong anti-tumor effect leading to prolonged overall survival (compared to CPI alone)<sup>1</sup>

High mOS of >25 months (not reached) and mPFS 6.3 months in PD-L1+ patients

Endpoint	All patients (n = 47 <sup>2</sup> )		PD-L1+ (n = 24 <sup>3</sup> )	
	Value	95% CI	Value	95% CI
ORR	19%	(9%-33%)	29%	(13%-51%)
CR	6%	(1%-18%)	8%	(1%-27%)
DCR	60%	(44%-74%)	75%	(53%-90%)
MR	19%	(9%-33%)	17%	(5%-37%)
mDOR, months	<b>17.1</b>	(2.6-n.r.)	<b>17.1</b>	(2.2-n.r.)
mPFS, months	<b>4.1</b>	(2.1-6.2)	<b>6.3</b>	(3.6-16.9)
mOS, months	<b>16.9</b>	(8.3-n.r.)	<b>n.r. (&gt; 25)</b>	N.A

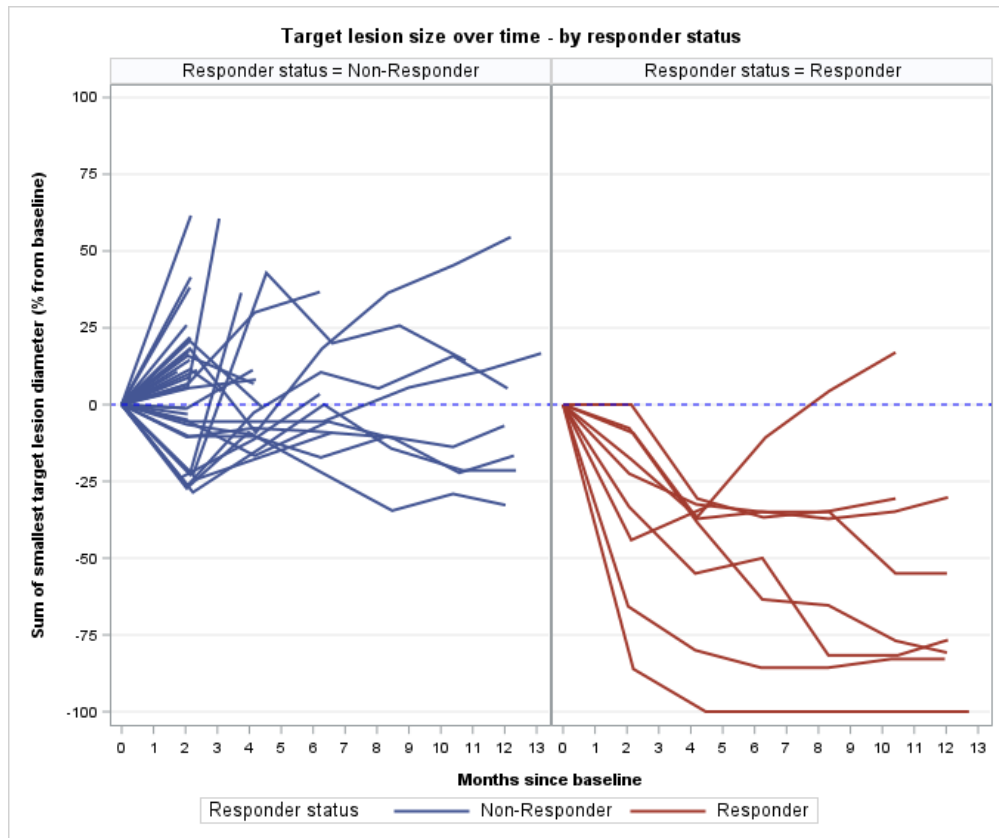
- ◆ Strong and durable anti-tumor efficacy across all patients with 16.9 months mOS
- ◆ Even stronger signal in PD-L1+ sub-population with mOS not reached (25+ months) and mPFS 6.3 months

Note: <sup>1</sup>Chung et al. Efficacy and safety of pembrolizumab in previously treated advanced cervical cancer: Results from the phase II KEYNOTE-158 study. J Clin Oncol 2019; Tewari et al. Survival with cemiplimab in recurrent cervical cancer. N Engl J Med 2022; Tabernero et al. Phase II multicohort study of atezolizumab monotherapy in multiple advanced solid cancers. ESMO Open. 2022.

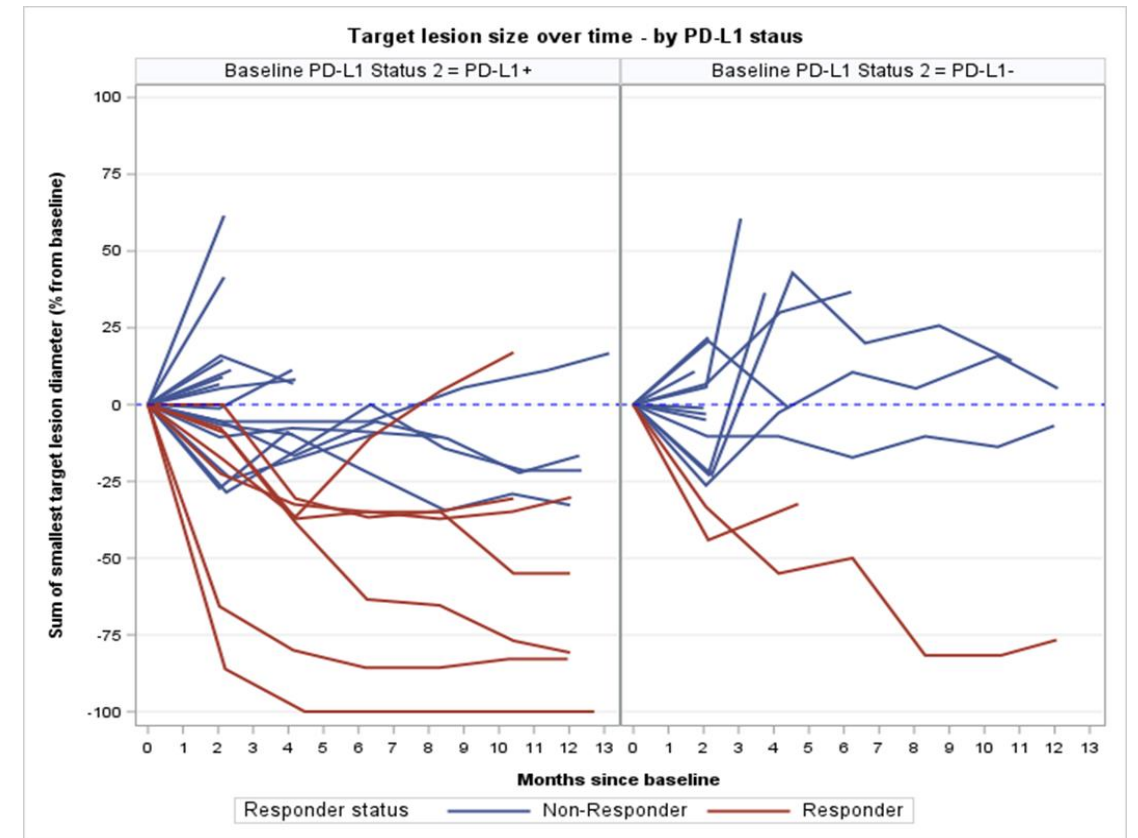
<sup>2</sup> The number of patients evaluable for a response is 47 (the Efficacy Analysis Set, EAS); <sup>3</sup> 24 out of 47 patients with PD-L1+ marker; CI: Confidence interval; CR: Complete response; MR: Minimal response (SD with tumor shrinkage ≥ 10% to < 30%); ORR: overall response rate

# VB10.16 coupled with CPI led to lasting responses

All (n = 47)



By PD-L1 status (n = 40)

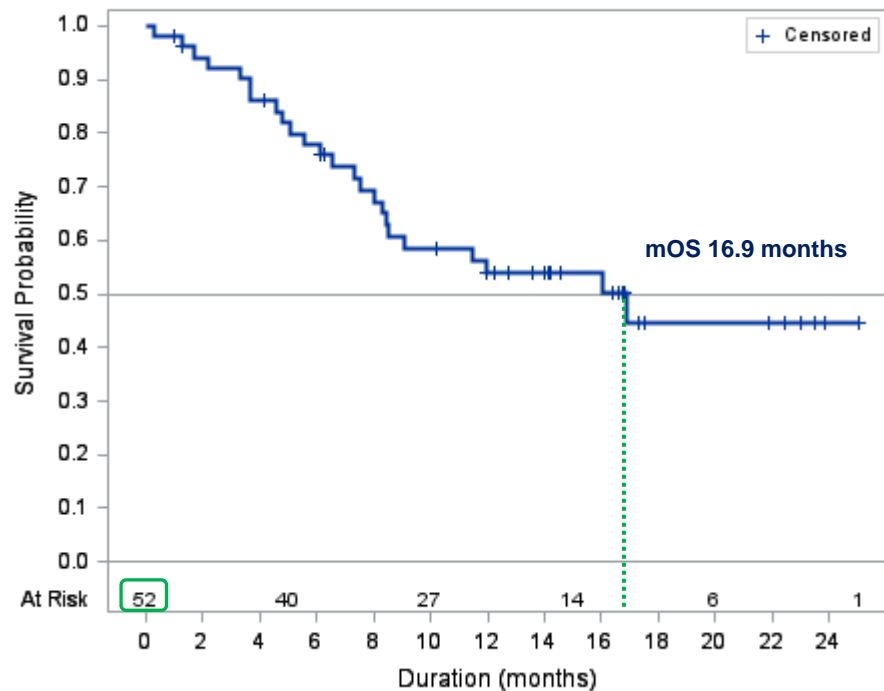


Note: 7 out of 47 responders had PD-L1 unknown status, 40 out of 47 had known PD-L1 status

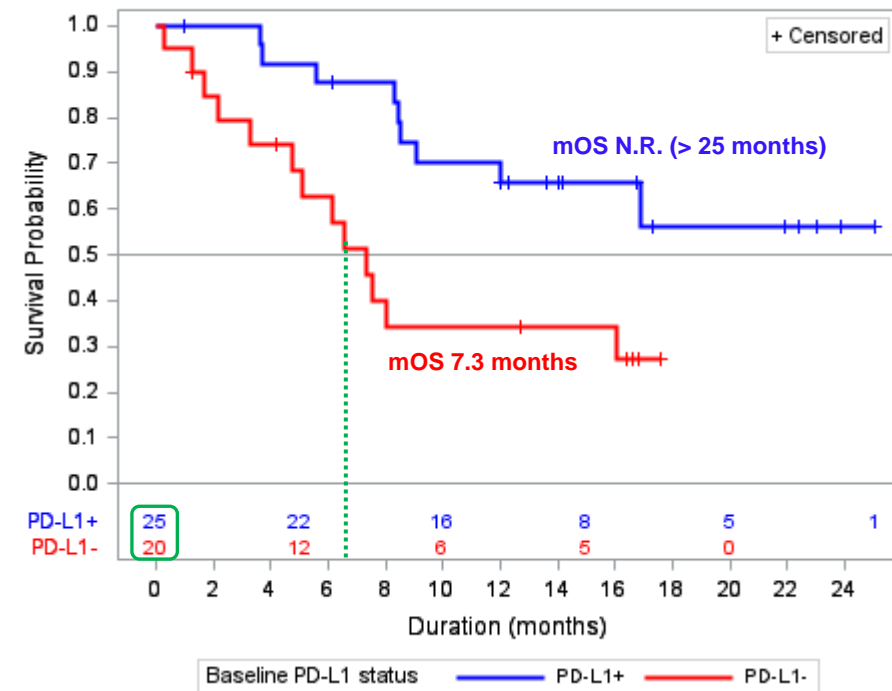
# VB10.16 led to prolonged overall survival in advanced cervical cancer patients

Median overall survival of 16.9 months in overall population, mOS not reached (> 25 months) in PD-L1+ patients

Overall survival



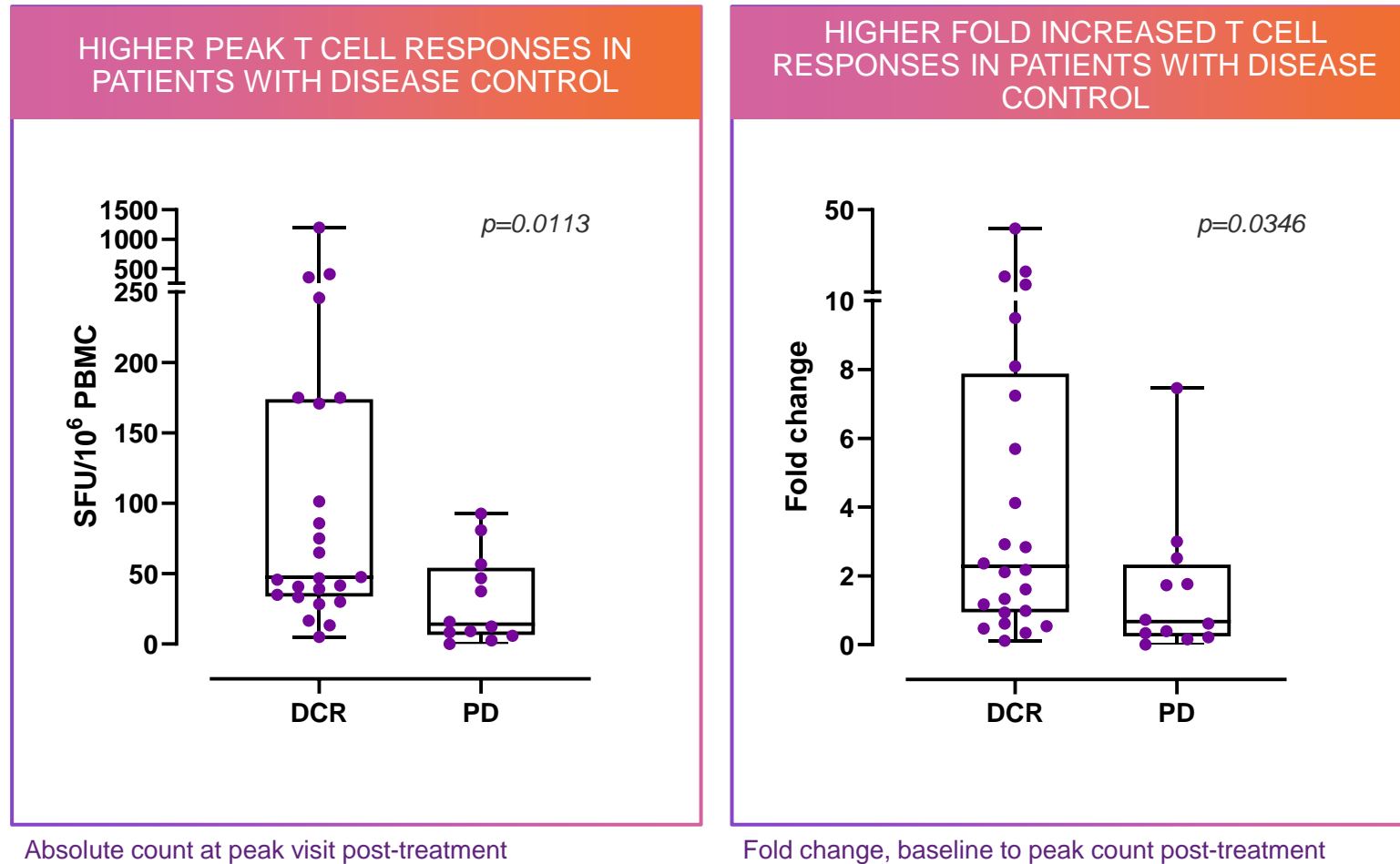
Overall survival (PD-L1+ vs. PD-L1-)



Note: All patients evaluated for OS, n = 7 where PD-L1 status unknown



# VB10.16 induced HPV16-specific T cell responses that are significantly correlated with clinical response



Note: Ex vivo ELISpot analysing HPV16 E6 and E7 responses with background subtracted n = 36 (n = 24 DCR, n = 12 PD). Data not available for 11 subjects

# Data from the VB10.16 Ph2 trial compared with relevant current and future SoC as evaluated in third-party trials

Endpoint	VB10.16 plus atezolizumab in PD-L1+ (n = 24)	Pembrolizumab in PD-L1+ (Keynote-158, n = 82)**	Cemiplimab in PD-L1+ (Empower-Cervical 1, n = 82, cemiplimab arm) ††	Tisotumab vedotin (PD-L1 agnostic) (InnovaTV 204, n = 101) †‡
ORR	29%*	17%	18%	24%
mPFS	6.3 mo‡	2.1 mo	3.0 mo	4.2 mo
mOS	Not reached (25.0+ mo)	11.0 mo	13.9 mo	12.1 mo

Notes: The data shown on this slide represents third-party clinical trials involving different trial designs and patient populations. These trials are not head-to-head evaluations of VB10.16 against standard of care

NA = not available in publication / presentation / abstract

\* 40% (6/15) in PD-L1+ with **1 prior line** of systemic anticancer therapy (SACT)

† 80% (12/15) in PD-L1+ with **1 prior line** of SACT

‡ 16.9 mo in PD-L1+ with **1 prior line** of SACT (n = 15)

\*\* Chung et al. Efficacy and safety of pembrolizumab in previously treated advanced cervical cancer: Results from the phase II KEYNOTE-158 study. J Clin Oncol 2019

†† Tewari et al. Survival with cemiplimab in recurrent cervical cancer. N Engl J Med 2022

‡‡ Coleman et al. Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): A multicentre, open-label, single-arm, phase 2 study. Lancet Oncol 2021

(Tabernero et al. Phase II multicohort study of atezolizumab monotherapy in multiple advanced solid cancers. ESMO Open. 2022 did not report PD-L1+ patient data).

# VB10.16 has broad potential across HPV-driven cancers

## FINALIZED. REPORTED POSITIVE DATA

### C-01 Ph 1/2a Pre-cancerous Cervical Lesions

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

## ONGOING. REPORTED POSITIVE INTERIM DATA

### C-02 Ph 2a Cervical Cancer

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

## EXPANSION PLANNED FOR 2023

### C-03 Ph 1/2a Head and Neck Cancer

- ◆ VB10.16, up to 9 mg in combination with pembrolizumab (Keytruda®)
- ◆ 1<sup>st</sup> line unresectable recurrent or metastatic head and neck cancer (HNSCC) and PD-L1+
- ◆ CTA submitted, Q4 2022
- ◆ First patient dosed, expected 1H 2023


### C-04 Ph 2 Cervical Cancer

- ◆ VB10.16 in combination with atezolizumab (Tecentriq®)
- ◆ Potentially **registrational trial** in the U.S.
- ◆ Collaboration with GOG
- ◆ Recurrent/ metastatic cervical cancer and PD-L1+ tumors
- ◆ First patient dosed, expected 4Q 2023

## FURTHER POTENTIAL

### Earlier lines and other HPV+ driven cancers

- ◆ Adjuvant/locally advanced HPV16+ cervical and HNSCC
- ◆ Additional HPV16+ cancers (anal, penile, vaginal)
- ◆ PD-L1- HPV16+ tumors



# **VB10.NEO- Individualized cancer immunotherapy**

# 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

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 for individualized cancer neoantigen immunotherapy


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

- ◆ Trained on Vaccibody'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

## 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

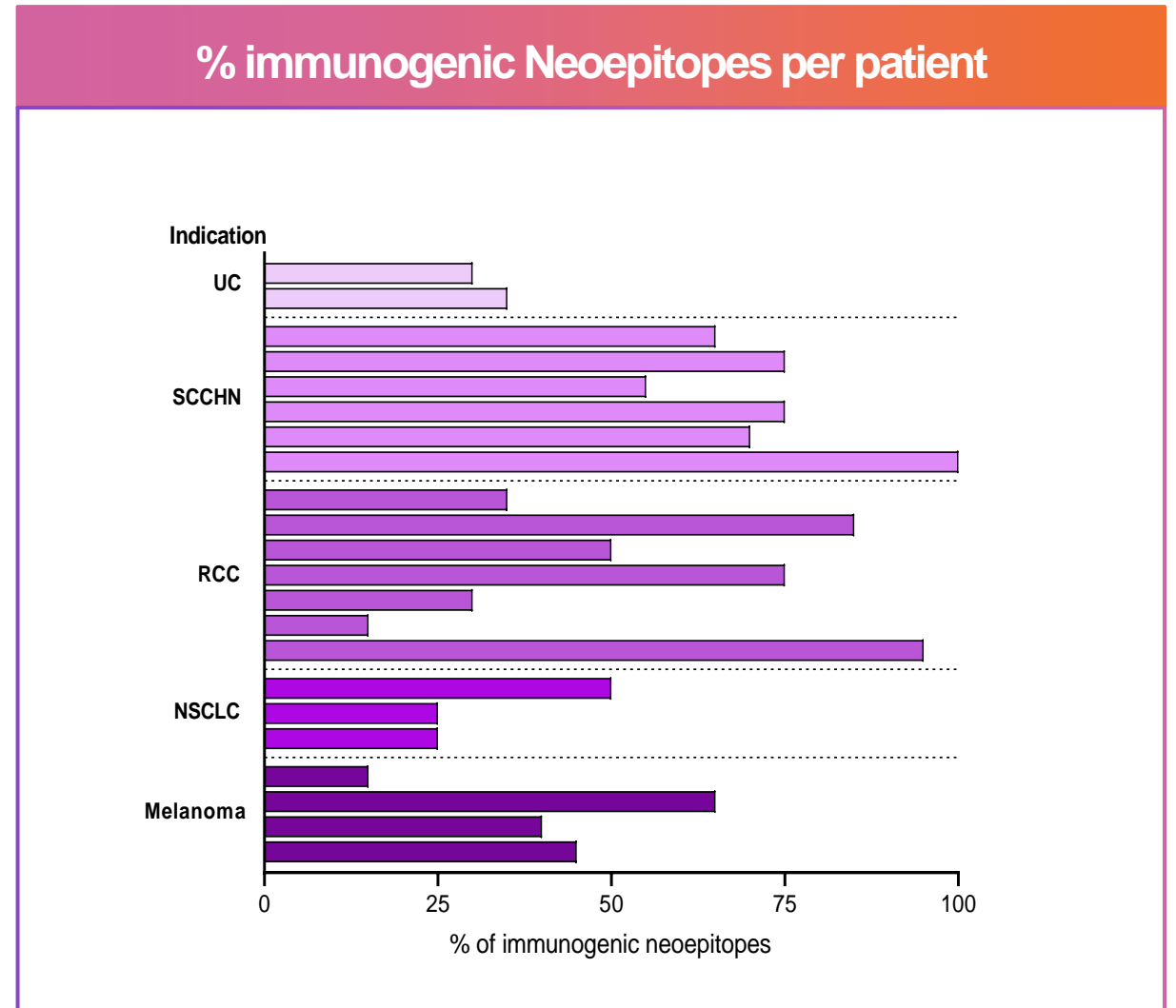


**VB10.NEO**  
Fully individualized immunotherapy against the patient's individual cancer specific mutations

# 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)

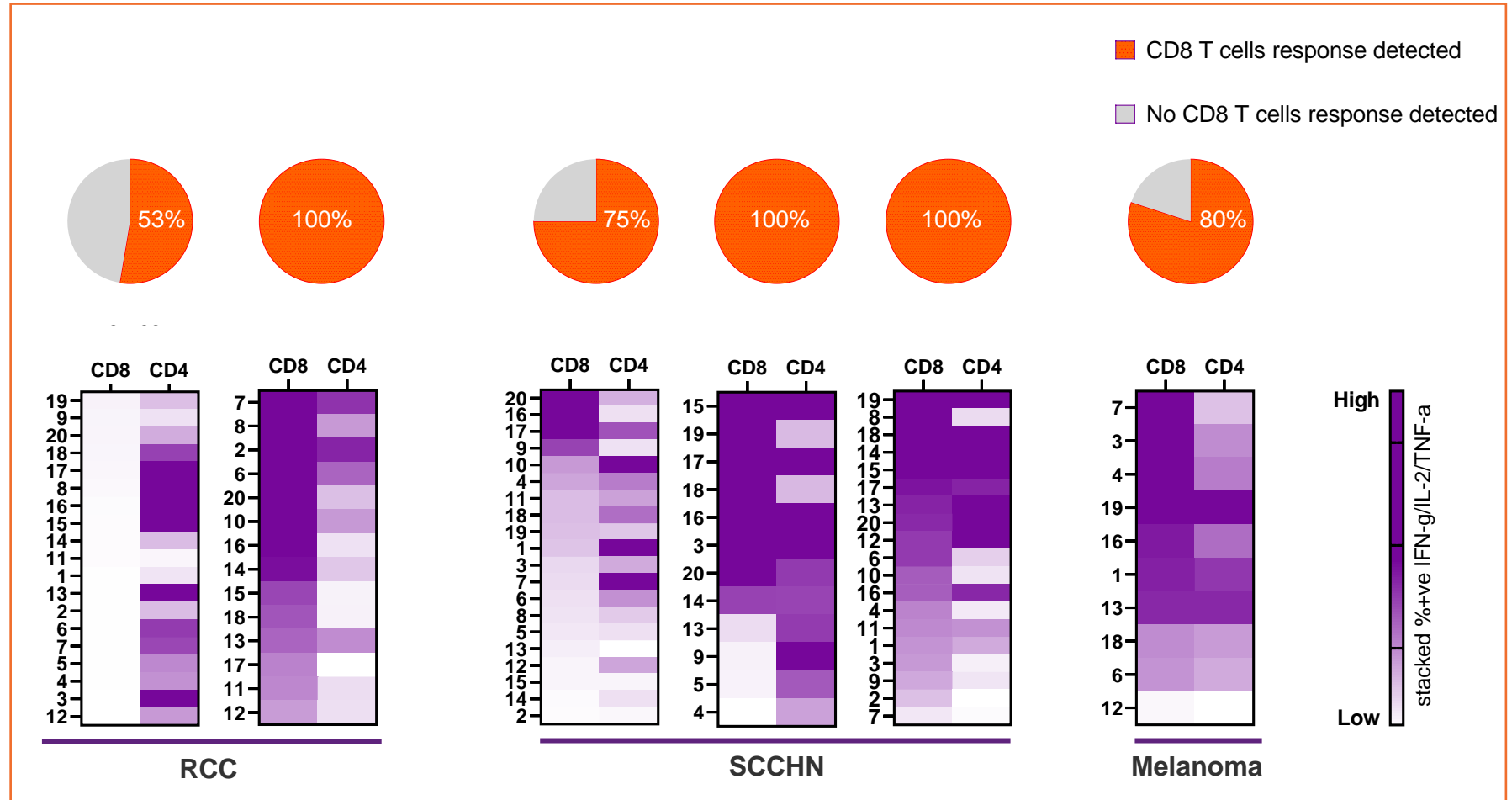
On average, 53% of selected neopeptopes were immunogenic, ranging from 3 to all 20 neopeptopes in the VB10.NEO immunotherapy demonstrating a broad response



# 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



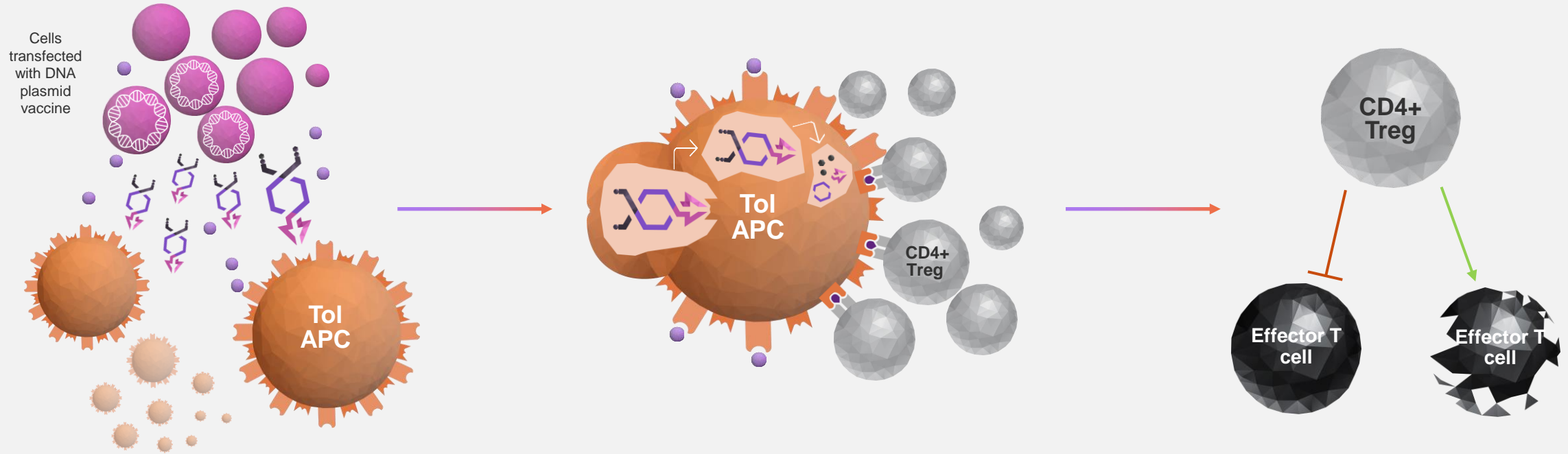




# Autoimmunity and Further platform potential

# Tolerance induction

## MECHANISM OF ACTION – TOLERANCE INDUCTION



**1** Cells encode and secrete Tol APC-targeted Vaccibody proteins together with immunosuppressive molecules/modulators to enhance tolerogenic APC function.

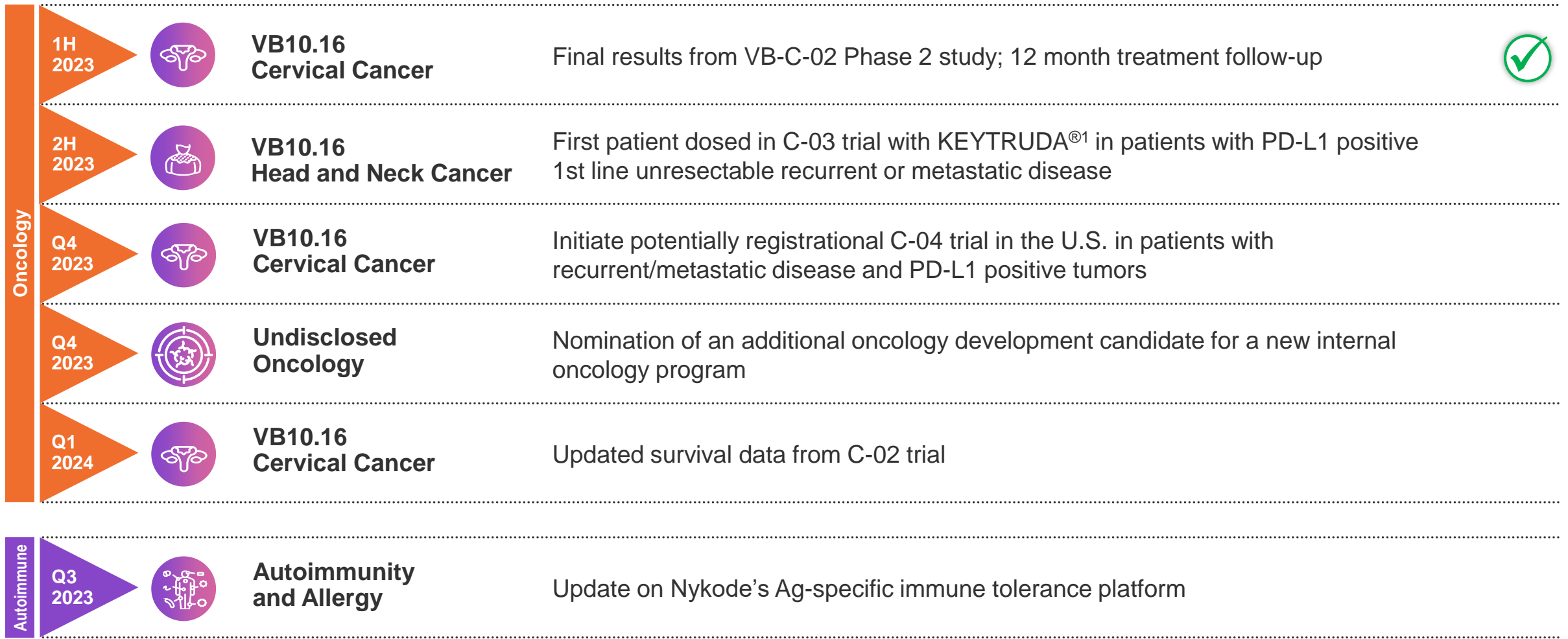
**2** The Tol APCs present vaccine antigens in a tolerogenic milieu supported by the vaccine co-encoded suppressive molecules, and prime regulatory T cell (Treg) activation and expansion.

**3** The Tregs inhibit or delete disease-specific effector T cells.



# Outlook and financial overview

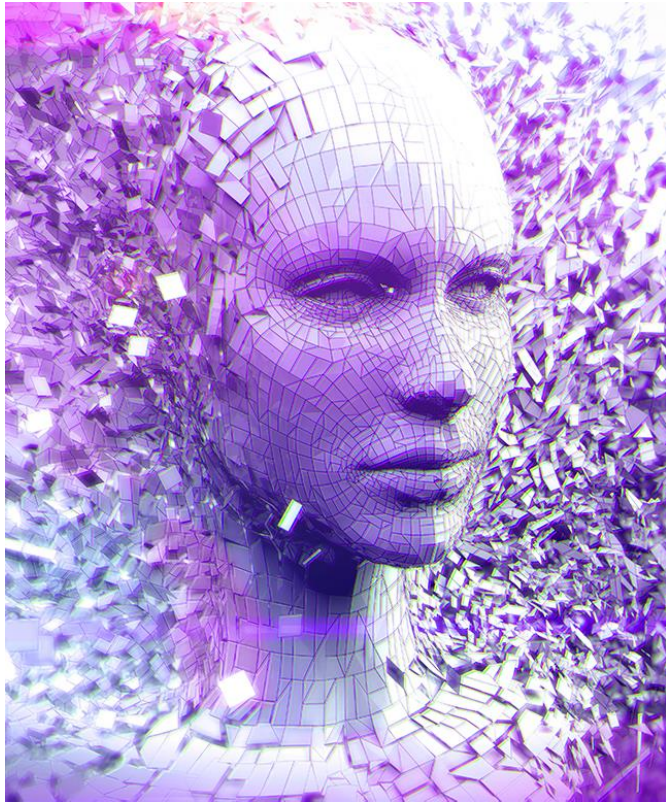
# Rich calendar of milestones expected in the next 12 months



Note: The news flow from the collaboration with Genentech and Regeneron is at their discretion, respectively  
1: KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

# Strong financial foundation for achieving our vision

Cash position of \$174m end Q2 2023



- ◆ Financially well positioned to execute the Company's strategy over the next years
- ◆ Nykode continues to explore a potential listing on the Nasdaq Global Market in the United States

# UNLOCKING THE FUTURE OF MEDICINE

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