

## ABGSC Life Science Summit

Stockholm



## **Forward-looking statement**

This announcement and any materials distributed in connection with this presentation may contain certain forwardlooking 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>



副

Well-capitalized with a cash position of \$186m at March 31, 2023

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

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** 





**PPD** 

∽ KLIFO



AGNETE FREDRIKSEN

Chief Business Officer & Co-founder







MIKKEL W. PEDERSEN Chief Scientific Officer

SERVIER,\*

symphoger

KLAUS EDVARDSEN

Chief Development Officer







HARALD GURVIN Chief Financial Officer





Nykode Therapeutics | ABGSC Life Science Summit

## **Rich and diversified pipeline**

	Asset	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Rights
Oncology	Oncology						
	VB10.16	HPV16+ cervical cancer					nykode
	VB10.16	HPV16+ head and neck cancer					<sup>2</sup> nykode
Off-the-shelf	Regeneron programs	Undisclosed					
	Internal	Undisclosed					nykode
Individualized	VB10.NEO	Melanoma, lung, bladder, renal, head and neck cancer; locally advanced and metastatic tumors					4 Nykode Genentech A Member of the Rache Group
	VB10.NEO	Locally advanced and metastatic tumors					4 Genentech
Infectious Disease							
	Regeneron programs	Undisclosed					
	Internal	Undisclosed					nykode
Autoimmune							
	Internal	Undisclosed					nykode

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



## 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

- 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%</li>

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



#### HPV-related cancer incidence is expected to grow

HPV+ cervical cancerHPV+diagnosed incident cases3diagnosed in(U.S. + EU5 + China + Japan)(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://hpvcentre.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	<ul> <li>Squamous cell carcinoma</li> </ul>	81% (42/52)
	<ul> <li>Adenocarcinoma</li> </ul>	15% (8/52)
	<ul> <li>Adenosquamous carcinoma</li> </ul>	2% (1/52)
	<ul> <li>♦ Unknown</li> </ul>	2% (1/52)
Prior lines of SACT	<ul> <li>0</li> </ul>	4% (2/52)
(range 0-5) <sup>3</sup>	<ul><li>◆ 1</li></ul>	50% (26/52)
		46% (24/52)
ECOG PS	<ul> <li>0</li> </ul>	56% (29/52)
	<ul><li>◆ 1</li></ul>	44% (23/52)
PD-L1 expression <sup>4</sup>	<ul> <li>PD-L1+</li> </ul>	48% (25/52)
	<ul> <li>PD-L1-</li> </ul>	39% (20/52)
	Unknown	14% (7/52)

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

Note: 1 Total may not sum to 100% due to rounding; 2 Safety analysis set; 3 Prior lines of therapy did not include CPI. 4 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 (%)
All AEs related to VB10.16	15 (31%)	1 (2%)
General disorders and adm. site conditions.	10 (19%)	-
Administration site pain	2 (4%)	-
Fatigue	1 (2%)	-
Injection site bruising	2 (4%)	_
Injection site discomfort	3 (6%)	_
<ul> <li>Injection site haematoma</li> </ul>	1 (2%)	_
Injection site pain	2 (4%)	-
Injury, poisoning and procedural complications	1 (2%)	-
Infusion related reaction	1 (2%)	-
Metabolism and nutrition disorders	1 (2%)	-
Decreased appetite	1 (2%)	_
Musculoskeletal and connective tissue disorders	2 (4%)	1 (2%)
Arthralgia	_	1 (2%)
Myalgia	2 (4%)	-
Skin and subcutaneous tissue disorders	4 (8%)	-
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> Tabernero 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 = $47^2$ ) PD-L1+ (n = $24^3$ )		= 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	17.1	(2.6-n.r.)	17.1	(2.2-n.r.)
mPFS, months	4.1	(2.1-6.2)	6.3	(3.6-16.9)
mOS, months	16.9	(8.3-n.r.)	n.r. (> 25)	N.A

- Strong and durable anti-tumor efficacy across all patients with 16.9 months mOS
- Even stronger signal in PD-L1+ subpopulation 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) <sup>††</sup>	Tisotumab vedotin (PD-L1 agnostic) (InnovaTV 204, n = 101) <sup>‡‡</sup>
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

<sup>++</sup> Tewari et al. Survival with cemiplimab in recurrent cervical cancer. N Engl J Med 2022

<sup>‡‡</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 has broad potential across HPV-driven cancers



# VB10.16 in combination with atezolizumab showed promising clinical profile with favorable tolerability in patients with advanced HPV16+ cervical cancer, an area of high unmet medical need

- Clinically relevant endpoint mPFS was 4.1, 6.3 and 16.9 months for all, PD-L1+ and PD-L1+ with one prior treatment line, respectively
- Clinically relevant endpoint mOS was 16.9 months and not reached (> 25 months) for all patients and PD-L1+ patients, respectively
- VB10.16 plus atezolizumab demonstrated ORR 19% with median duration of response 17.1 months and DCR of 60%
- In the PD-L1+ and PD-L1+ plus one prior treatment line subgroups, overall response rates were 29% and 40%, respectively

Together these findings indicate a potentially differentiated and lasting anti-tumor response pattern of the combination treatment compared to checkpoint inhibitor monotherapy<sup>1</sup>

The subgroup analyses support the planned studies with VB10.16 in PD-L1+ patients who have received max 1 prior line of systemic anticancer treatment in the advanced disease setting

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.

## VB10.NEO-Individualized cancer immunotherapy

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



#### ONGOING IN >10 INDICATIONS, COLLABORATION WITH GENENTECH



- 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

**VB10.NEO** 

mutations

Fully individualized

patient's individual cancer specific

immunotherapy against the

#### **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

## **T-cell responses to the majority of selected neoepitopes**

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

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

#### % immunogenic Neoepitopes per patient



# 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**



# Nykode's modular platform is designed to unlock multiple applications across targets and therapeutic areas



# Outlook and financial overview

## **Rich calendar of milestones expected in the next 12 months**

	1H   VB10.16     2023   Cervical Cancer		Final results from VB-C-02 Phase 2 study; 12 month treatment follow-up	
Oncology	1H 2023	VB10.16 Head and Neck Cancer	First patient dosed in C-03 trial with KEYTRUDA <sup>®</sup> in patients with PD-L1 positive 1st line unresectable recurrent or metastatic disease	
	4Q 2023	VB10.16 Cervical Cancer	Initiate potentially registrational C-04 trial in the U.S. in patients with recurrent/metastatic disease and PD-L1 positive tumors	
	4Q 2023	Undisclosed Oncology	Nomination of an additional oncology development candidate for a new internal oncology program	
	1Q 2024	VB10.16 Cervical Cancer	Updated survival data from C-02 trial	
Autoimmune	3Q 2023	Autoimmunity and Allergy	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

## Strong financial foundation for achieving our vision

### Cash position of \$186m end Q1 2023



- Financially well positioned to grow and execute the Company's strategy over the next years
- Published inaugural ESG report for 2022
- Nykode continues to explore a potential listing on the Nasdaq Global Market in the United States

# UNLOCKING THE FUTURE OF MEDICINE

Contact: Agnete Fredriksen CBO IR@nykode.com

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