

vaccibody

Vaccibody

Lunsjpresentasjon hos Arctic Securities

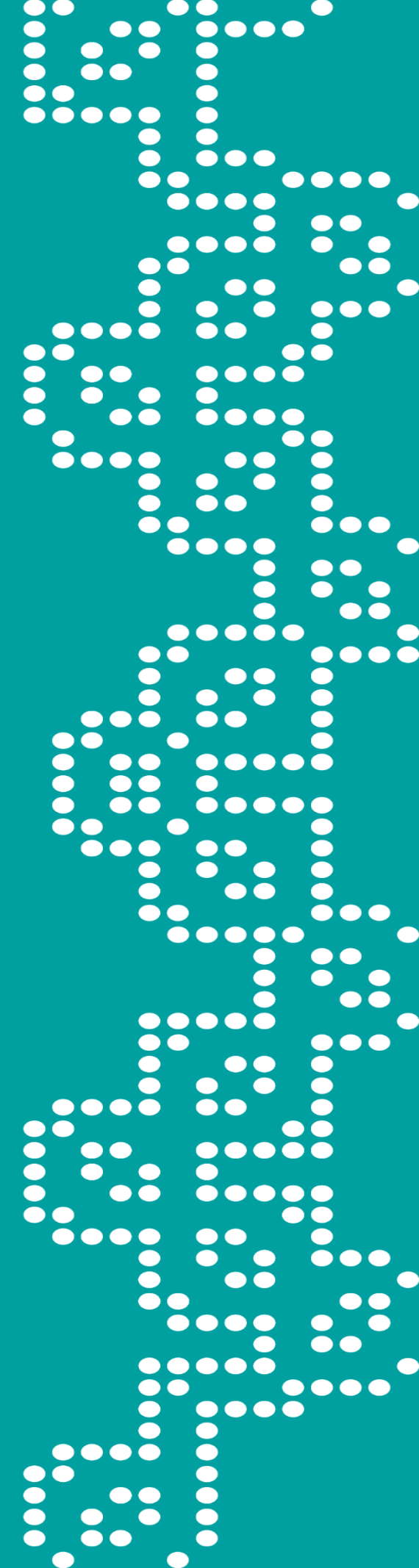
Oslo, Onsdag 4. september 2019

Agnete Fredriksen, PhD
President & CSO

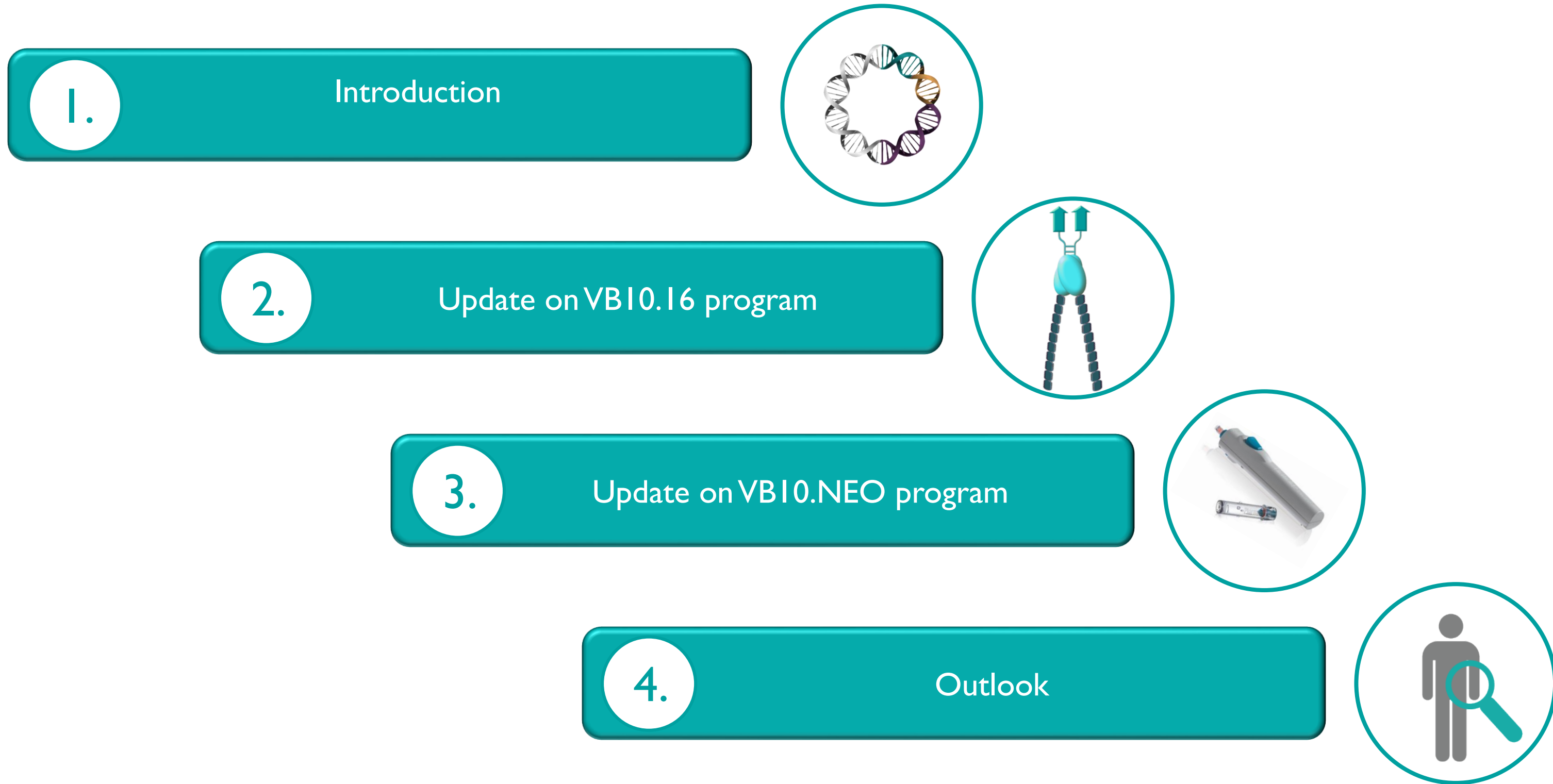
abfredriksen@vaccibody.com

Michael Engsig, M.Sc, BComm,
CEO

mengsig@vaccibody.com



Agenda



Personal introduction

- Technical University of Denmark - Biotechnology
- Copenhagen University - B.Com, Leadership & Organisation

- Nordic Bioscience - Early stage drug discovery
- Alfred Berg Investment Bank - Equity analyst Biotech & Pharma
- Nycomed - Late stage drug development, global clinical trial operations
- Takeda - commercial operations
- PPD international - Regional head Clinical Trial Management
- KLIFO - Heading Drug development Counselling



Experience across the entire value chain from early drug discovery over late stage development and commercialisation

Vaccibody AS in summary

- Founded in 2007 in Oslo, Norway
- Privately held clinical stage immuno-oncology company, spun-out from Oslo University, 25 employees
- Proprietary, patented vaccine technology
- Experienced, international management team with oncology expertise and thorough drug development experience



Michael Engsig,
CEO



Agnete B. Frederiksen,
Founder, President and CSO

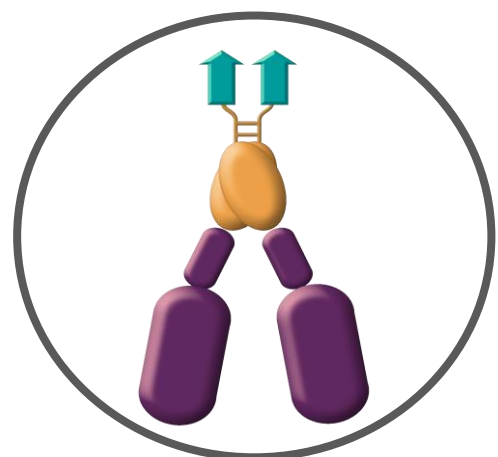


Mads B. Axelsen,
CMO



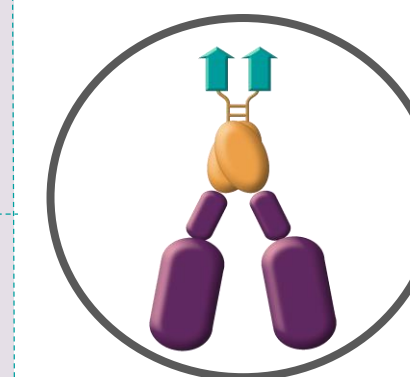
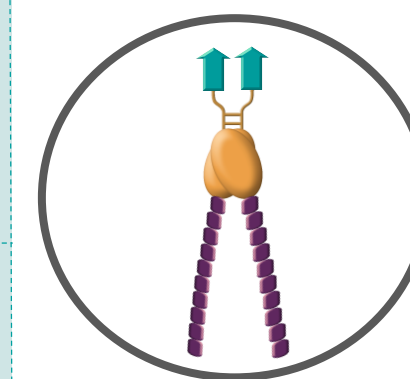
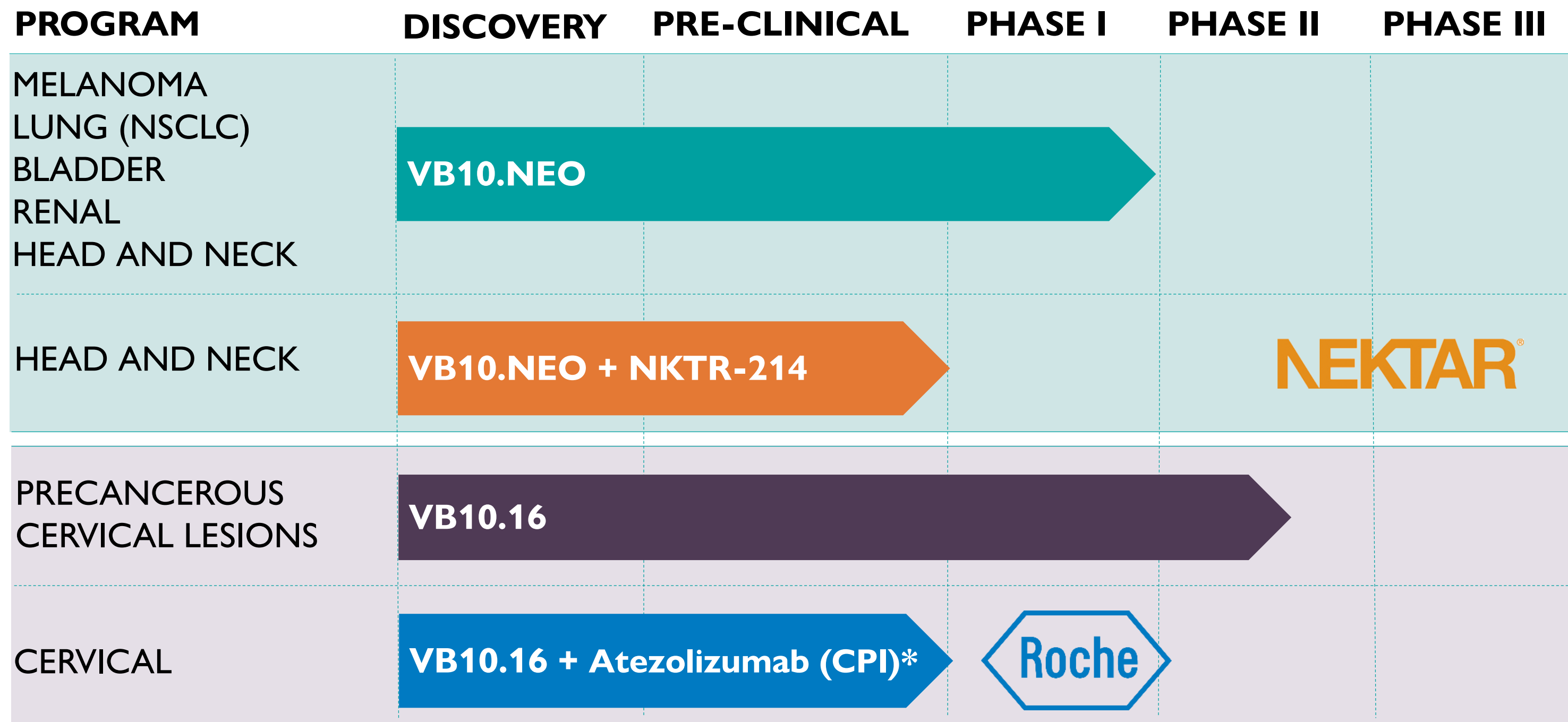
Mette Husbyn,
CTO

Vaccibody achievements



- **Clinical proof of principle established from VB C-01**
 - Ability to raise an antigen specific immune response in humans
 - Immune response translate into meaningful clinical improvement in pre-cancer setting
- **Promising initial data from VB N-01**
 - Developed a promising concept for addressing patients own immunogenic somatic mutations in cancers
 - Proven feasibility in value chain from biopsy to patient specific cancer vaccine product
 - Well tolerated product for IM administration
 - Demonstrated neoantigen vaccine can raise best in class specific immune response against somatic mutations
- **Technology platform that can be applied to a range of diseases with unmet medical need**

Vaccibody Product Pipeline



Vaccibody's solid base

- 322 mNOK in cash and cash equivalents as of June 30, 2019
- Diverse and active shareholder base, approx. 280 shareholders
- Raised 509 mNOK in equity since inception
- Traded “over the counter” by Arctic, ABG, DNB, Carnegie

- Solid IP base with multiple layers of protection
- Experienced and engaged team

Update since February

- Raised 230 mNOK to continue development program of VBI0.NEO and VBI0.I6 programs
- First immunogenicity data released - major de-risking factor
- 100% manufacturing success rate
- Reported outcome of VB C-01 clinical trial
- Ready to start enrolling in NEKTAR arm of VB N-01
- Elaborating on Vaccibody's unique ability to induce a strong and broad CD8 response
- Accelerating efforts to progress VB N-01 trial - opening 6 new clinical sites

Agenda

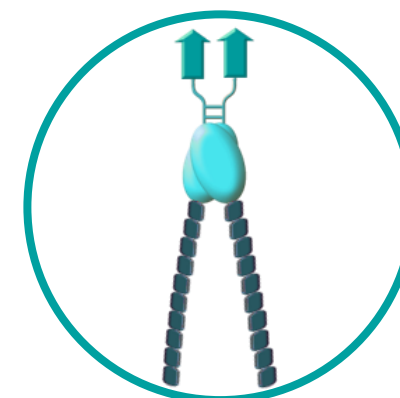
1.

Introduction



2.

Update on VBI0.16 program



3.

Update on VBI0.NEO program



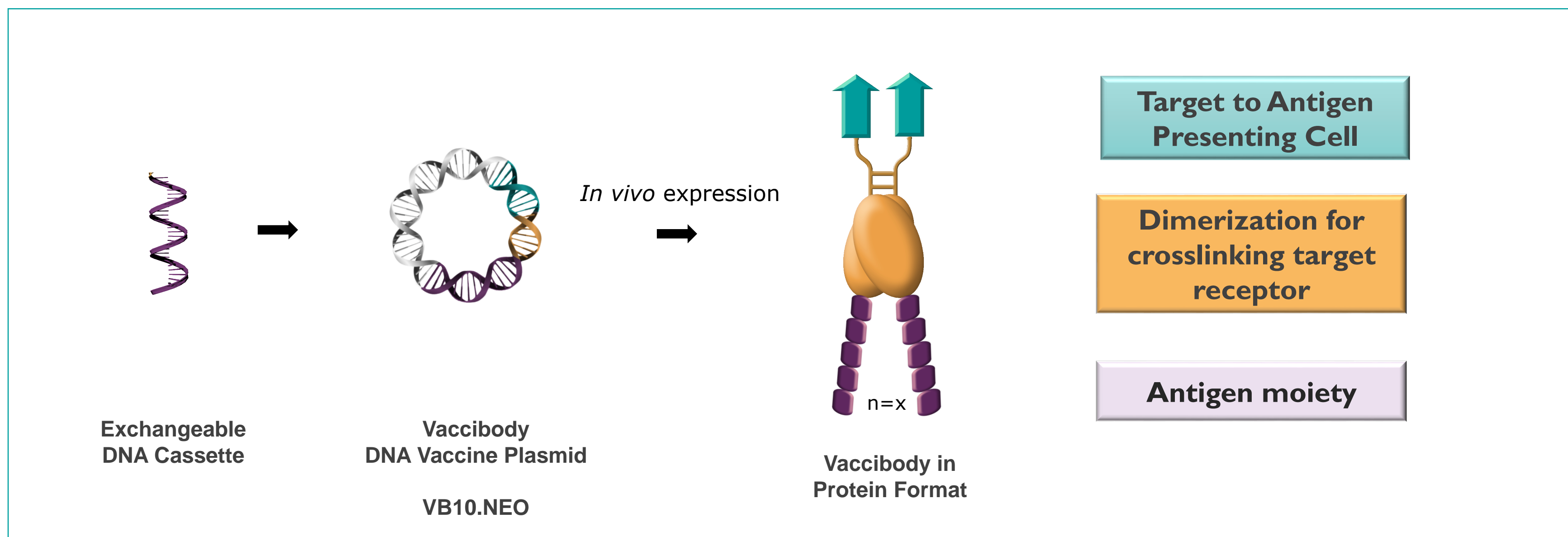
4.

Outlook

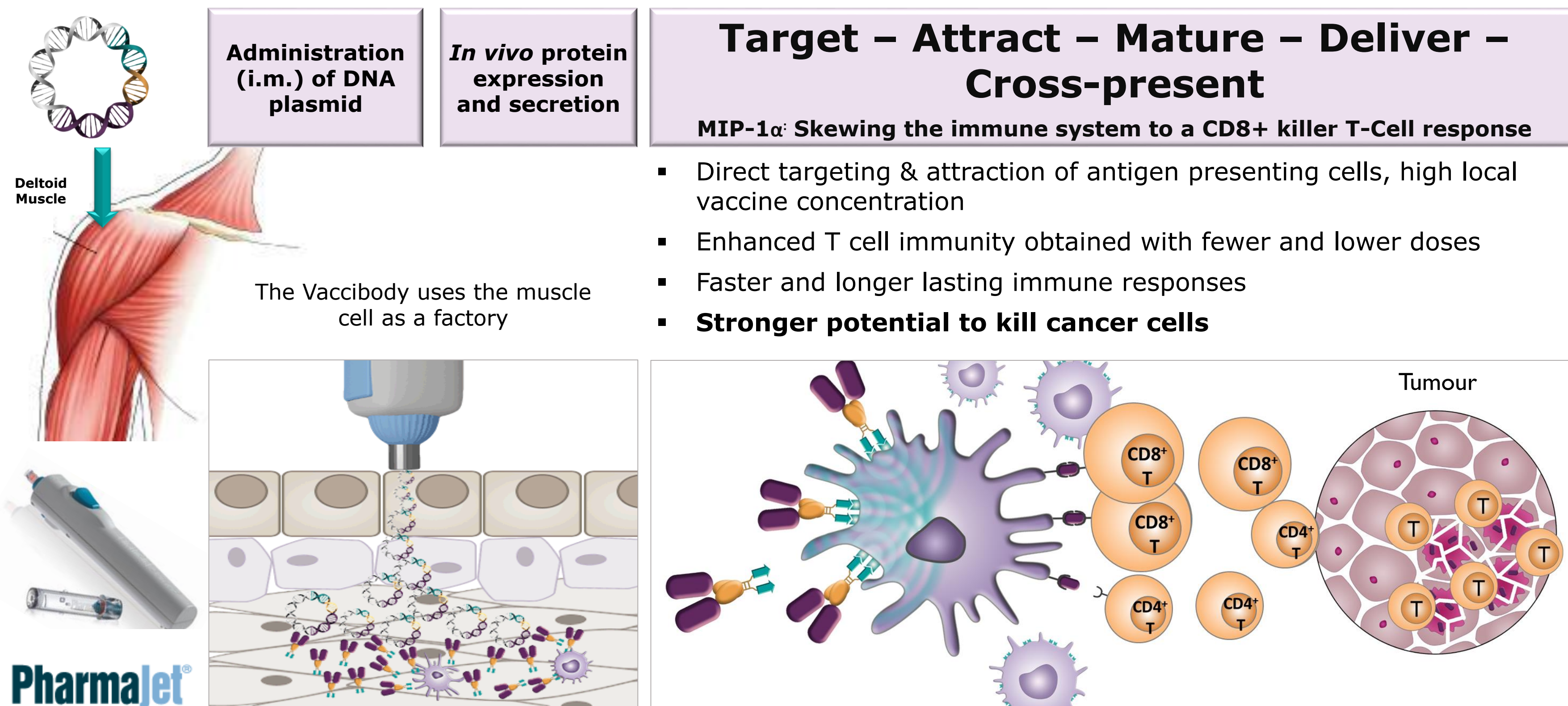


Vaccibody – Proprietary Vaccine Technology Platform

The Vaccibody Technology Platform was developed based on the concept of **targeting antigen to APC** in order to create more efficacious vaccines.

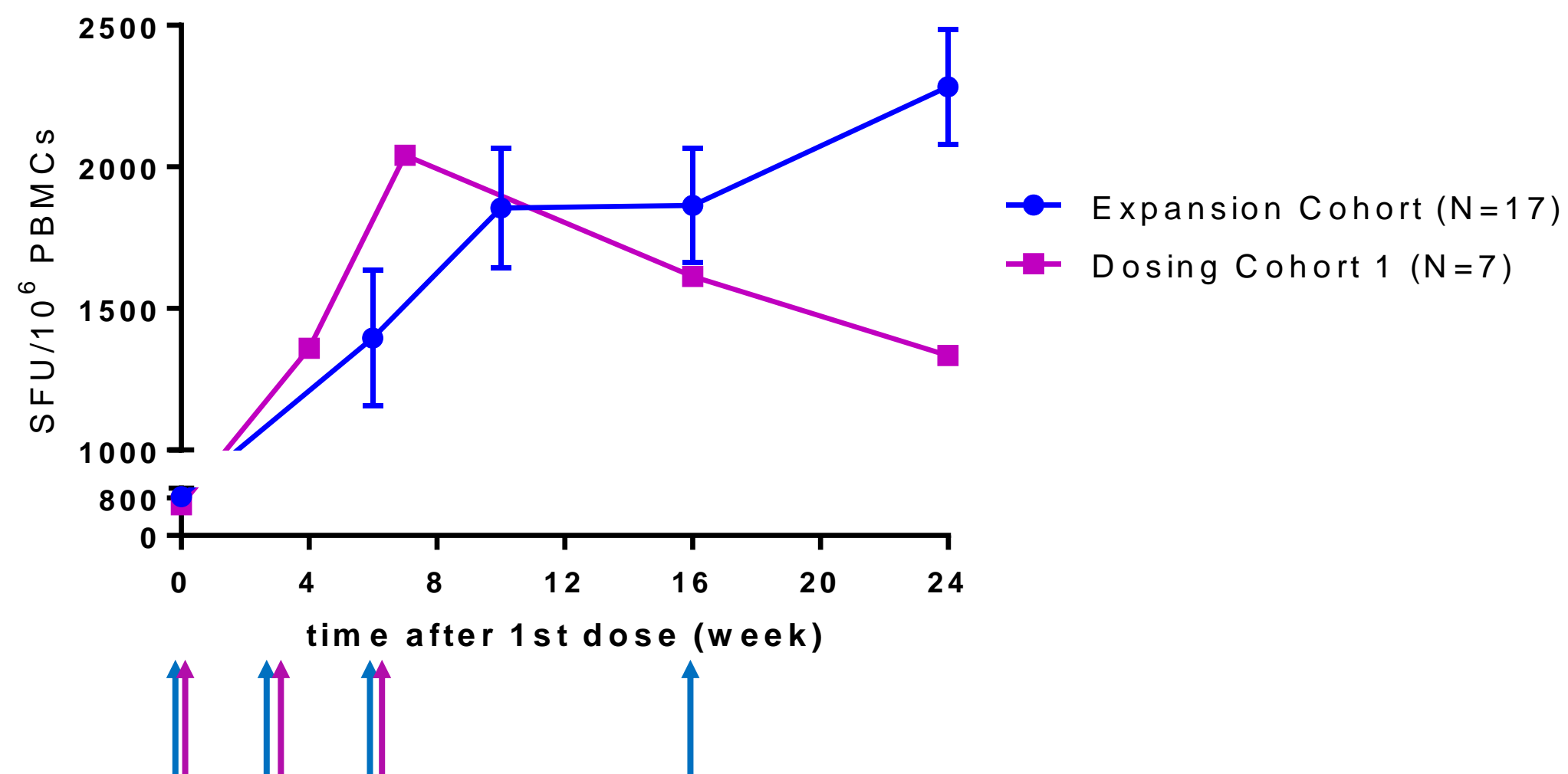


Mechanism of action: the multiple effect of MIP-1 α as targeting unit



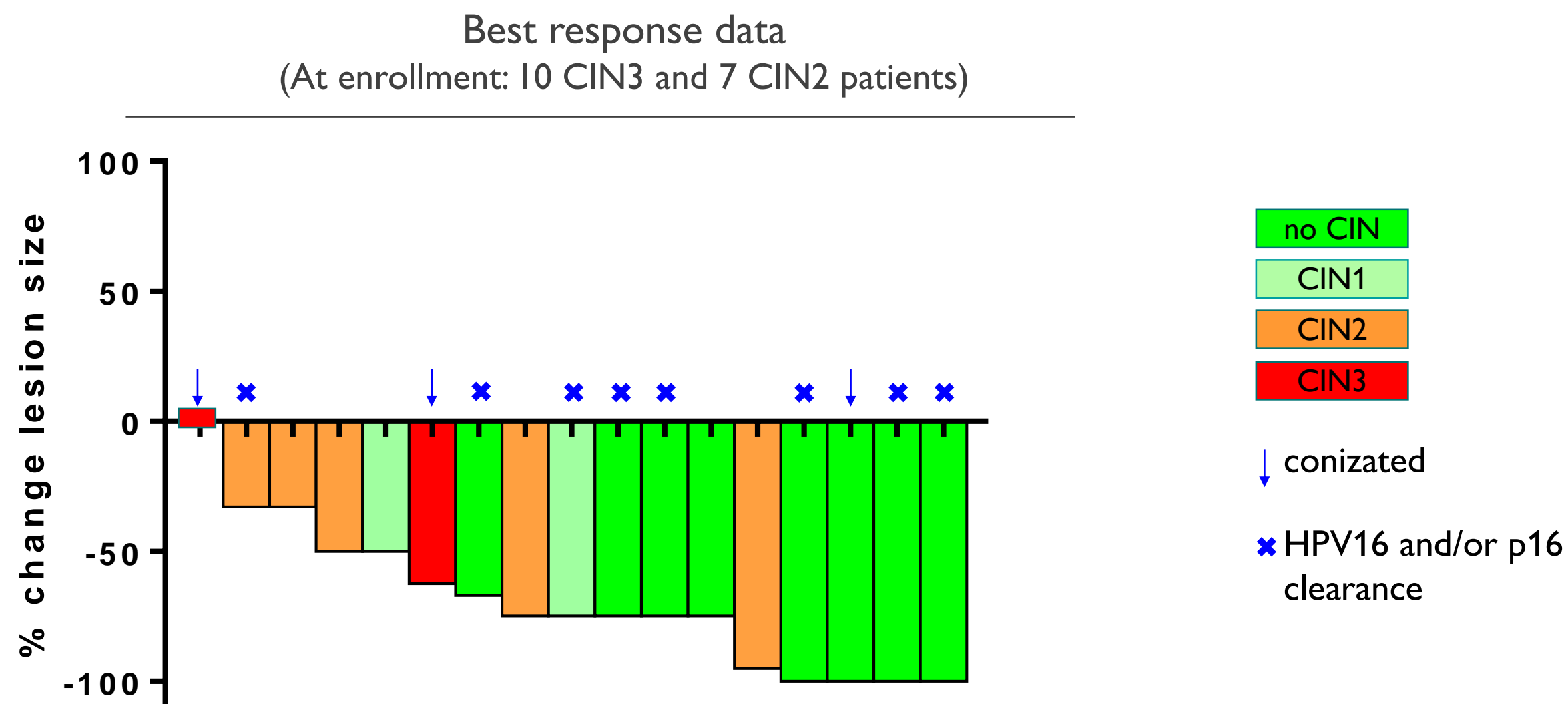
Targeting is elicited by the MIP-1 α chemokine

Strong, long-lasting immune responses. Effective homologous boost.



- The vaccination regiment from cohort 1 (week 0, 3 and 6) plus a booster vaccination at W16 was introduced in phase IIa
- 16 of 17 patients (94%) from phase IIa elicited increased HPV16-specific T cell responses after vaccination with VBI0.16.
 - Rapid, strong and long-lasting

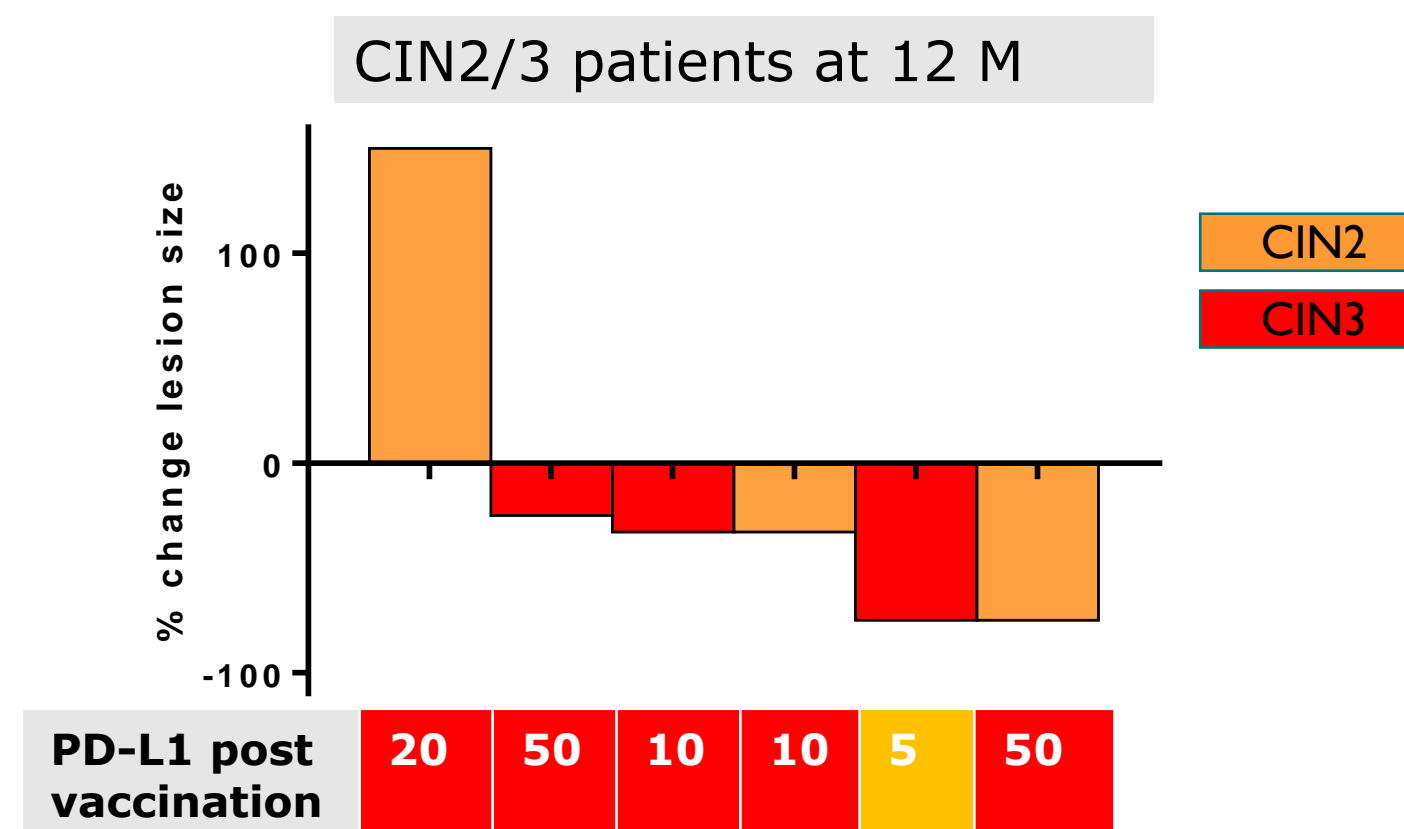
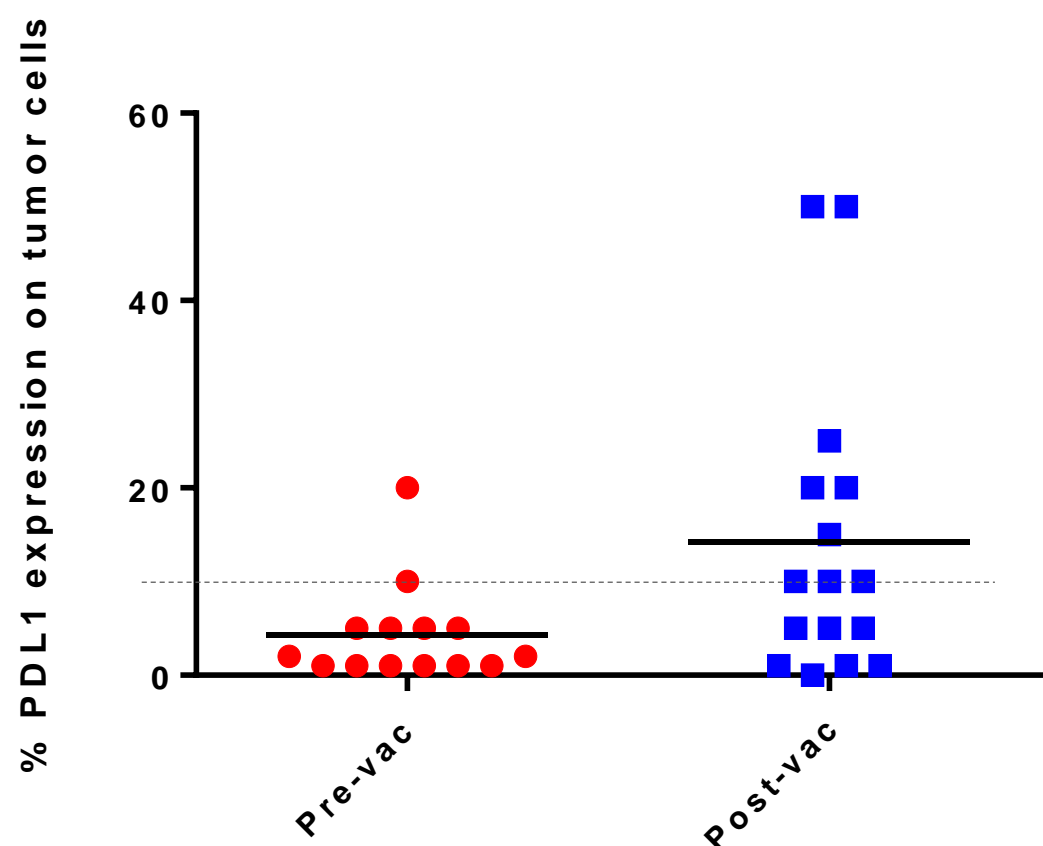
Promising clinical efficacy with excellent safety, VB C-01



VB10.16 as a monotherapy in HPV16-positive, precancerous cervical lesions induces:

- Lesion size reduction in all patients followed >4 months
- CIN regression to CIN1 or no CIN in 10 patients
- HPV16 and/or p16 clearance in 8 patients

VB10.16 upregulates PD-L1, suggesting effect of combination therapy

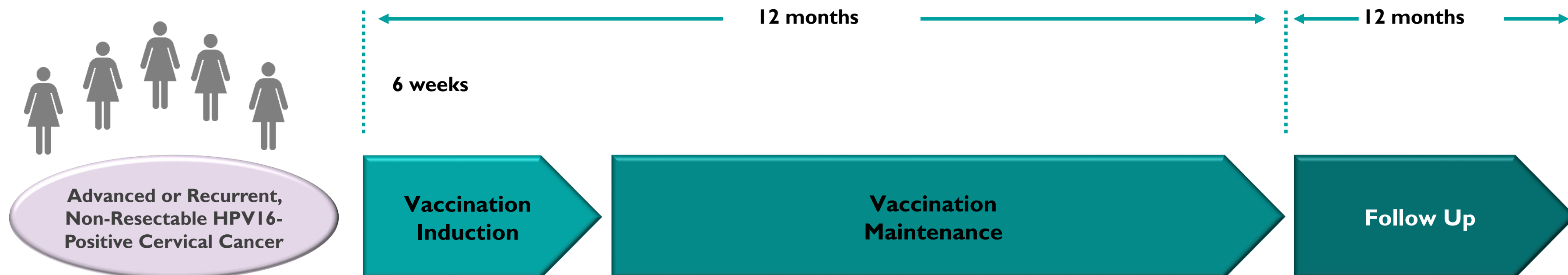


- 5 of 6 patients that were CIN2/3 after completing the study (12M) showed **upregulation of PD-L1** $\geq 10\%$ (1 patient 5%)
- PD-L1 is upregulated by a strong local T cell response and may inhibit an efficacious long-term immune response
- Anti-PD-1/PD-L1 inhibitors blocks the brake and activates the immune system to attack PD-L1+ tumour cells
- VB10.16 induces a strong T cell response and creates a target for PD-1/PD-L1 inhibitors. Thus, there is a strong rationale for combination of VB10.16 with an anti-PD-1/PD-L1 checkpoint inhibitor to improve its effect, especially in PD-L1 negative patients

Study design for VB10.16 + Tecentriq®

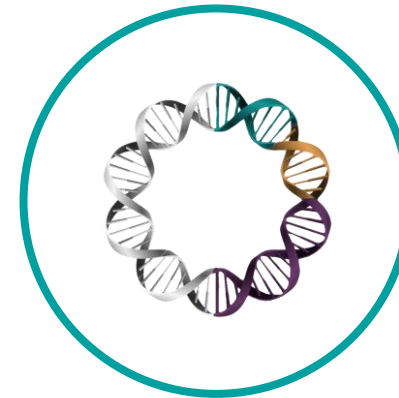
In patients with advanced or recurrent, non-resectable HPV16+ cervical cancer

- Dosing of VB10.16 in combination with Atezolizumab (Tecentriq®)
- Purpose is to assess the safety/tolerability, immunogenicity and the efficacy of multiple doses of 3 mg VB10.16 immunotherapy in combination with Atezolizumab
- **On track for first patient, first visit est. in Q1 2020**
- Up to 50 patients are planned to be enrolled
- The study will be conducted in Europe in 6 countries, including Norway

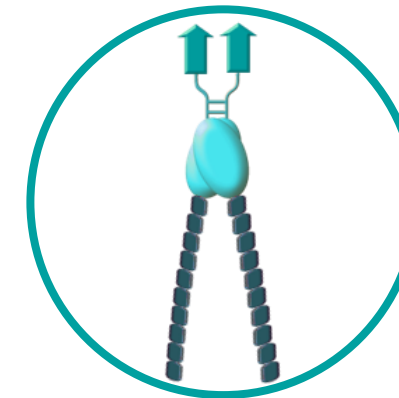


Agenda

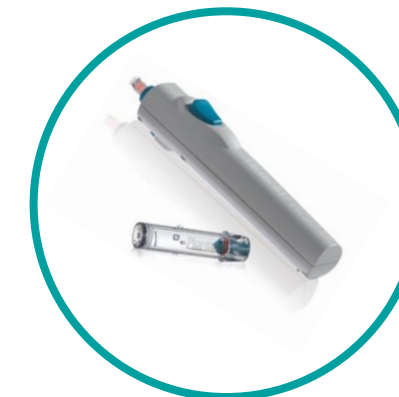
1. Introduction



2. Update on VBI0.16 program



3. Update on VBI0.NEO program



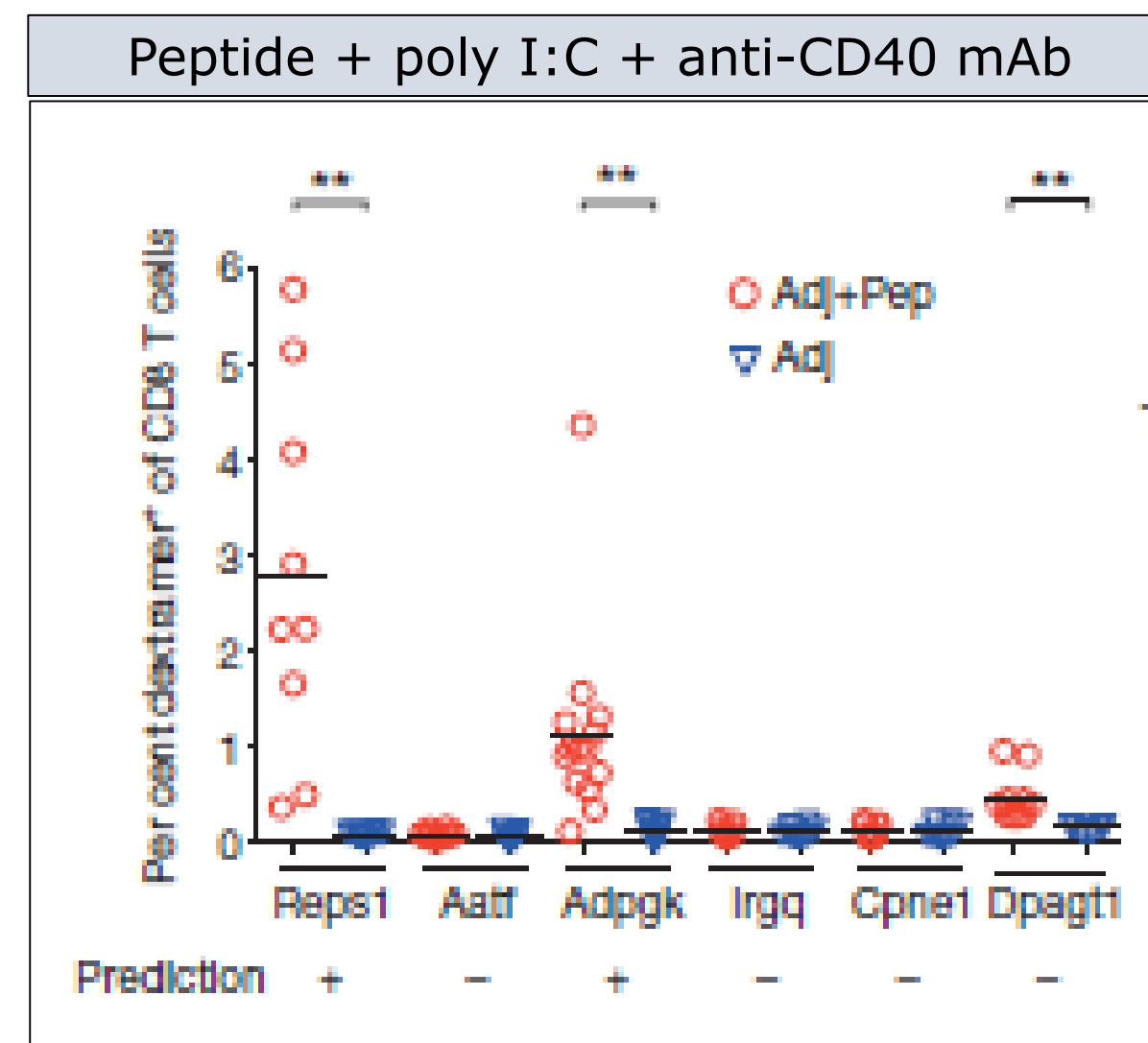
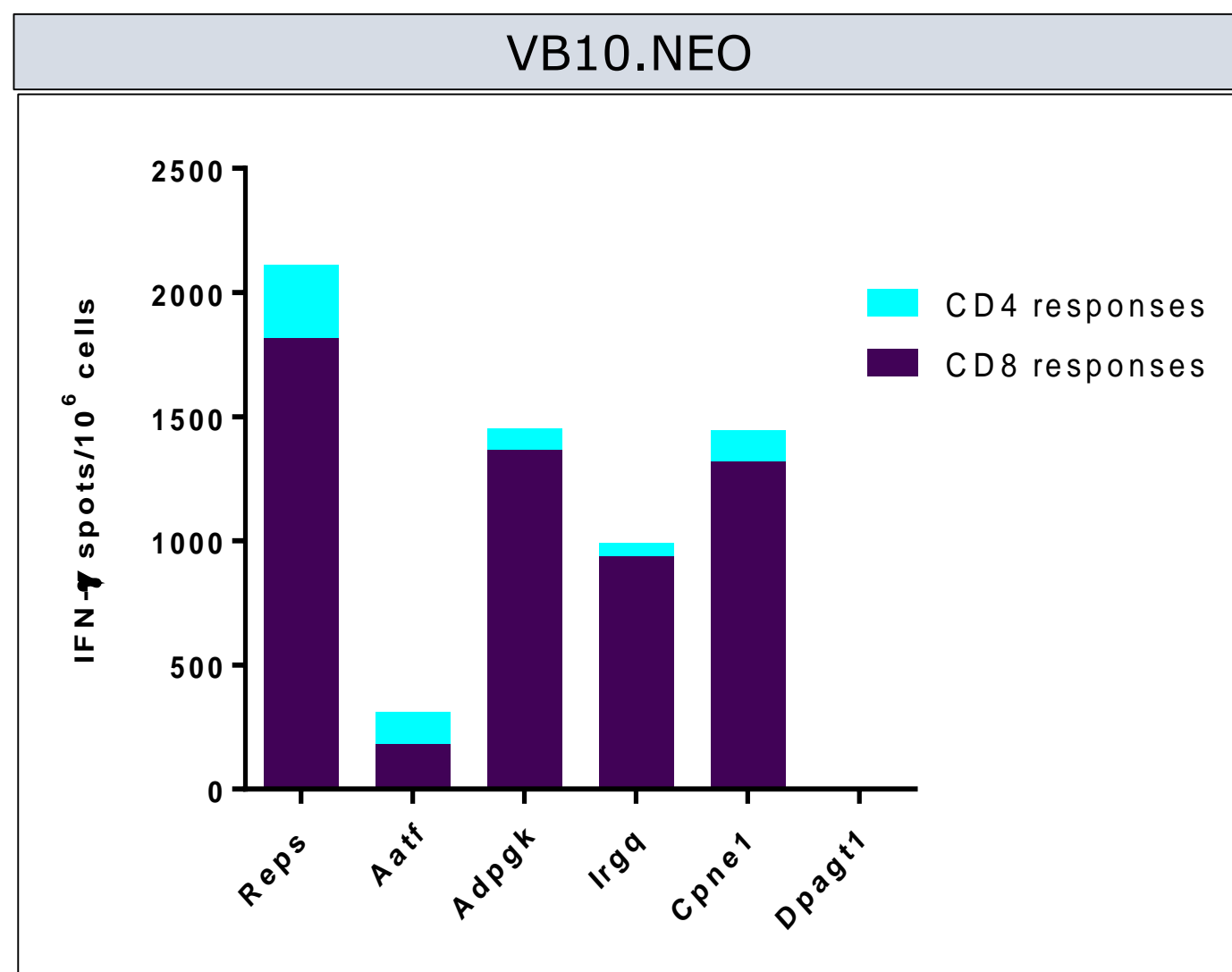
4. Outlook



Substantiation of VB10.NEO's unique ability to induce strong neoepitope-specific CD8 responses-in mice

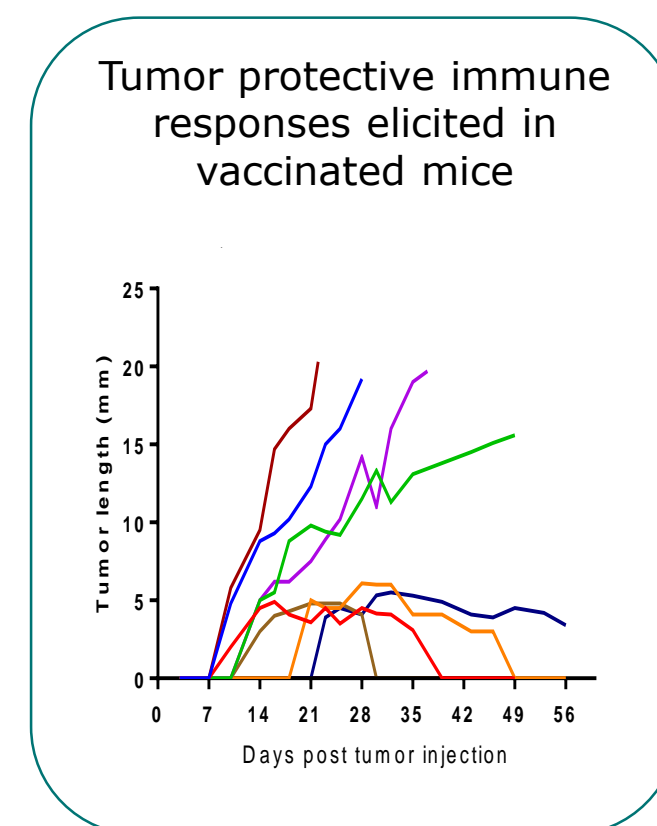
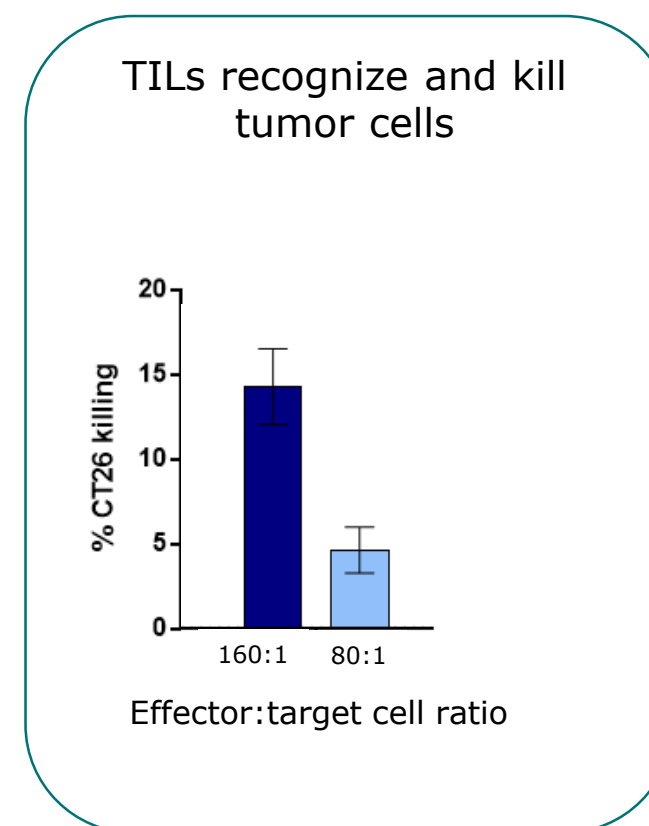
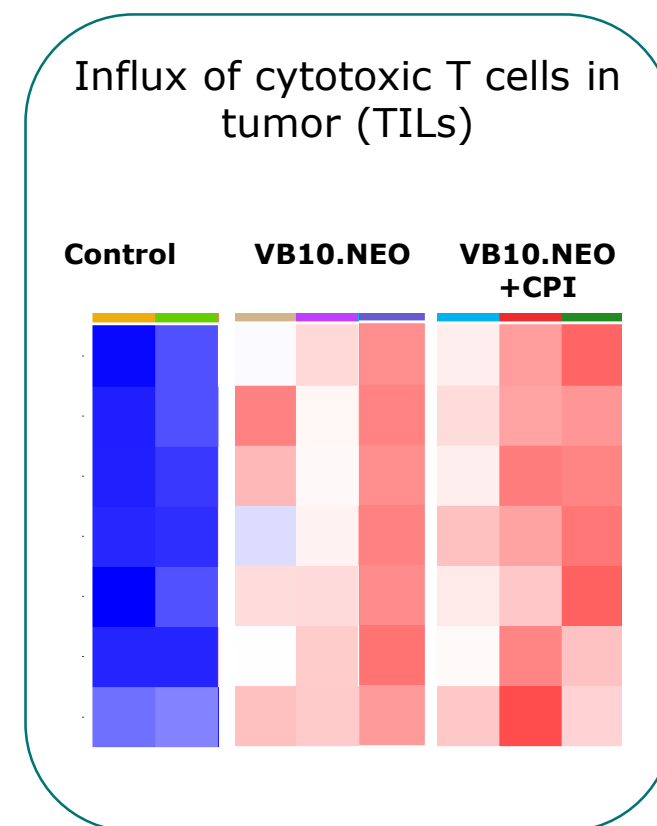
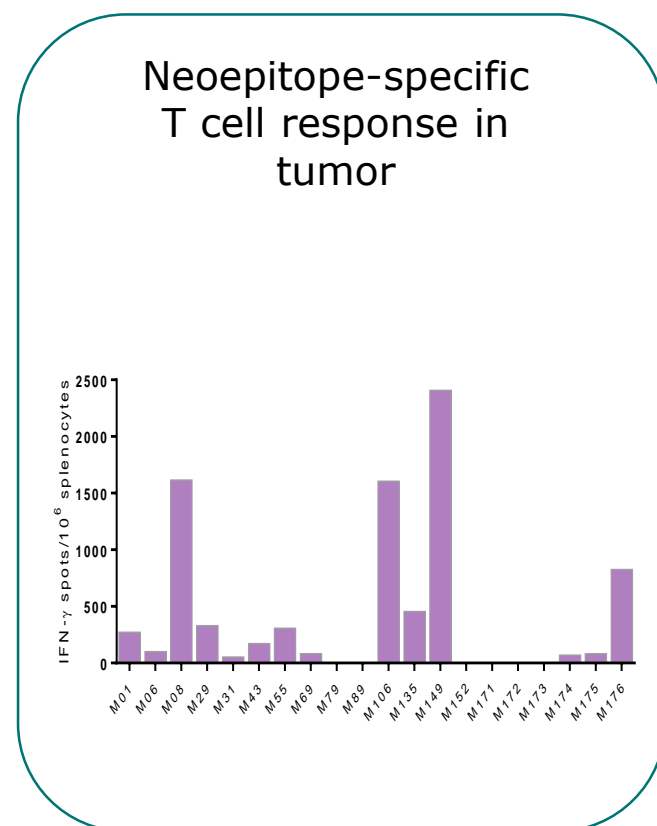
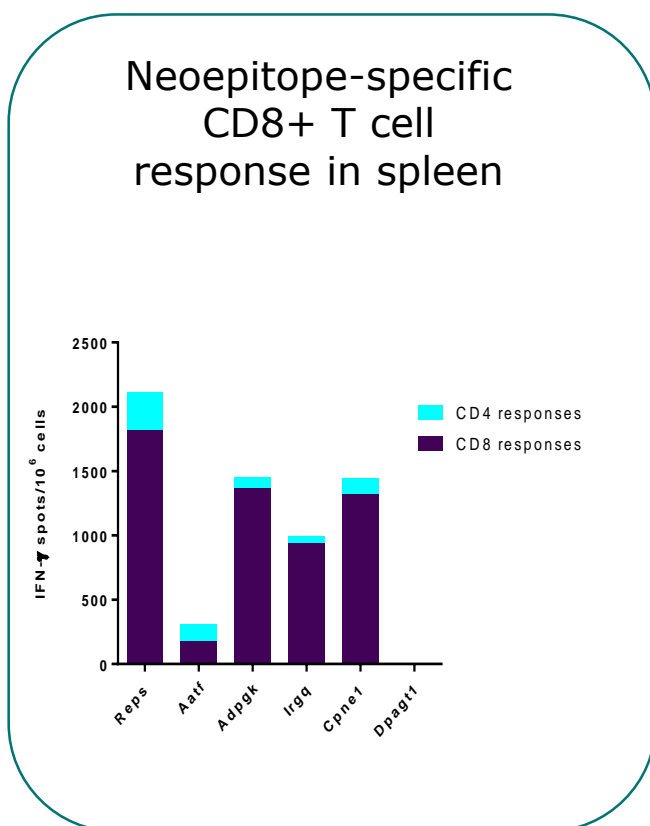
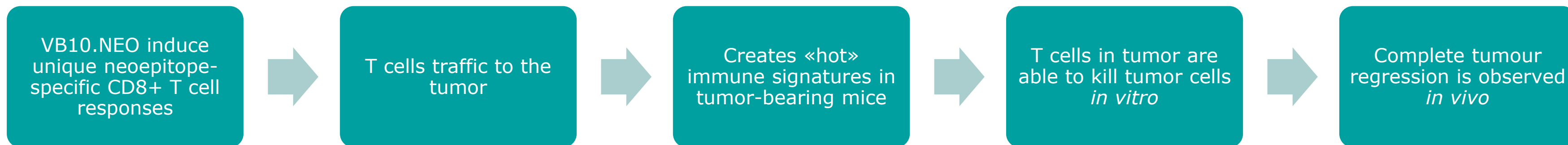
MC38 colon carcinoma

Yadav et al., 2014



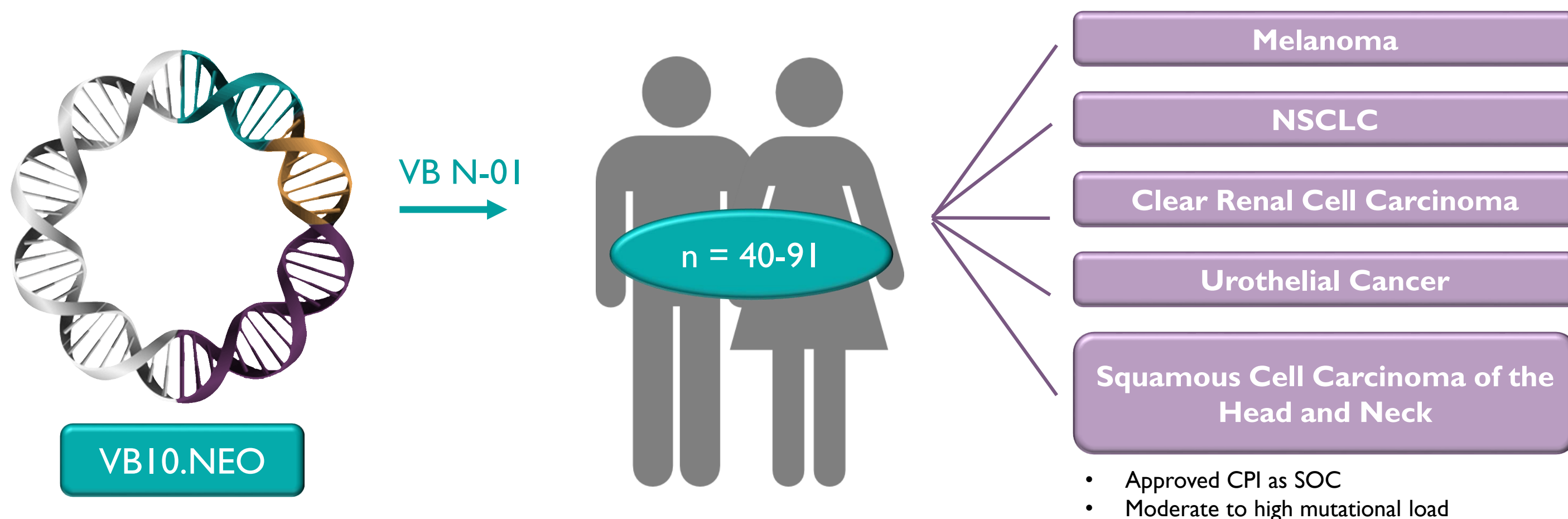
- VB10.NEO induces a strong CD8 T cell response**, combined with a CD4 response to 5 of 6 MC38 neoantigens.
- 3 of these neoepitopes have been shown to be **non-immunogenic delivered as peptide + adjuvant**
- Confirmation of VB10.NEO's ability to induce best in class CD8 responses to neoantigens, both broader and stronger**

VB10.NEO proven to induce an effective anti-tumour response



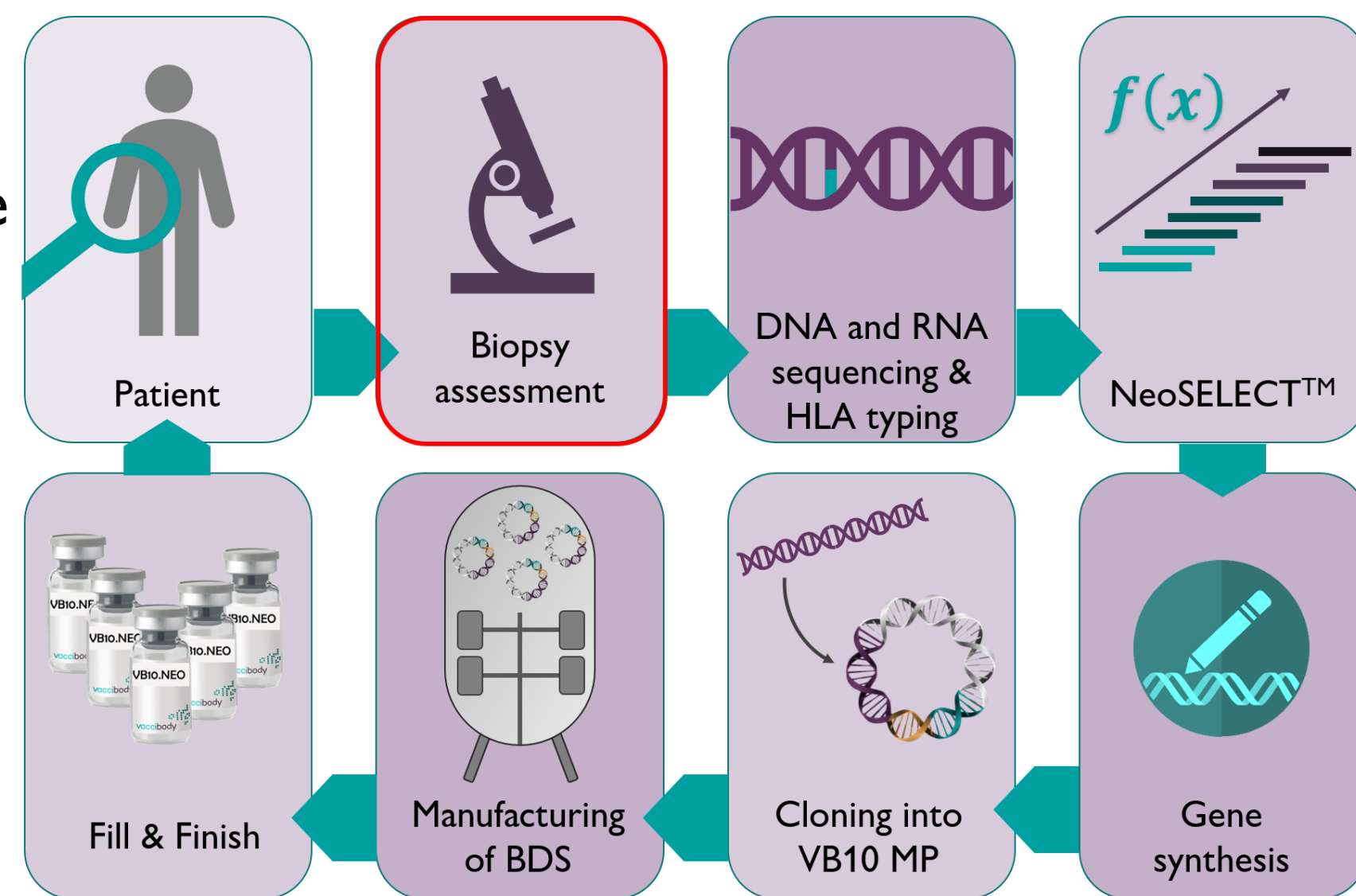
Clinical Trial VB N-01

VB N-01: An open labelled first human dose phase I/2a study to evaluate safety, feasibility and efficacy of multiple dosing with individualised VBI0.NEO immunotherapy in patients with locally advanced or metastatic melanoma, NSCLC, clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of head and neck, who did not reach complete responses with current standard of care immune checkpoint blockade



High focus on successful and fast manufacturing

- So far, 100% manufacturing success rate for patients providing a successful biopsy -**Best in class**
 - Top choice of 20 neoepitopes used for every patient
 - Proven feasibility and stability data from all initial batches
- Consistent efforts to improve manufacturing lead time
 - Latest batches approximately 12 weeks
 - Further improvements on lead time to be expected
 - scientific advice November 2019

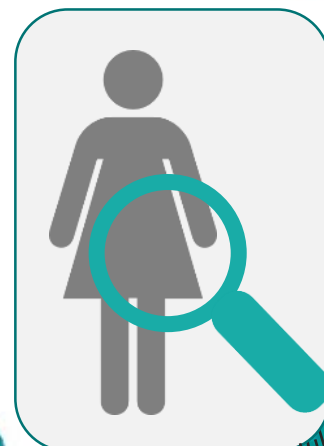


Expansion of Clinical Sites - speeding up enrollment

vaccibody

23 patients enrolled in 3 clinical sites

Plan to activate all 6 new sites H2 2019



<p>01 NCT Heidelberg Prof. Krauss*</p>	<p>04 Charité Campus Benjamin Franklin, Berlin Dr. Ochsenreither</p>	<p>07 Universitätsklinikum Ulm Dr. Laban</p>
<p>02 Klinikum rechts der Isar, München Prof. Krackhardt</p>	<p>05 Universitätsklinik Würzburg Dr. Gesierich</p>	<p>08 Universitätsklinikum Tübingen Dr. Mauz</p>
<p>03 Krankenhaus Nordwest, Frankfurt Prof. Jäger</p>	<p>06 Universitätsmedizin Mannheim Prof. Utikal</p>	<p>09 Universitätsklinikum Halle (Saale) Dr. Eisenmann</p>

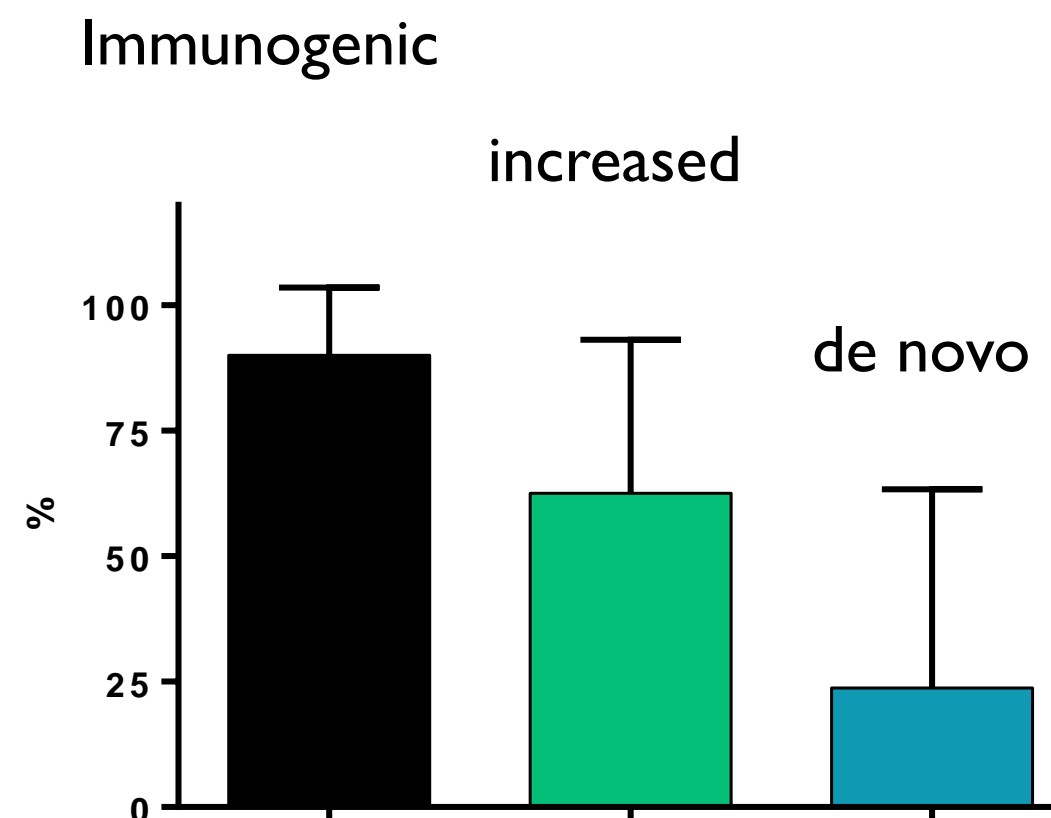
Site not yet activated

* Coordinating Investigator

VB10.NEO induce best in class, broad and strong immune responses even in patients with low TMB

First 4 patients tested after 3-6 vaccinations

Patient	Indication	TMB	#months on CPI before VB10.NEO	Disease at VB10.NEO start
1	RCC	Low (1.7)	18	Stable
2	SCCHN	Low (2.6)	32	Relapsed
3	SCCHN	Low (3.2)	15	Stable
4	RCC	Low (2.1)	12	Stable



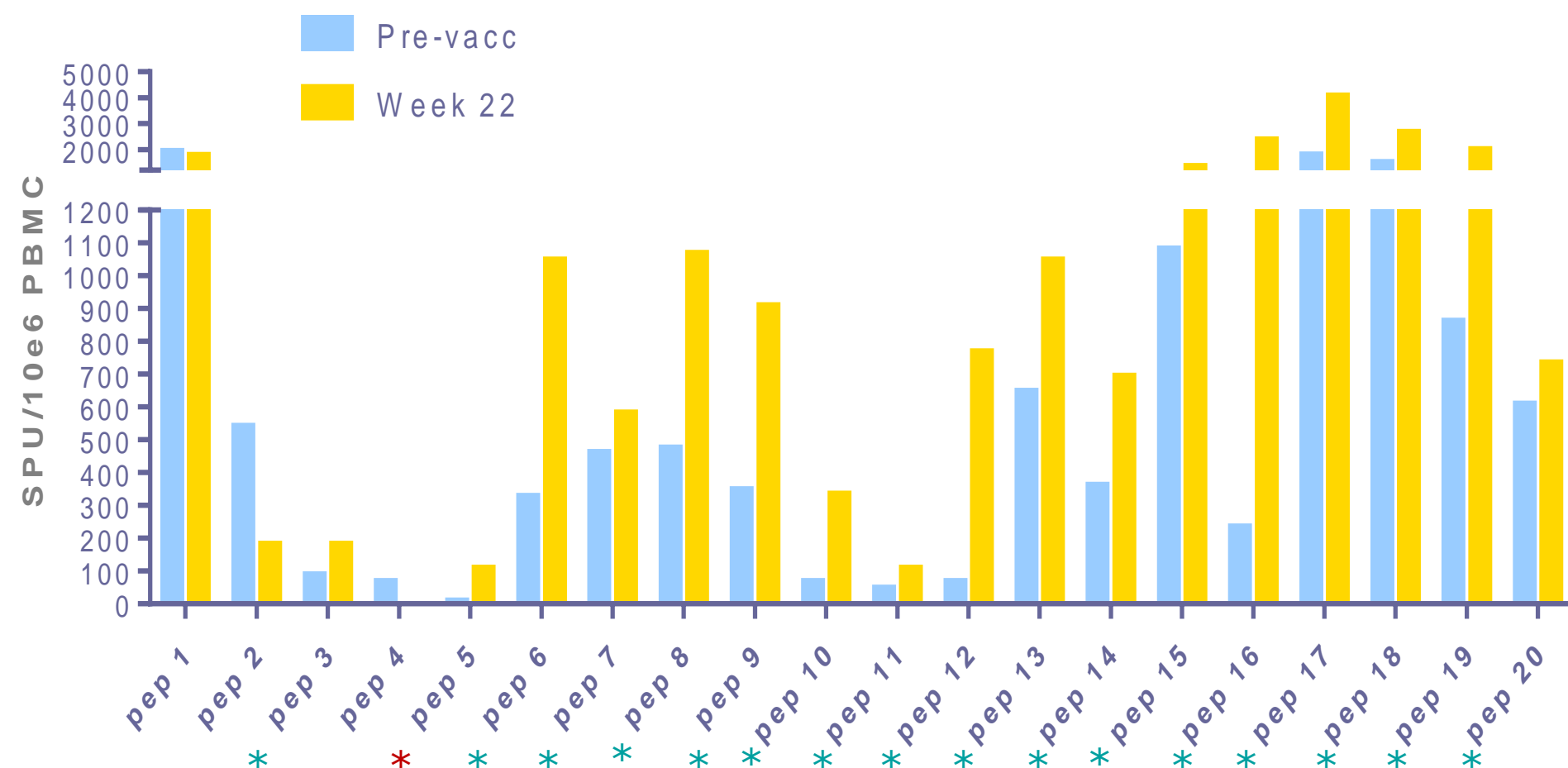
- First patients are all low TMB and with SD as best response to long-term CPI treatment.
- One patient relapsed before VB10.NEO treatment.

- High% of immunogenic neoepitopes selected with NeoSELECT prediction.
- Majority of neoepitopes increased by VB10.NEO
- Boosting pre-existing as well as de novo responses

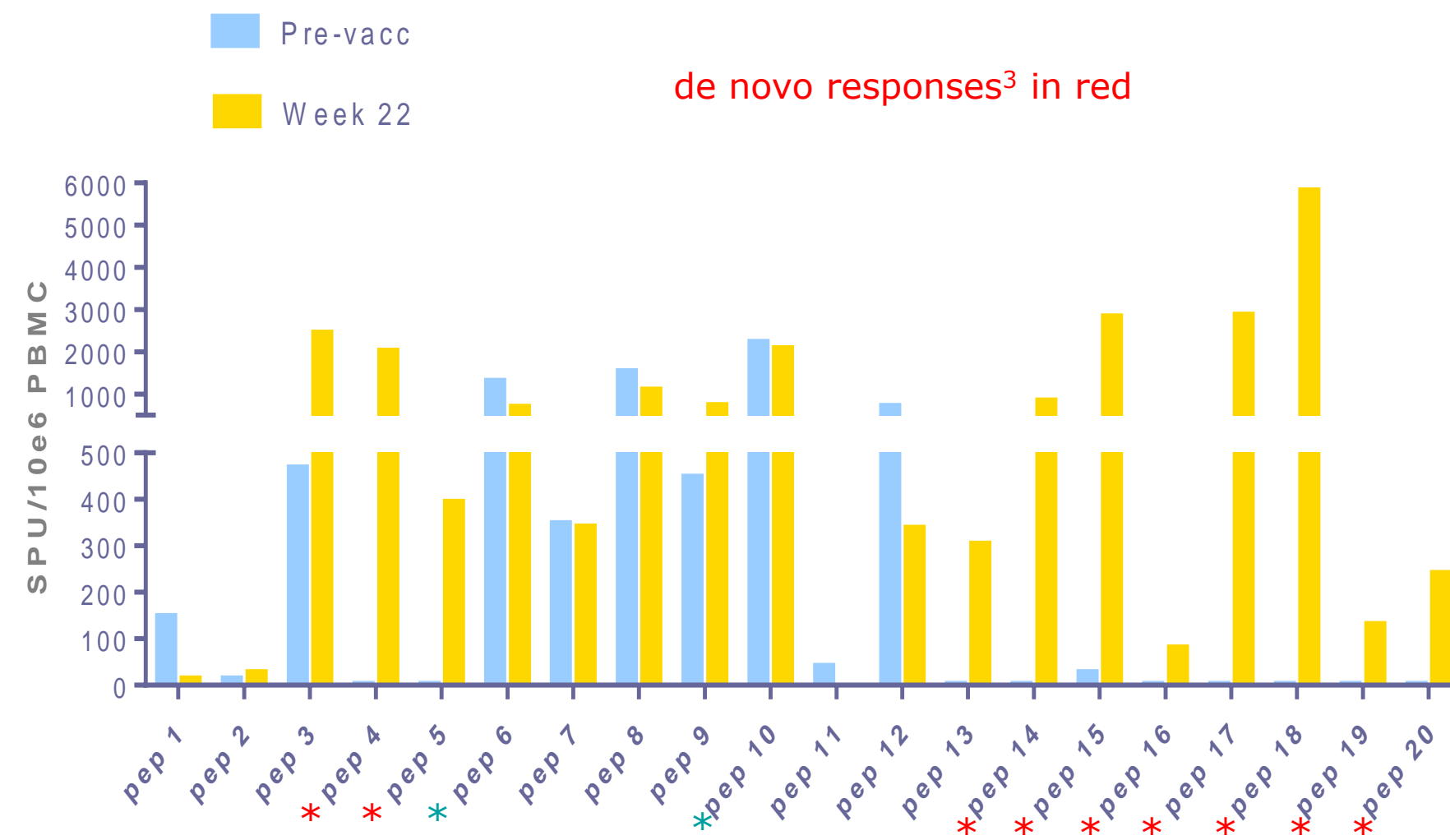
VB10.NEO induce best in class immune responses

Example of T cell response to the 20 neoepitopes in the vaccine for 2 Head & Neck patients (week 22)

Patient 2

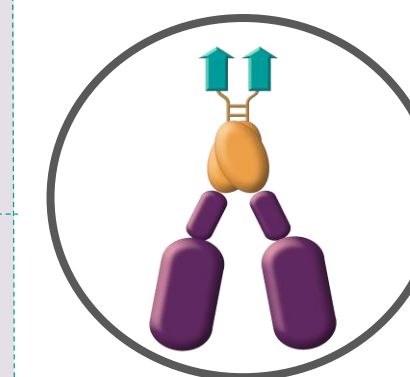
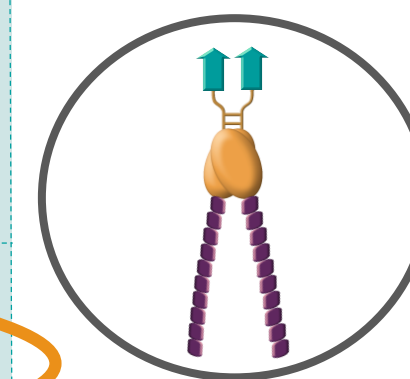
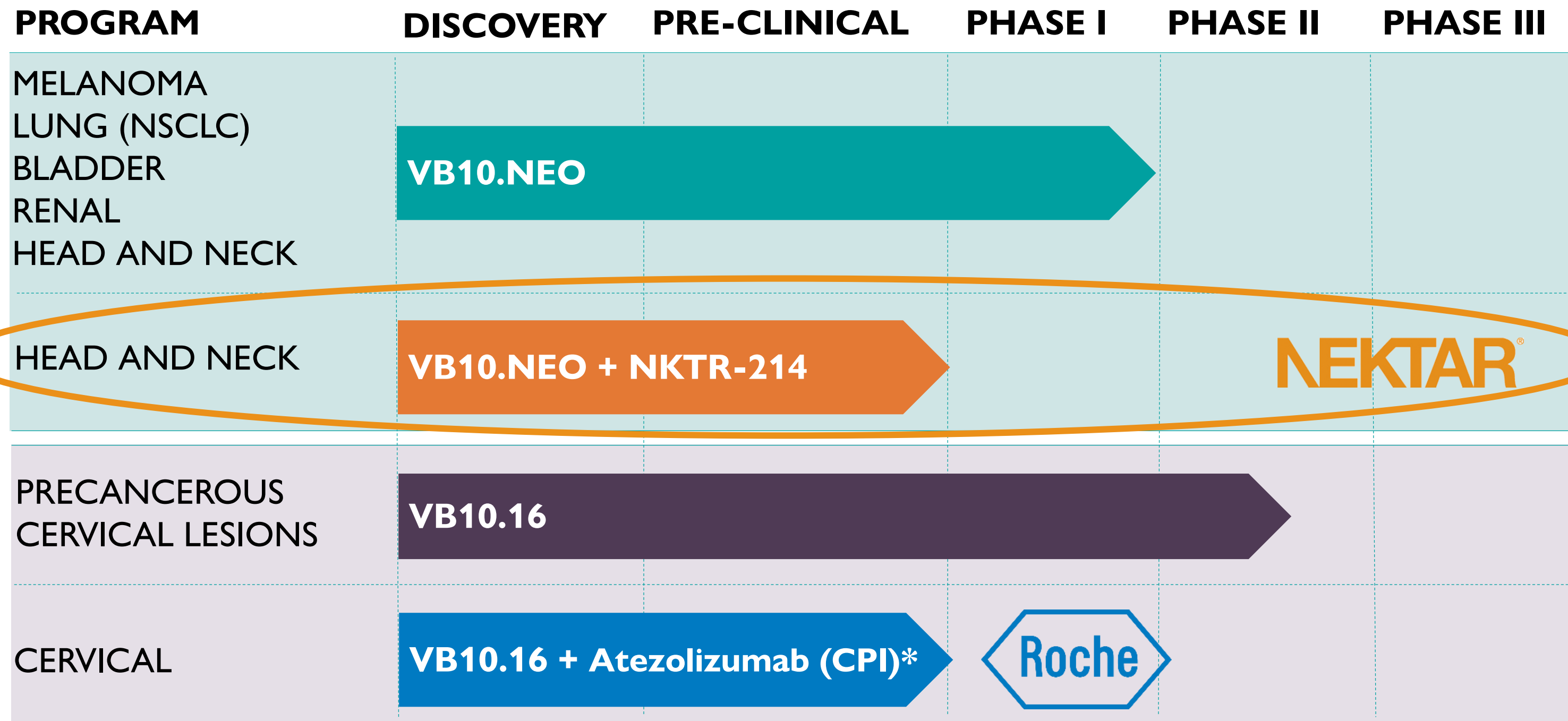


Patient 3

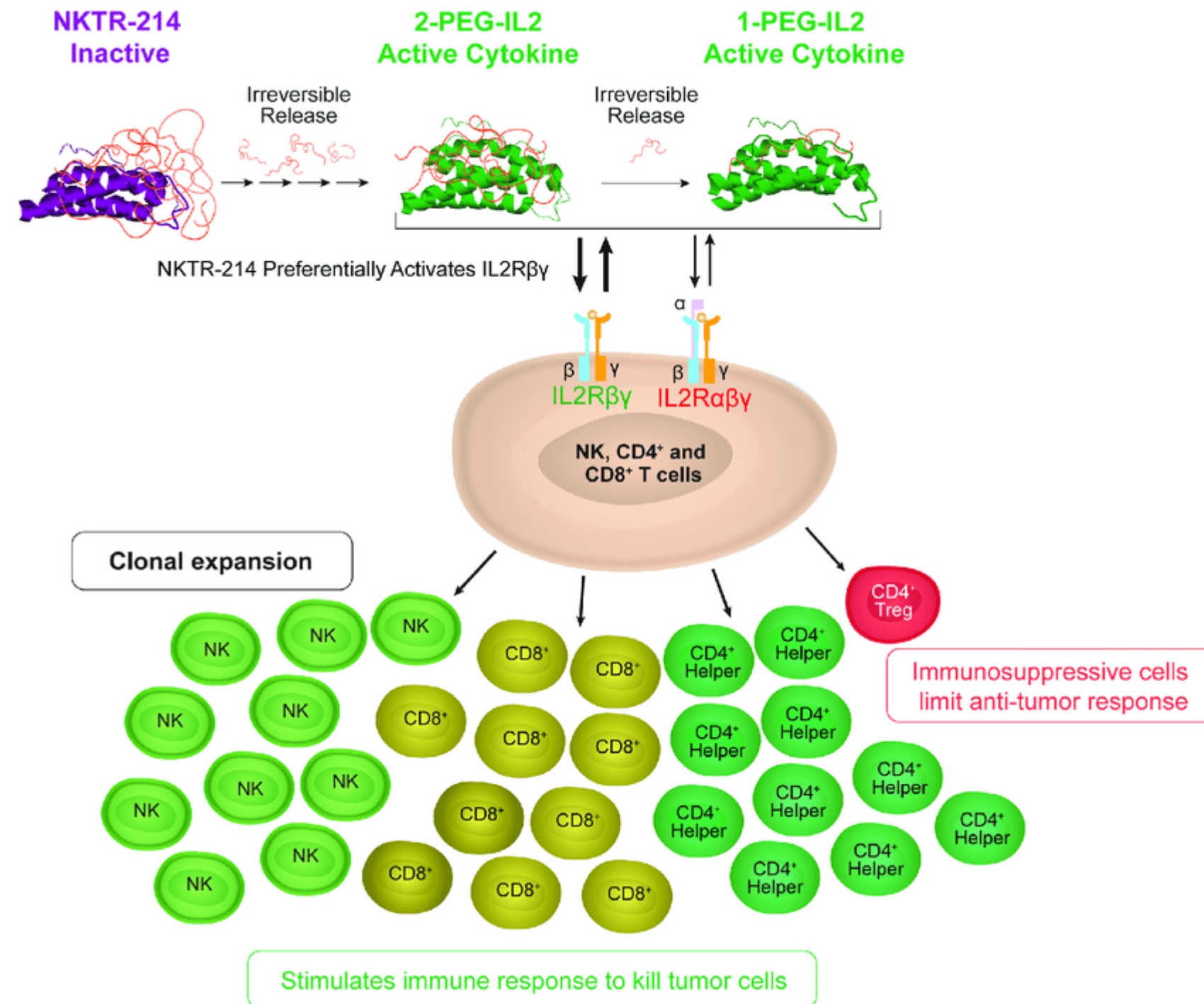


- Strongly increased T cell responses to the majority of the selected neoepitopes after VB10.NEO vaccination.
- Highest number of neoepitopes increased for patient 2 (85%), but biggest fold increase (~>1000 times) and highest number of *de novo* responses observed for patient 3 (83%).

Vaccibody Product Pipeline

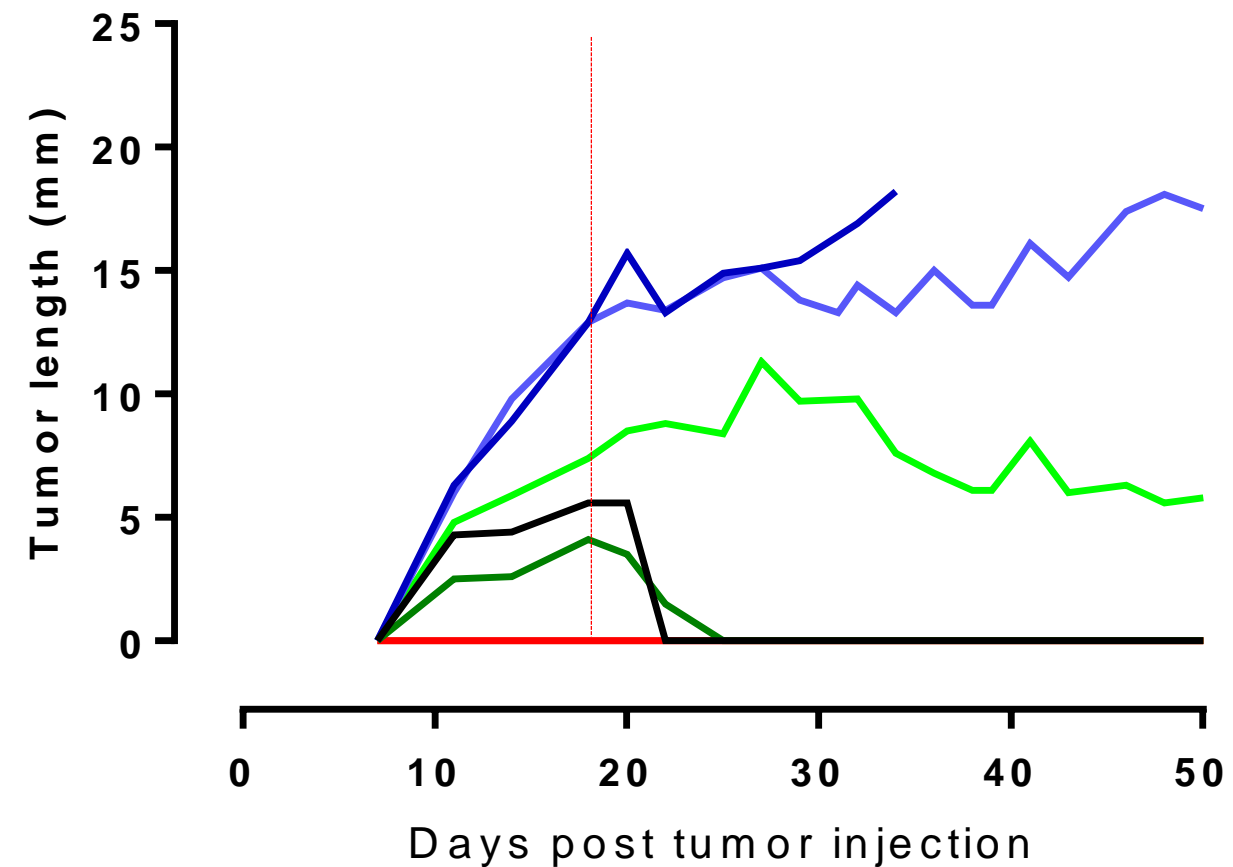
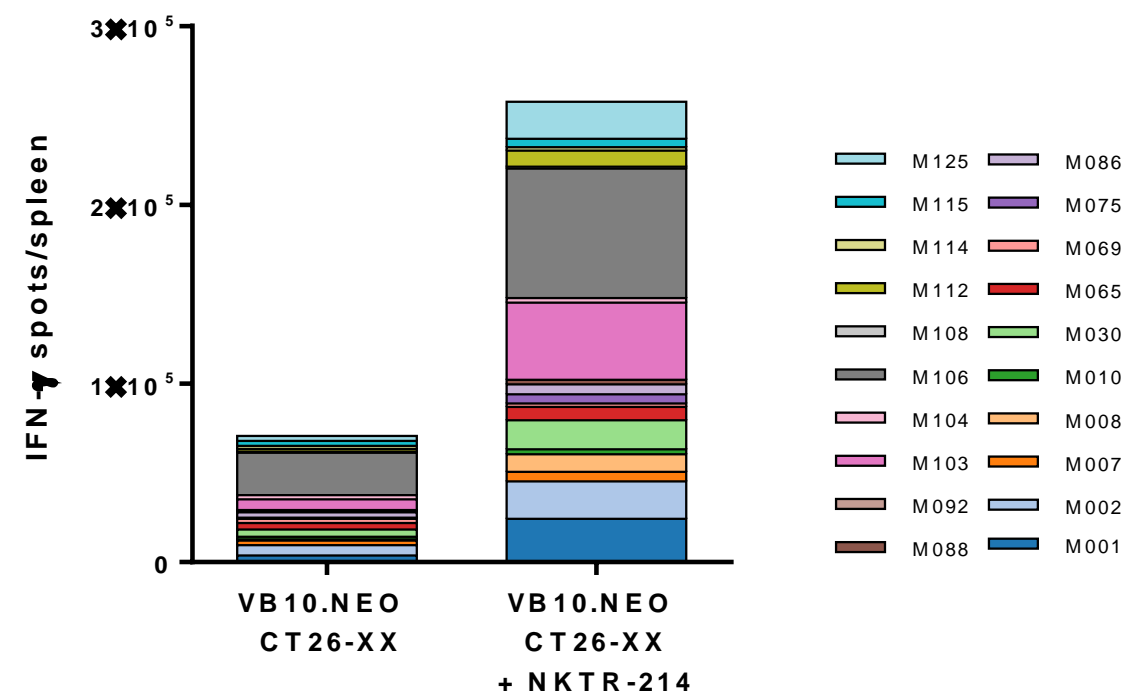


Bempegaldesleukin (NKTR-214) has the potential to significantly expand T cells



Combination of VB10.NEO and NKTR-214 greatly synergizes

Total T cell response per spleen



- Combination of VB10.NEO and bempegaldesleukin (NKTR-214) synergizes to elicit greater breadth and depth of neoantigen-specific T cell responses than each individual treatment
- Adding NKTR-214 (from day 18) to a VB10.NEO and anti-PD-1 treatment induce rapid, complete and durable tumour regression of small tumours and long-lasting stabilization of large tumours.

Expansion of the study planned in 2019– add NKTR-214 and expansion cohorts

Part A



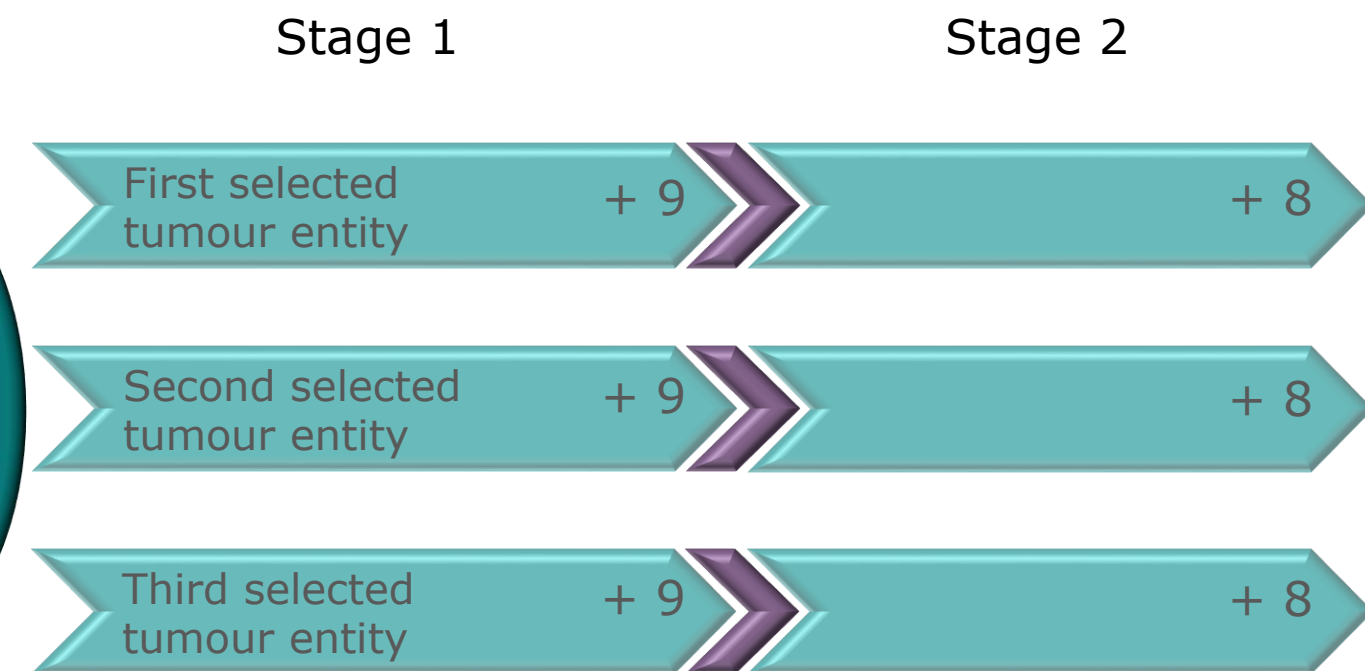
Part B

Expansion



1	Melanoma	VB10.NEO	≤ 10
2	NSCLC	VB10.NEO	≤ 10
3	RCC	VB10.NEO	≤ 10
4	Urothelial	VB10.NEO	≤ 10
5A	SCCHN	VB10.NEO	≤ 10
5B	SCCHN	VB10.NEO + NKTR-214	≤ 10

Interim analysis

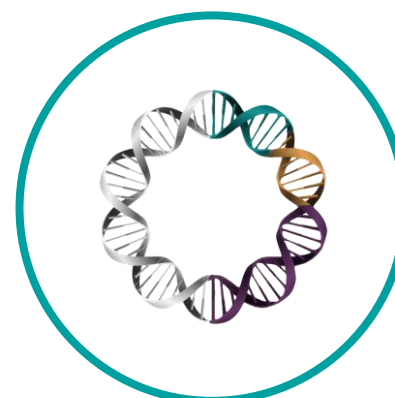


- First patient enrolled planned H2 2019

Agenda

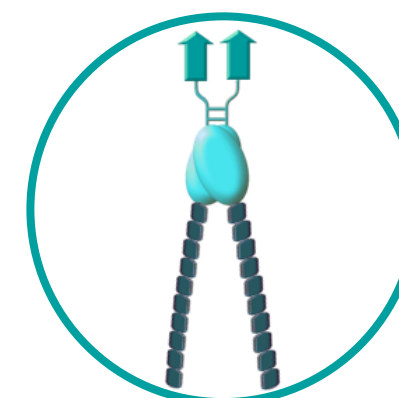
1.

Introduction



2.

Update on VBI0.16 program



3.

Update on VBI0.NEO program



4.

Outlook



Outlook for the next 12 months

Clinical trial for cancer neoantigen vaccine (VBI0.NEO)

- Complete enrolment of phase I trial
- Interim data

Nektar collaboration

- First patient dosed in clinical trial evaluating the combination of VBI0.NEO and NKTR-214

Clinical trial in cervical cancer combining VBI0.16 and checkpoint inhibitor atezolizumab

- Submission of the clinical trial application (Ph IIa) to regulatory bodies
- First patient dosed in the clinical trial evaluating the combination of VBI0.16 and atezolizumab

In Summary

Achievements

- Vaccibody technology platform provides best in class broad and strong immune response across indications
- Clinical proof of concept for both VBI0.16 and VBI0.NEO
- Cutting edge experience in manufacturing and supply chain
- Strong collaboration partners to improve positioning

Key priorities to drive asset value

- Progress clinical activities
- Expand footprint
- Strengthen manufacturing setup
- Leverage our technology platform

Vaccibody team ready to execute and deliver!



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