vaccibody

Vaccibody

Lunsjpresentation hos Arctic Securities

Oslo, Onsdag den 10. Oktober 2018

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Martin Bonde, BComm, PhD
CEO
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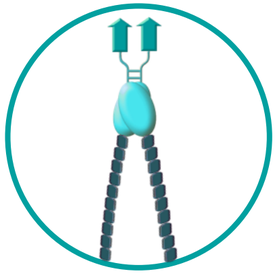
Agenda

1. Introduction



2. Deal with Nektar Therapeutics

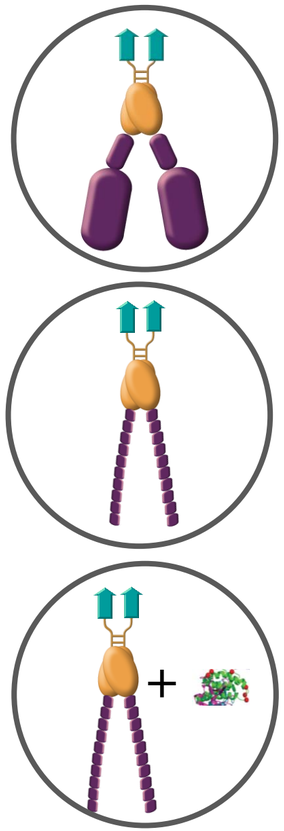
NEKTAR

3. 6-Months data from VB10.16 phase IIa clinical study

4. Update on VB10.NEO clinical trial

Vaccibody Product Pipeline

PROGRAM	DISCOVERY	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
Precancerous cervical lesions	VB C-01 (VB10.16)				
MELANOMA LUNG (NSCLC) BLADDER RENAL HEAD AND NECK	VB N-01 (VB10.NEO)				
HEAD AND NECK	VB10.NEO + NKTR-214		NEKTAR®		



Vaccibody's Solution to Personalised Cancer Treatment

1. Tumour biopsy and sequencing

2. Neoepitope selection

VB10.NEO specific proprietary selection method

3. Vaccine manufacturing (n=1)

-Robust, rapid, cost-effective manufacturing
- stable, safe DNA plasmid format
-hold up to 20 neoepitopes

4. Vaccine administration and immunogenicity

-Needle-free delivery
-Rapid, strong, long-lasting
-Broad and CD8 dominated

Rapid, cost-effective, efficacious

Neoantigens have emerged as some of the hottest targets in cancer immunotherapy

Date	Company/Inst.	Comments	Phase	Acquirer/Licensor	Deal type	Size/Upfront (USDm)	Max. deal value (USDm)
Oct 2015	NEON THERAPEUTICS	Spun out from Broad Inst & Dana Faber Backed by Third Rock Ventures	Preclinical	NA	PP (series A)	USD 55m	NA
Oct 2015	gritstone ONCOLOGY	From MSKCC (US) & King's College London (UK) Backed by i.e. Versant Ventures, The Column Group, Clarus Ventures & Frazier Healthcare Partners	Preclinical	NA	PP (series A)	USD 102m	NA
Jun 2016	moderna™ messenger therapeutics	Strategic collaboration and license agreement. Multiple studies in several types of cancer, following human POC, Merck has the right to make an additional undisclosed payment, so the companies will equally share costs and profits under a WW collaboration	Pre-clinical	MERCK	Co-development and commercialisation agreement	USD 200m	**USD 200m**
Aug 2016	ADVAXIS IMMUNOTHERAPIES™	Amgen received exclusive WW rights to develop and commercialize ADXS-NEO. Amgen will be fully responsible for funding clinical and commercial initiatives.	Pre-clinical	AMGEN	Co-development and commercialisation agreement	USD 40m + USD 25m equity stake	**USD 540m**
Sep 2016	BIONTECH	Genentech agreed to share profits from certain programs. BioNTech retaining copromotion rights and option to pick up programs Genentech drops.	Phase I	Genentech	Co-development and commercialisation agreement	Not disclosed ("upfront & nearterm payouts")	**USD 310m**
Jan 2017	NEON THERAPEUTICS	Led by Partner Fund Management. Joined by Third Rock Ventures, Access Industries, Fidelity, Wellington, Inbio Ventures and Nextech Invest	Phase I	NA	PP (series B). Est. valuation	USD 70m	NA
Jul 2017	Wash-U	Collaboration to advance both clinical and preclinical research. Proposed clinical trials will be reviewed and approved by MedImmune.	Pre-clin/Phase I	MedImmune A member of the AstraZeneca Group	Research and clinical alliance	NA	NA
Oct 2017	gritstone ONCOLOGY	Led by Lilly Asia Ventures, joined by GV, Trinitas Capital & Alexandria Venture Investments	Pre-clinical	NA	PP (series B)	USD 93m	NA
Oct 2017	CUREVAC the RNA people®	Co-development of five vaccines against "certain neoantigens"	Pre-clinical	Lilly	Co-development and commercialisation agreement	USD 50m + USD 53m equity stake	**USD 1.8bn**
Nov 2017	nousCom	Backed by a syndicate of leading transatlantic life sciences investors led by new investor Abingworth with participation from 5AM Ventures, and existing investors LSP and Versant Ventures.	Pre-clinical	NA	PP (series B)	USD 49m	NA
Jun 2018	NEON THERAPEUTICS	Neon Therapeutics was listed on Nasdaq ($NTGN) on June 27, raising USD 100m by offering 6.25m shares at USD 16 (midpoint). Insiders purchased up to USD 35m of the IPO. Morgan Stanley, BofA Merrill Lynch and Mizuho Securities acted as lead managers on the deal.	Phase I (3)	NA	IPO and offering of shares	USD 100m	NA
Sep 2018	gritstone ONCOLOGY	Gritstone was listed on Nasdaq ($GRTS) on Sep 28, raising USD 100m by offering 6.7m shares at USD 15 (high end). Insiders purchased up to USD 35m worth of shares in the offering.Goldman Sachs, Cowen and Barclays acted as joint bookrunners on the deal.	Phase I (Oct '18)	NA	IPO and offering of shares	USD 100m	NA

Busy days in Vaccibody since Arctic Lunch Meeting February 5

- Approval of Clinical Trial Application (CTA) for cancer neoantigen trial announced on March 8
- Capital Markets Day held on April 3
- First patient enrolled in neoantigen study on April 4
- Strong killer T cell responses (CD8+) in VB10.16 trial announced April 26

Significant media attention on Vaccibody

Vaccibody team at summer party June 28, 2018

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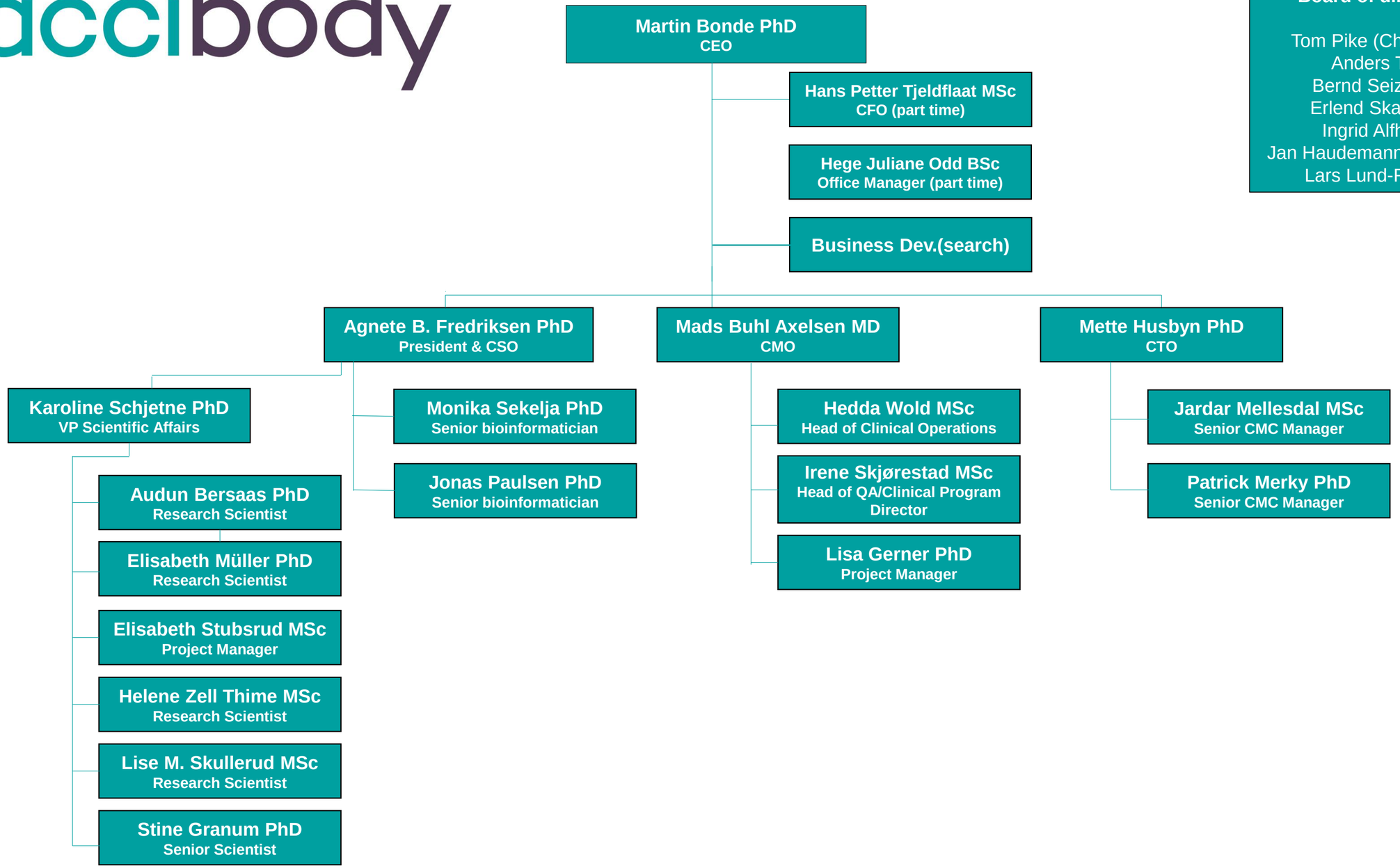
Organization chart



Board of directors

Tom Pike (Chairman)
Anders Tuv
Bernd Seizinger
Erlend Skagseth
Ingrid Alfheim
Jan Haudemann-Andersen
Lars Lund-Roland

Nektar collaboration and VB10.16 results announced in September

SEPTEMBER 20, 2018. VACCIBODY ANNOUNCES CLINICAL COLLABORTATION WITH NEKTAR THERAPEUTICS FOR EVALUATION OF VACCIBODY'S PERSONALIZED CANCER NEOANTIGEN VACCINE IN COMBINATION WITH NEKTAR'S CD-122-BIASED AGONIST, NKTR-214.

Vaccibody AS today announced a new clinical collaboration with Nektar Therapeutics to evaluate Vaccibody's personalized cancer neoantigen vaccine, VB10.NEO, in combination with Nektar's CD-122-biased agonist, NKTR-214. VB10.NEO is designed to specifically activate the patient's immune system to tumour specific antigens, called neoantigens. NKTR-214 is designed to...

SEPTEMBER 26, 2018. POSITIVE RESULTS FROM THE 6-MONTHS INTERIM ANALYSIS OF THE PHASE IIA CLINICAL STUDY IN HIGH GRADE CERVICAL DYSPLASIA PROVIDES PROOF-OF-CONCEPT FOR VACCIBODY'S IMMUNOTHERAPY PLATFORM

Vaccibody AS today announced positive 6-months interim results from the phase IIa part of the clinical study VB C-01. This study is a first human dose, open-label, multicenter phase I/IIa study of VB10.16 immunotherapy for the treatment of high grade Cervical Intraepithelial Neoplasia (CIN 2/3)...

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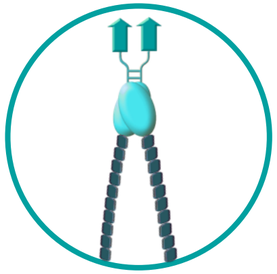

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Headlines for Nektar collaboration

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Oslo, Norway, September 20, 2018.

Vaccibody announces clinical collaboration agreement with Nektar Therapeutics for evaluation of Vaccibody's personalized cancer neoantigen vaccine in combination with Nektar's CD-122-biased agonist, NKTR-214

Vaccibody AS today announced a new clinical collaboration with Nektar Therapeutics to evaluate Vaccibody's personalized cancer neoantigen vaccine, VB10.NEO, in combination with Nektar's CD-122-biased agonist, NKTR-214.

VB10.NEO is designed to specifically activate the patient's immune system to tumour specific antigens, called neoantigens. NKTR-214 is designed to lead to further stimulation and proliferation of the immune cells. Preclinical results indicate a synergistic effect of VB10.NEO and NKTR-214 resulting in enhanced neoantigen-specific T cell responses. The clinical evaluation will take place in patients with squamous cell carcinoma of the head and neck. The first stage of the clinical trial will be a pilot study which will enroll 10 patients.

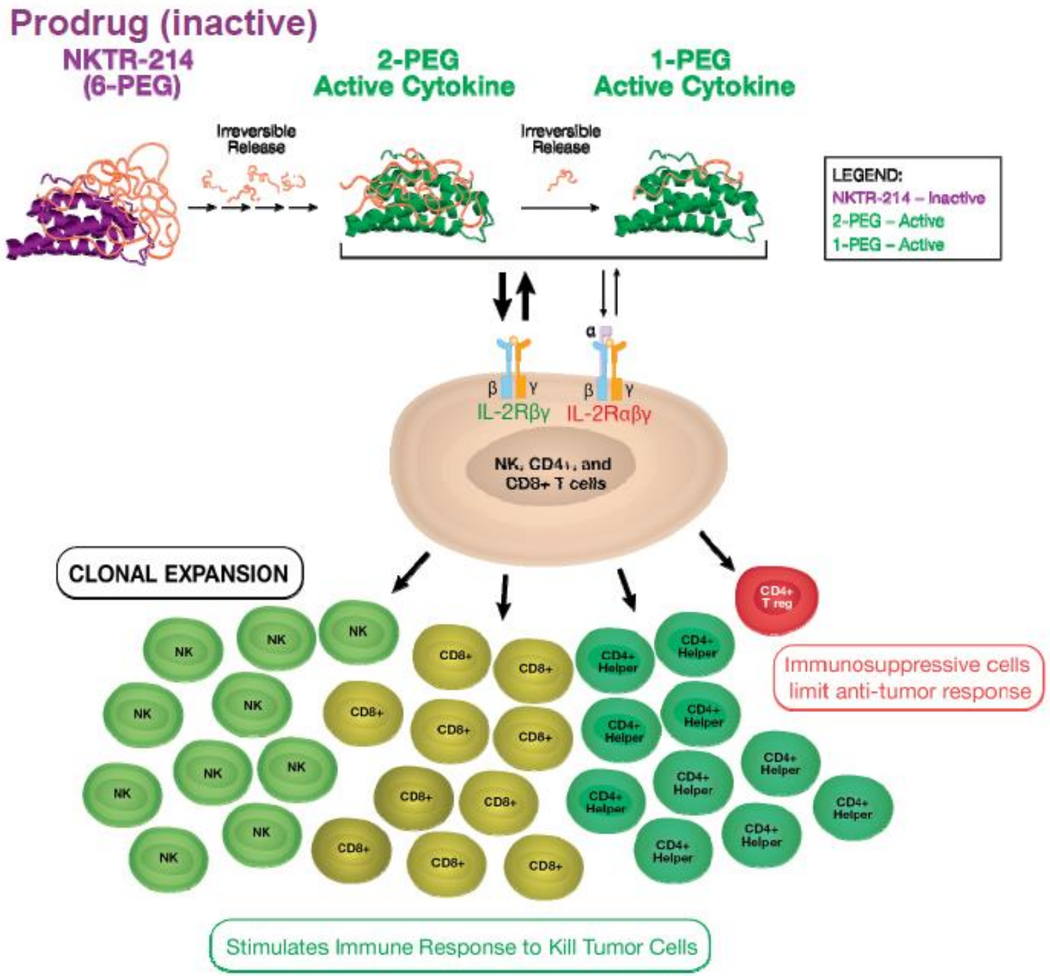
Nektar and Vaccibody each will maintain ownership of their own compounds in the clinical collaboration, and the two companies will jointly own clinical data that relate to the combination of VB10.NEO and NKTR-214. Under the terms of the agreement and following the completion of the pilot study, the two companies will evaluate next steps for development of the combination regimen.

Martin Bonde, CEO of Vaccibody, commented: *We are very pleased to be joining forces with Nektar Therapeutics in this new clinical research collaboration. The preclinical in-vivo studies of NKTR-214 in combination with Vaccibody's neoantigen vaccines generated very promising results. We look forward to further evaluate the Vaccibody neoantigen vaccine in combination with NKTR-214 in the clinic. The combination is designed to improve clinical outcome in patients that need additional help to elicit a strong, neoantigen-focused immune response and thus such combination may broaden the patient population benefitting from either therapy alone.*

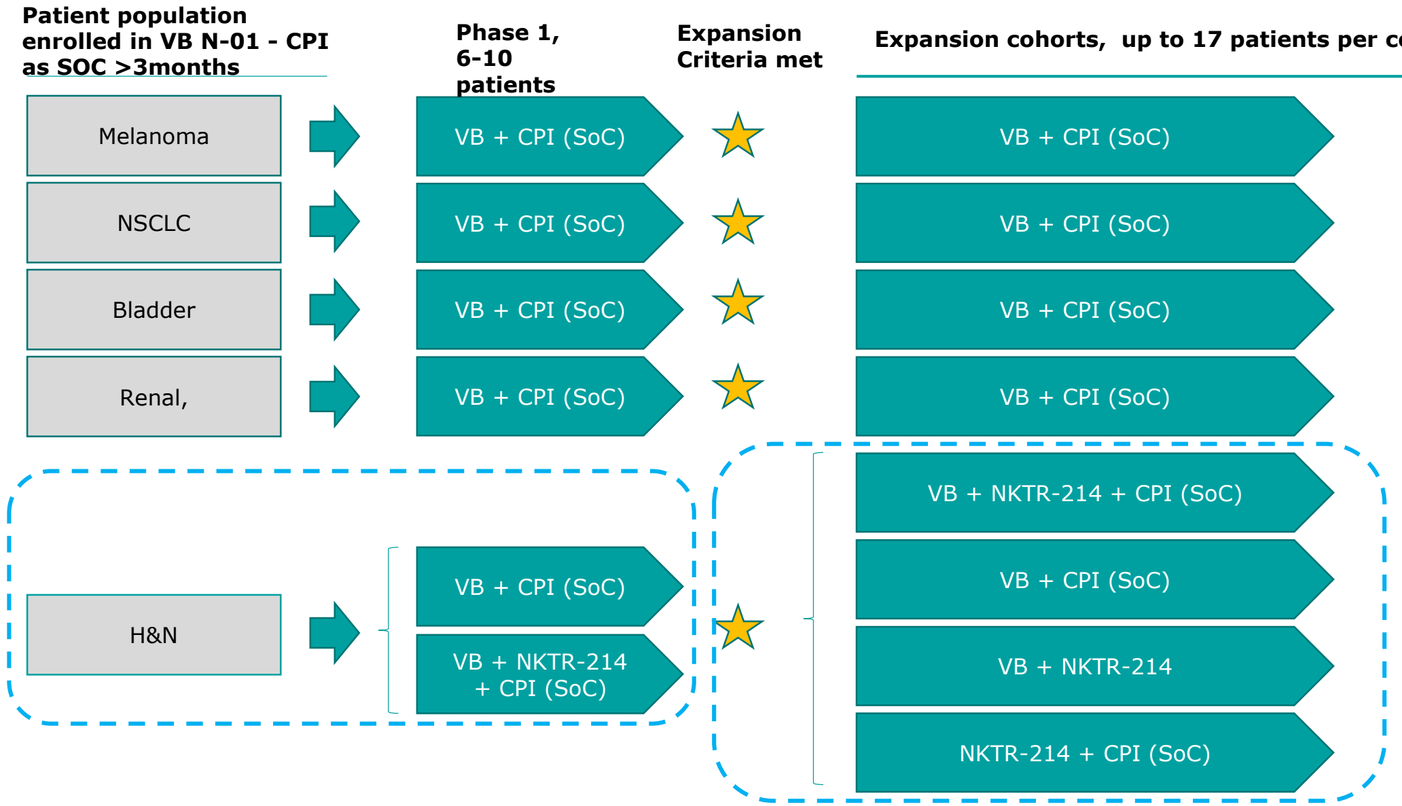
Jonathan Zalevsky, CSO of Nektar, said: *Vaccibody technology holds the potential of combining a personalized cancer vaccine approach which is designed to drive antigen presentation with NKTR-214, which can drive specific clonal T cell expansion to vaccine epitopes. We look forward to working with Vaccibody to seek the advancement of this unique combination into the clinic.*

- Clinical Trial Collaboration in 10 patients with squamous cell carcinoma of the head and neck – combining VB10.NEO and NKTR-214
- Nektar and Vaccibody maintain ownership to their own compounds
- Will jointly own clinical data relating to the combination of VB10.NEO and NKTR-214
- «No strings attached» – will evaluate outcome and then eventually continue collaboration
- Financial terms not disclosed

What is NKTR-214?



Step wise incorporation of NKTR-214/VB10.NEO combo into current Vaccibody study may reduce the regulatory risk



Extra arm with NKTR-214 as add on to VB and CPI

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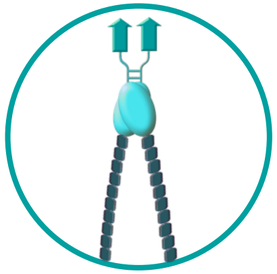

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Topline results from VB10.16 interim (6-months) phase IIa

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Oslo, September 26, 2018. Positive results from the 6-months Interim analysis of the phase IIa clinical study in high grade cervical dysplasia provides Proof-of-Concept for Vaccibody's immunotherapy platform.

Vaccibody AS today announced positive 6-months interim results from the phase IIa part of the clinical study VB C-01. This study is a first human dose, open-label, multicenter phase I/IIa study of VB10.16 immunotherapy for the treatment of high grade Cervical Intraepithelial Neoplasia (CIN 2/3) caused by human papillomavirus 16 (HPV16). 12-months data will be announced in Q1, 2019.

The phase IIa enrolled 18 CIN 2/3 patients, 1 patient was withdrawn and 17 patients each received four doses of 3 mg of VB10.16 at week 0, 3, 6 and 16 weeks. The primary objective of the study was to evaluate the safety and tolerability of VB10.16. The secondary objectives were to assess T cell mediated immune responses in the peripheral blood and to evaluate early signs of efficacy by means of CIN regression and HPV clearance. The vaccine was delivered with a pain-less PharmaJet® Stratis Needle-free Injection System.

The treatment with the four doses of VB10.16 was well tolerated in the phase IIa part as it was in the phase I part of the study. No serious adverse advents (SAEs) or unexpected adverse events were reported. The most frequently reported AEs were transient mild to moderate reactions at the injection site.

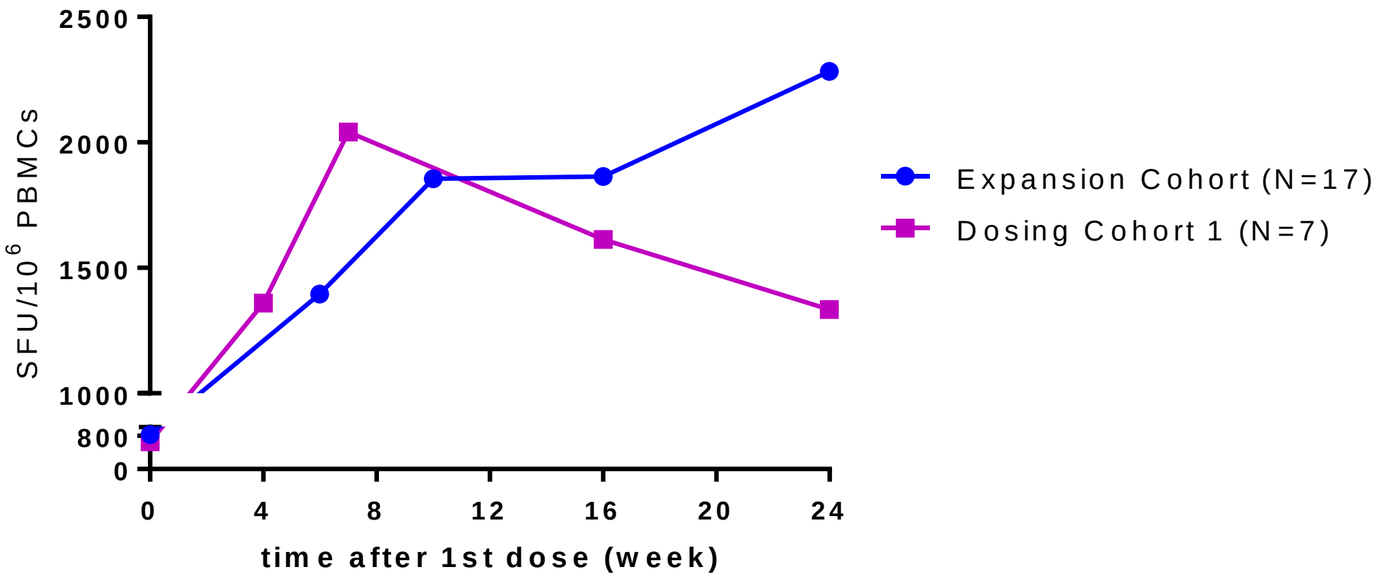
Immunological analyses of the peripheral blood demonstrated a strong HPV16-specific T cell immune response in 17 of 17 patients evaluated. The response was induced by the vaccine in 16 of 17 patients against both antigens used in the vaccine (HPV16 proteins E6 and E7). One patient had a strong baseline response and thus was not further induced by the vaccine. These results constitute a proof-of-concept for the Vaccibody DNA vaccine technology delivered by jet injection regarding its ability to generate a rapid, strong and long-lasting response.

One patient had conization at 4 months and could not be assessed at 6 months. Of the remaining 16 patients, 15 patients showed a partial or complete response at 6 months (13 partial responders, 2 complete responders, 1 stable disease). 14 patients showed a reduction in lesion size from colposcopic examination at 6 months (median reduction for these 14 patients was 50%). Histopathological regression to low grade neoplasia (CIN 1) or no disease was seen in 8 patients. Of the 8 patients that has not regressed to CIN1 or less at 6 months, 6 patients showed upregulation of PD-L1 in the lesions which may delay or inhibit elimination of all affected cells. Three of these patients had also persistent co-infection with other high-risk HPV strains, including one patient which had cleared HPV16.

Adding a 4th vaccination at 4 months significantly boosted the T cell response and the strongest response was observed at 6 months. Change in lesion size and CIN regression will be monitored until 12 months after first vaccination.

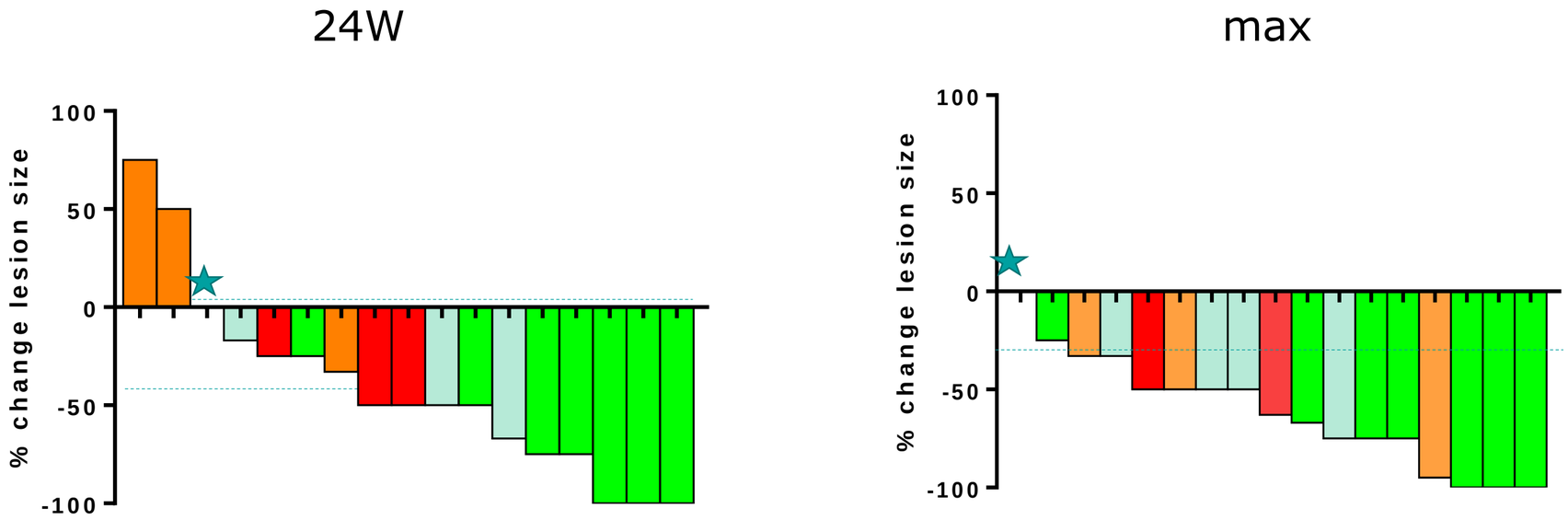
- Excellent safety profile in all 18 patients
- Very strong HPV16-specific T cell immune response in 17 of 17 patients evaluated; induced by vaccine in 16 of 17 patients
- One patients had conization – of the remaining 16 patients 15 showed a partial or complete response at 6 months (13 partial, 2 complete, one stable disease.
- Regression to CIN1 or no CIN was seen in 8 patients.
- 8 patients not regressed: 6 upregulated PD-L1

Strong, long-lasting immune responses elicited to HPV16, VB C-01



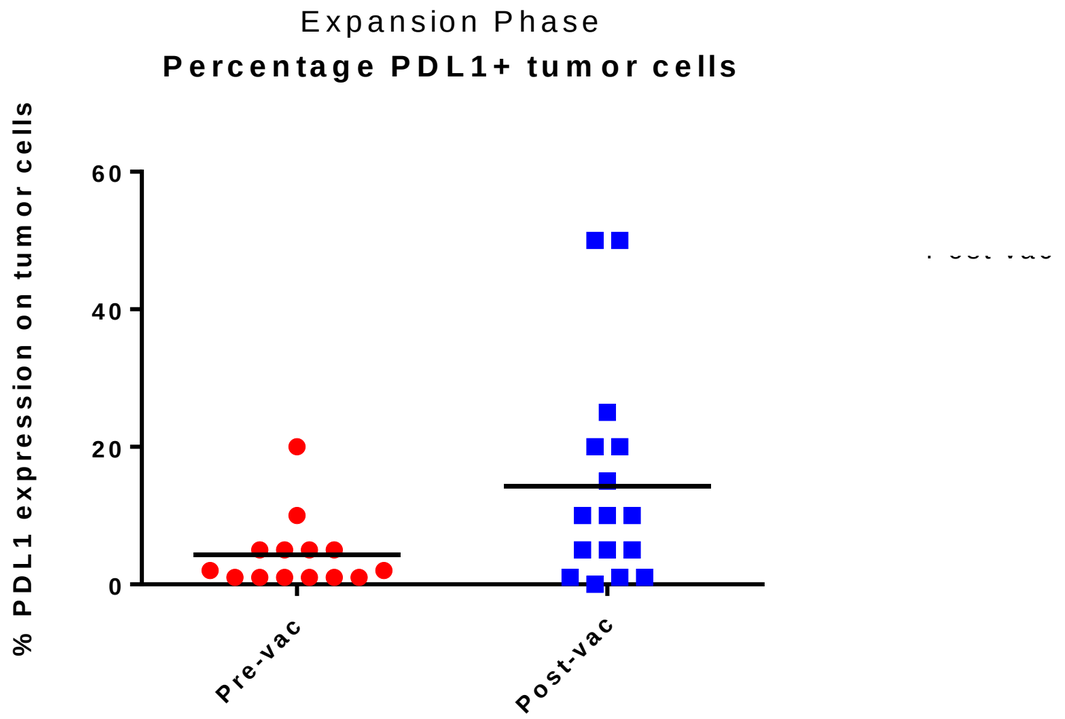
- The vaccination regiment from cohort 1 (week 0, 3 and 6) plus a booster vaccination at W16 was introduced in phase IIa
- 16 of 17 patients (94%) from phase IIa elicited increased HPV16-specific T cell responses after vaccination with VB10.16.
  - Rapid, strong and long-lasting

Lesion size reduction observed in majority of patients, VB C-01



- 16 of 17 patients from phase IIa showed reduction in lesion size
- ★ The one patient without lesion size reduction chose early conization (week 16)
- At 24 weeks, 14 patients showed decreased lesion size, 2 patients an increase
- 13 PR, 2 CR, 2 SD (one of these were conizated early)

VB10.16 upregulates PD-L1 locally, VB C-01



- Strong rationale for combination with anti-PD-1/PD-L1 to improve effect of CPI, especially in PD-L1 negative patients

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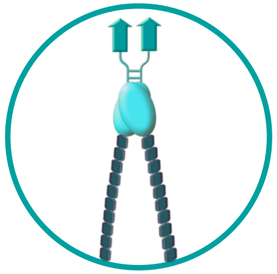


2. Deal with Nektar Therapeutics

NEKTAR®

3. 6-Months data from VB10.16 phase IIa clinical study

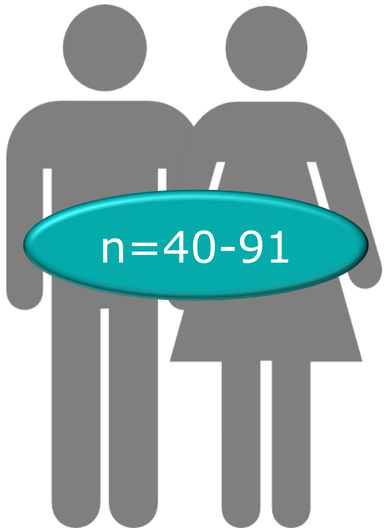
4. Update on VB10.NEO clinical trial

Clinical Trial VB N-01 planned FPI Q12018

VB N-01: An open labelled first human dose phase 1/2a study to evaluate safety, feasibility and efficacy of multiple dosing with individualised VB10.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

VB10.NEO

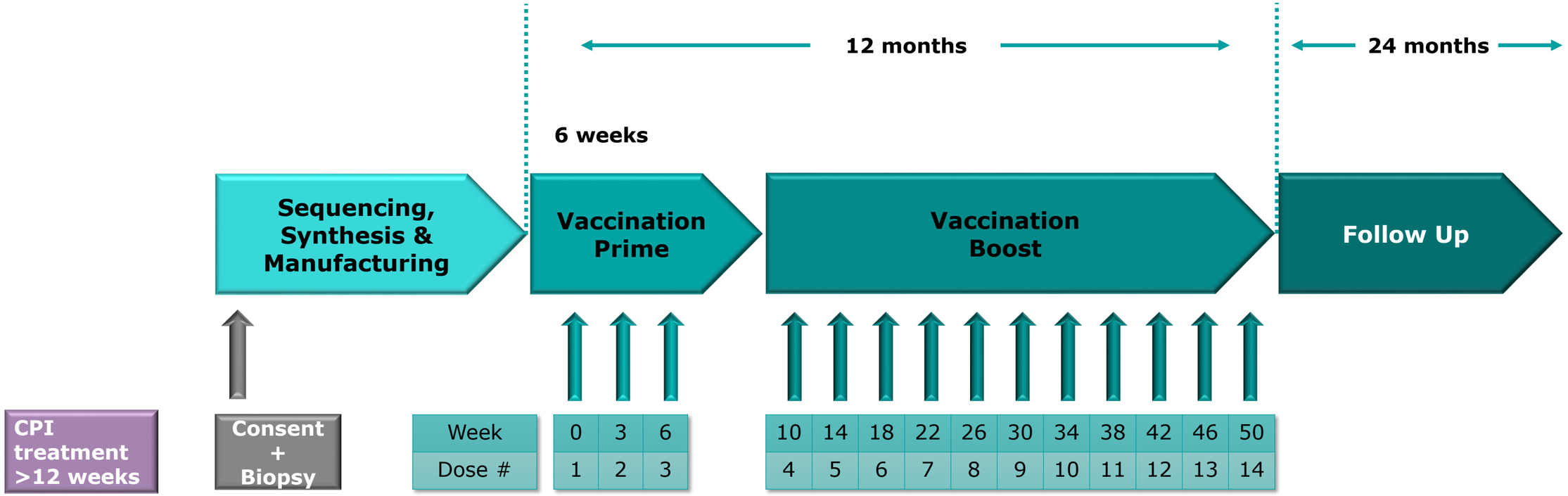
VB N-01



- **Melanoma**
- **NSCLC**
- **Clear Renal Cell Carcinoma**
- **Urothelial Cancer**
- **Squamous Cell Carcinoma of the Head and Neck**

- Approved CPI as SOC
- Moderate to high mutational load

Study Design and Treatment Schedule VB N-01



Renowned, International Clinical Sites

Prof Dr med Jürgen Krauss*
Head of Clinical Immunotherapy
National Centre for Tumour Diseases (NCT), Medical Oncology

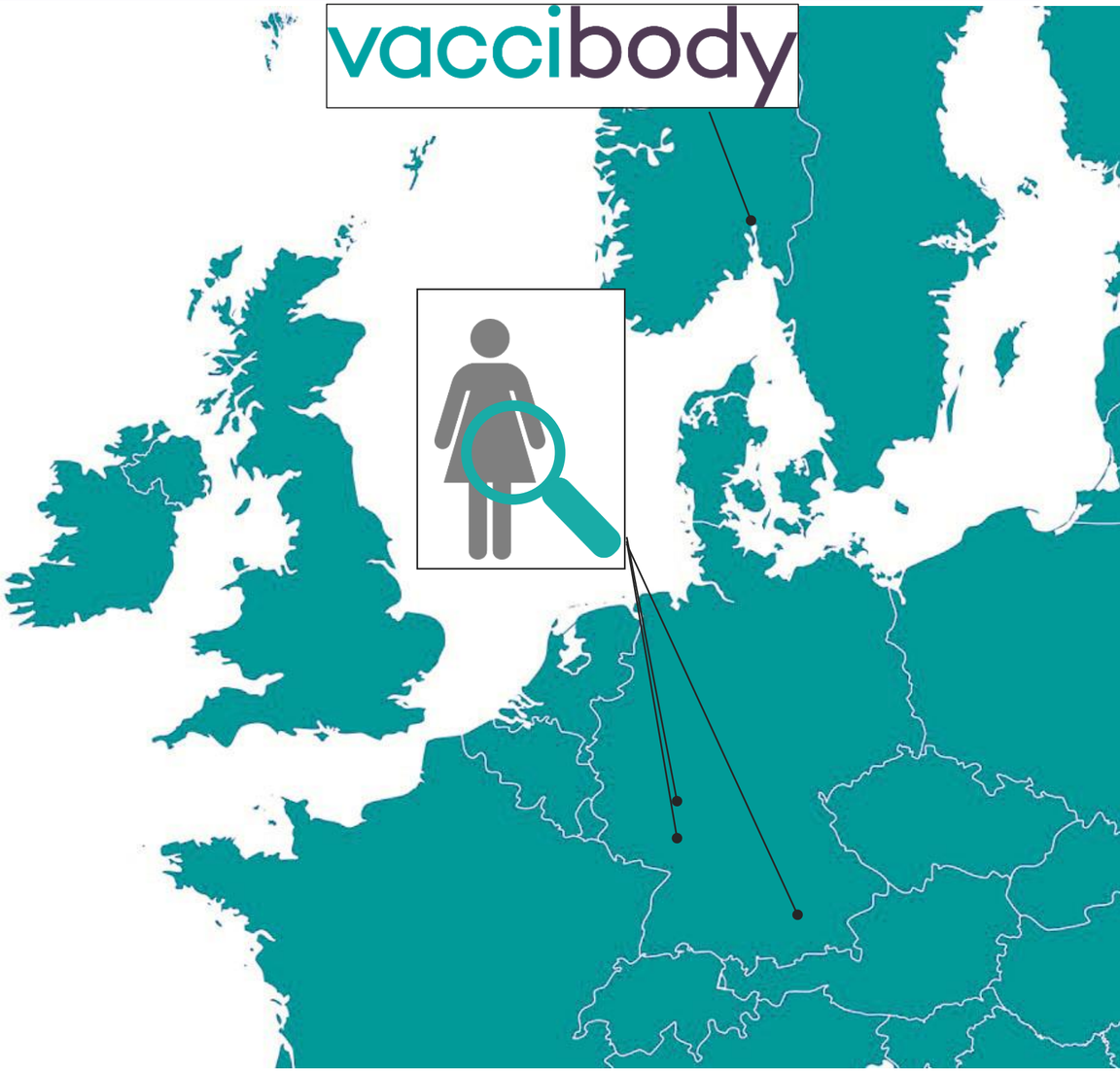
Heidelberg, Germany

Prof Dr med Angela Krackhardt
Director Tumour Immunology and Translational Immunotherapy
University Hospital Klinikum Rechts der Isar

Munich, Germany

Prof Dr med Elke Jäger
Director Department of Oncology and Hematology
Clinic Nordwest

Frankfurt am Main, Germany



* Coordinating Investigator

Update on VB10.NEO clinical trial

- Patient enrolment progressing nicely – first 10 patients enrolled.
- Vaccinations started.
- Systemic immune responses from first few patients expected in Q1, 2019.
- Interim report on 12-20 patients mid-2019.

Vaccibody team ready to execute and deliver

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www.vaccibody.com