PRESS RELEASE

VACCIBODY ANNOUNCES INITIAL POSITIVE CLINICAL RESPONSES IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC CANCER TREATED WITH VB10.NEO NEOANTIGEN CANCER VACCINE

VB10.NEO is the first neoantigen cancer vaccine to demonstrate induction of strong cancer-specific immune responses which leads to clinical responses in several patients with locally advanced or metastatic disease.

Interim results from phase I/IIa clinical trial suggests a clear link between selection of high-quality neoepitopes, generation of strong neoepitope-specific CD8+ T cell responses and clinical responses.

Poster detailing these results to be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting held in Maryland, USA, 9 November 2019

Oslo, November 5, 2019 Vaccibody AS, a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel cancer vaccines, today announces strong preliminary data from the ongoing VB N-01 phase I/IIa clinical trial of the VB10.NEO neoantigen cancer vaccine. The data is from the first 16 patients assessed for safety after treatment with a VB10.NEO, and the first 14 patients assessed for clinical responses.

Key highlights include:

- Clinical responses were observed after treatment start with VB10.NEO in 50% of all analysed patients across tumour types
    - Lesion size reductions of 10-100% or stabilization of prior progressing lesions.
    - All four head and neck cancer (SCCHN) patients, the melanoma patient, the non-small cell lung cancer (NSCLC) patient and one of eight renal cancer (RCC) patients show a clinical response after starting VB10.NEO vaccinations.
- Clinical responses correlate with high quality neoepitopes and strong *de novo* CD8 positive neoepitope-specific T cell responses induced by VB10.NEO.

Prof. Dr. med. Jürgen Krauss, of the Department of Medical Oncology, National Center for Tumor Diseases, University Hospital Heidelberg, Germany, and coordinating investigator of the study, said:
"*I am very pleased with the progress of this clinical phase I/IIa for Vaccibody's neoantigen cancer vaccine. The data indicate that VB10.NEO induces best in class neoepitope-specific immune responses and the clinical responses observed in the first patients are highly intriguing. Since we have not observed any safety concerns with this treatment so far, there is a very high interest to broaden the patient population exposed to this innovative treatment. We are highly committed to continue this exciting program and we hope this clinical trial will help pave the way for a novel class of new efficacious and safe treatment for cancer patients.*"

Agnete Fredriksen President and CSO of Vaccibody, commented:
"*We are very excited to see a clinical response with a clear effect on both the size and the growth of the lesions in a high number of the first patients treated with VB10.NEO as early as 9 weeks after the first dose of VB10.NEO.*

Since we enrolled patients that had been treated with checkpoint inhibitor therapies for at least 5 months before the first dose of VB10.NEO, we are confident that in the cases of actual reductions of lesion sizes this effect can be attributed to the vaccine since most responses to checkpoint inhibitors happens within the first 3-5 months. After this period, further reductions in lesions size are unexpected and lesions that progress usually continue to grow without further interventions. Also, the observation of a strong correlation between high quality neoepitopes in the vaccine and the strength of de novo CD8 neoepitope-specific immune responses that translate into clinical responses is very encouraging. Importantly, this confirms the ability of Vaccibody's vaccine delivery platform to generate strong CD8 T cell responses, critical for tumour killing.

Importantly, responses were also observed in patients with low tumour mutational burden that progressed after long-term checkpoint inhibitor therapy."

Michael Engsig, CEO of Vaccibody, continued:
"To our knowledge, this is the first time that a neoepitope cancer vaccine shows the ability to actually shrink tumours, even in heavily pre-treated patients with advanced or metastatic disease.

Taken together, we are very encouraged to build on these findings and continue development of our neoantigen cancer vaccine program."

Results
Before VB10.NEO vaccination, most patients had received multiple lines of prior anti-cancer therapy and had been treated with a checkpoint inhibitor (CPI) (nivolumab or pembrolizumab) for 5-32 months. All had stable disease or mixed progressive disease when enrolled into the study. Five patients were progressing between enrolment and first dose of VB10.NEO and one had a partial response, while the remaining patients were stable. Twelve of the 14 patients

continued treatment with a CPI during VB10.NEO treatment. A clinical response, defined as either >10% reduction in the target lesions (as identified at screening) or converting progressive lesions into stable lesions (<20% increase, up to 37 weeks follow-up) after starting VB10.NEO treatment, was observed in seven of the 14 patients (4 SCCHN, 1 melanoma, 1 NSCLC and 1 RCC). The strongest clinical responses were most often seen in the lesions that were used to select the neoepitopes.

Eleven patients had low tumour mutational burden (TMB), two patients had medium TMB and one patient had high TMB. The top 20 neoepitopes predicted by Vaccibody's proprietary NeoSELECT^{TM} algorithm were selected for each of the fully personalized VB10.NEO neoantigen vaccines. Vaccibody's proprietary DNA vaccine manufacturing process has so far yielded 100% manufacturing success with the top 20 selected neoepitopes for all patients.

One RCC patient who discontinued CPI and started immunosuppressive treatment prior to first dose of VB10.NEO was not included in the immunogenicity analyses. Immunogenicity to each individual neoepitope was assessed in eight patients after six vaccinations by *in vitro* pre-stimulated IFN-γ ELISpot. The breadth and the strength of neoepitope-specific T cell responses were increased with number of vaccinations. Patients showing a clinical response also had the strongest immune responses and the highest frequency of high quality neoepitopes.

The safety data for the 16 patients who has received at least one dose of VB10.NEO shows that VB10.NEO is well tolerated. Most common adverse events attributable to the VB10.NEO treatment were injection-related hypertensive episodes and injection site reactions.

Four patients with SCCHN were assessed, three with low TMB and one with medium TMB. Two patients had progressive disease, one had stable disease and one had partial response at start of VB10.NEO vaccination. The patients had been on CPI for 12-32 months before starting VB10.NEO treatment. Strong neoantigen-specific T cell responses were seen in the vast majority (60-90%) of the selected neoepitopes after VB10.NEO vaccination with up to 1000-fold increase. A clinical response was observed in all four SCCHN patients: In the patients who had progressed on CPI before starting VB10.NEO a stabilisation or reduction in the size of the target lesions were observed after starting VB10.NEO treatment. In patients with stable disease or partial response on CPI, a reduction in lesion size was observed after starting VB10.NEO treatment. If the patients had multiple target lesions, the strongest response was observed in the lesions used to select neoantigens for the vaccine. Eradication of tumour cells containing the mutations targeted by the vaccine was observed in a follow-up biopsy from one of the patients.

One melanoma patient was assessed. The patient had high TMB and stable disease at start of VB10.NEO vaccination and the patient had been on CPI for 10 months before treatment with VB10.NEO vaccination. An increased neoantigen-specific T cell response was seen to 50% of the selected neoepitopes after VB10.NEO vaccination with the majority being *de novo* responses. A clinical response with lesion size reduction was observed in the patient.

One NSCLC patient was assessed. The patient had medium TMB and stable disease as best response during nine months of CPI treatment before start of vaccination. Disease progression was observed during vaccine manufacturing with the occurrence of a new lesion. A clinical response in the form of rapid reduction in the target lesion was observed nine weeks after the first VB10.NEO vaccination.

Eight patients with RCC were assessed for clinical response, all with low TMB. Two patients had progressive disease and six had stable disease at start of VB10.NEO vaccination. One patient was taken off CPI and started immunosuppressive therapy prior to the first dose of VB10.NEO. Limited clinical responses have been observed until data-cut off (up to 37 weeks after first VB10.NEO vaccination). Interestingly, only one of the RCC patients has had an increase of >20% in the sum of target lesions and none of the lesions used to select neoantigens for the vaccine has progressed (defined as >20% increase in size.) Correlating with the limited clinical responses, fewer high-quality epitopes and neoepitope-specific immune responses were observed.

The Poster

The Poster (ID: P424) will be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting Saturday, 9 November, 7:00 am - 8:30 pm local time in National Harbor, Maryland. Vaccibody staff will be available during the poster session at SITC.

About Vaccibody

Vaccibody is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies. The company is a leader in the rapidly developing field of individualized cancer neoantigen vaccines and is using the Vaccibody technology to generate best-in-class therapeutics to treat cancers with a high unmet medical need. A phase I/IIa neoantigen clinical trial is now enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma as well as urothelial or squamous cell carcinoma of head and neck. Vaccibody has a collaboration with Nektar Therapeutics, planning to start testing VB10.NEO in combination with bempegaldesleukin (NKTR-214) in squamous cell carcinoma of head and neck in H2 2019. Vaccibody's most advanced program (VB10.16) is a therapeutic DNA vaccine against HPV16 induced pre-malignancies and malignancies. The first-in-human study (phase I/IIa), evaluating the safety and immunogenicity of VB10.16 in women with high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3) has been finalized and has published positive 12 months data. Vaccibody has recently started a collaboration with Roche, exploring VB10.16 in combination with CPI atezolizumab (Tecentriq™) in up to 50 patients with advanced or recurrent cervical cancer. First patient is expected to be vaccinated in H1 2020. Further information about the company and its drug development programs and capabilities may be found online at http://www.vaccibody.com

About VB10.NEO

VB10.NEO, is Vaccibody's proprietary therapeutic DNA vaccine which uses the patient's own neoantigens for the personalized treatment of cancer patients. A phase I/IIa neoantigen clinical trial is currently enrolling patients with locally advanced or metastatic melanoma, non-small cell

lung carcinoma, clear renal cell carcinoma as well as urothelial cancer or squamous cell carcinoma of the head and neck.

About VB N-01
VB N-01 (DIRECT-01) is an open-label phase 1/2a study, designed to evaluate the safety, immunogenicity and efficacy of administrating personalized VB10.NEO in combination with checkpoint blockade in patients with locally advanced or metastatic solid tumors including melanoma, NSCLC, renal cell carcinoma, urothelial cancer or head and neck cancer, who have not achieved a complete response by at least week 12 on checkpoint blockade as respective standard of care (NCT03548467).

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