

Vaccibody to initiate a phase 1/2 trial to evaluate two second-generation SARS CoV-2 virus DNA vaccine candidates to address emerging variants of concern

- Vaccibody to initiate phase 1/2 trial to evaluate second-generation SARS CoV-2 virus DNA vaccine candidates to address emerging variants of concern
- 2-armed strategy with one RBD- and one T cell candidate
- CTA to be submitted in Q3 and first subject expected to be dosed in early Q4
- The clinical trial will be conducted in Norway at Oslo University hospital and Haukeland University hospital, Bergen
- Frequent regulatory and scientific advice consultations with the Norwegian Medicines Agency

Oslo, Norway, June 29, 2021 – Vaccibody AS (Euronext Growth (Oslo): VACC), a clinical-stage biopharmaceutical company dedicated to the discovery and development of vaccines and novel immunotherapies, announced today that it is initiating a phase 1/2, open label, dose escalation trial in healthy adult volunteers to determine safety and immunogenicity of two SARS CoV-2 virus DNA vaccine candidates: an RBD candidate and a T-cell candidate.

Vaccibody's development strategy is to develop second-generation SARS CoV-2 vaccines that may respond to the emerging threats of evolving variants with reduced sensitivity to first generation vaccines that were developed using the 2020 prototype spike protein. The trial is a continuation of the promising pre-clinical work published by Vaccibody in December 2020 showing that pre-clinical vaccine candidates induced rapid, strong and long-lasting neutralizing antibodies, as well as multifunctional, dominant CD8+ T cell and Th1 CD4+ T cell responses in mice, after a single dose.

Michael Engsig, CEO of Vaccibody comments: "The two SARS CoV-2 vaccine candidates are the first results of our vaccine strategy within infectious diseases. It is an important milestone, and we are proud to demonstrate the rapid development and fast turn-around time for our Vaccibody technology platform with these second-generation CoV-2 vaccine candidates. In addition, Vaccibody continues to work on other pathogens as part of the Company's infectious disease strategy."

The 2-armed trial takes its outset in two development candidates designed around the modular Vaccibody technology platform, targeting antigens to antigen presenting cells. The dose escalation trial will enroll both pre-treated and treatment naïve subjects.

The first new drug candidate is an RBD candidate encoding the receptor binding domain (RBD) derived from the SARS-CoV-2 virus. The RBD domain is responsible for binding to the ACE2 receptor and is a relevant target for neutralizing antibodies. It is expected to elicit protection against disease by inducing neutralizing antibodies alongside a balanced CD8+ and Th1 biased CD4+ response.

The second candidate builds on emerging evidence showing that T cell responses are likely to play an essential role in SARS-CoV-2 immunity and viral clearance, and that T cell-epitopes are less prone to immune evasion than the surface-exposed spike epitopes including current and future variants of concern. The candidate encodes multiple immunogenic and conserved T cell epitopes spanning multiple antigens across the SARS-CoV-2 genome.

Anne Margarita Dyrhol Riise, Professor, MD, PhD, Department Head Infectious disease, Oslo University hospital and the principal investigator for the trial says: “The SARS-CoV-2 pandemic has demonstrated the need for efficient and safe vaccine programs that address the paramount public health burden of COVID-19. The new emerging variants of concern demonstrate that there is still a large unmet patient need and we are very pleased to participate in this important trial.”

Chief Medical Officer of Vaccibody, Siri Torhaug, continues: “We are very excited about this upcoming trial. We are in close and frequent dialogue with regulatory and scientific advice consultations with the Norwegian Medicines Agency (NoMA). Vaccibody consults their experts in a rolling review of key documents to be included in the application for the trial. The primary objective of this flexible process is to proactively align expectations for the approval of the trial to allow for a rapid initiation of the clinical activities”.

The trial is currently in the planning phase and with the CTA (Clinical Trial Application) expected to be submitted in Q32021 and the first patient expected to be dosed in early Q42021. The trial plans to enroll approximately 100-200 patients.

About Vaccibody

Vaccibody AS, is a clinical-stage biopharmaceutical company, dedicated to the discovery and development of vaccines and novel immunotherapies. The Company develops vaccines for the treatment of cancer and infectious diseases. Vaccibody’s vaccine technology specifically targets antigens to Antigen Presenting Cells, which are essential for inducing rapid, strong and

long-lasting antigen-specific immune responses and elicit efficacious clinical responses. Its lead product candidates include VB10.NEO, a cancer neoantigen vaccine, which is exclusively outlicensed to Genentech and is in phase I/IIa clinical trial for the treatment of melanoma, lung-, head and neck, renal-, and bladder cancer; and VB10.16, a therapeutic vaccine for the treatment of human papilloma virus 16 induced malignancies, such as cervical cancer and cancer of the head & neck. Further, the Company has collaborations with Roche and Nektar Therapeutics within oncology.

Additionally, Vaccibody intends to leverage the potential of its platform in infectious disease indications, including initiating a phase 1/2 trial to evaluate its second-generation SARS CoV-2 virus vaccine candidates.

Vaccibody's shares are traded on Euronext Growth (Oslo), a trading platform operated by Euronext, the leading Pan-European market infrastructure. The ticker code is VACC. Further information about Vaccibody may be found at <http://www.vaccibody.com>

Contact for Vaccibody:

CEO Michael Engsig
Vaccibody AS
Cell: +45 6173 1509
mengsig@vaccibody.com

Vaccibody AS

Oslo Science Park
Gaustadalléen 21
0349 Oslo, Norway

Forward-looking statements for Vaccibody

This announcement and any materials distributed in connection with this announcement 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.