

## **Vaccibody doses first patient in Phase II clinical trial of VB10.16 in combination with immune-checkpoint inhibitor in advanced cervical cancer**

- *First patient in the VB C-02 trial has received the first dose of VB10.16 and Roche's immune-checkpoint inhibitor atezolizumab (Tecentriq®)*
- *First site to open was Oslo University Hospital in Norway*
- VB10.16 has previously demonstrated a beneficial safety and efficacy profile in a Phase I/IIa clinical trial in pre-cancerous cervical lesions thus providing a sound rationale for the VB C-02 trial in cervical cancer

**Oslo, Norway, July 2nd, 2020** – Vaccibody AS, a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, announces First Patient Dosed in its VB C-02 trial; a multi-centre, open-label Phase II clinical trial testing a combination of Vaccibody's VB10.16, a targeted DNA vaccine, and Roche's PD-L1-blocking immune-checkpoint inhibitor atezolizumab (Tecentriq®) in patients with advanced or recurrent, non-resectable HPV16 positive cervical cancer.

Siri Torhaug, Chief Medical Officer of Vaccibody, said: "We are excited to have the first patient dosed with VB10.16 at our Norwegian site at Oslo University Hospital, and to initiate the clinical collaboration with Roche. Today, advanced cervical cancer patients have limited treatment options. The trial addresses the high unmet medical need in this patient population, as well as the need for novel treatment options."

Agnete B. Fredriksen, President & Chief Scientific Officer of Vaccibody, added: "VB10.16 is the frontrunner in the Vaccibody cancer vaccine portfolio. The rationale for this trial is supported by the positive data from the Phase I/IIa clinical trial with VB10.16 as monotherapy in patients with precancerous cervical lesions and data supporting a scientific rationale for synergistic effect of combining VB10.16 with checkpoint inhibitors. We believe the combination of VB10.16 and atezolizumab can enhance the anti-tumor efficacy in advanced cervical cancer patients."

The planned open-label Phase II clinical trial is designed to evaluate the safety and efficacy of multiple dosing with VB10.16 immunotherapy in combination with atezolizumab in patients with advanced or recurrent non-resectable HPV16 positive cervical cancer, who failed or are not eligible for current standard of care. The VB C-02 clinical trial is a multi-centre, open-label clinical trial and will enroll up to 50 patients in six European countries. The clinical trial has the ClinicalTrials.gov Identifier: NCT04405349.

## **About VB10.16**

VB10.16 is an investigational therapeutic DNA vaccine developed to treat human papillomavirus type 16 (HPV16) induced malignancies and pre-malignancies. The drug candidate has demonstrated favorable 12M clinical data in a Phase I/IIa clinical trial in pre-cancerous HPV16 induced high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3).

## **About cervical cancer**

Cervical cancer is the most common cancer among women in developing countries and is the second most common cancer amongst women worldwide. An estimated 45 thousand cases of cervical cancer will be diagnosed in the US and EU in 2020 and similarly an estimated 18 thousand deaths from cervical cancer will occur in 2020. Cervical cancer is caused by high risk HPV. HPV16 is the virus type that most frequently causes cancer. It has been reported to be the most common genotype in high grade cervical intraepithelial neoplasia. It is detected in up to 60% of all cervical cancers, especially in younger women and it has also been found to play an essential role in the development of several other cancer types (approximately 90% of anal cancers; 70% of oropharyngeal cancers, 40% of penile-, vaginal-, and vulvar cancers; and 25% of oral cavity cancers). Gardasil® and Cervarix® are preventive HPV vaccines which prevent infection of HPV, but these do not have an effect in already infected patients. A high percentage of the eligible population for the preventive vaccines does not get vaccinated, thus HPV infection and HPV+ cancer still requires effective therapeutic interventions. There is currently no available therapy treating HPV specifically.

## **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. Further, the Company has initiated research on infectious diseases.

Vaccibody is developing cutting-edge, targeted DNA vaccines for clinical use, based on a deep understanding of immunological principles. Vaccibody's vaccines specifically target Antigen Presenting Cells (APC), which are essential for inducing rapid, strong and specific immune responses and elicit efficacious clinical responses. By intelligent design, Vaccibody's vaccines can be tailored to induce the desired immune response profile correlating with protection for each specific disease with any given antigen. Hence, the Vaccibody vaccine platform has the potential to address many disease areas with a high unmet medical need such as cancer and infectious diseases. In addition, Vaccibody has collaborations with Roche and Nektar Therapeutics.

Vaccibody's lead product candidates are VB10.NEO, a personalized therapeutic cancer neoantigen vaccine currently being evaluated in a Phase I/IIa clinical trial, and VB10.16, a therapeutic cancer vaccine against HPV16-related cancers that is currently being tested in a Phase II clinical trial.

Vaccibody's shares are traded on NOTC, a marketplace for unlisted shares managed by NOTC AS, which is owned 100% by Oslo Børs ASA, the Oslo Stock Exchange.

Further information about the Company may be found at <http://www.vaccibody.com>

**Contact:**

CEO Michael Engsig

Vaccibody AS

Cell: +45 6173 1509

[mengsig@vaccibody.com](mailto:mengsig@vaccibody.com)

**Vaccibody AS**

Oslo Research Park

Gaustadalléen 21

0349 Oslo, Norway