Ultimovacs’ UV1 in combination with pembrolizumab shows 60% Objective Response Rate in advanced melanoma Phase I data

- UV1/pembrolizumab results in 30% complete responses plus 30% partial responses
- Good safety and tolerability profile supports use of UV1 in combination treatments
- Data to be presented at ASCO and abstract to be discussed in webcast on May 20, 2021

Oslo, 19 May 2021: Ultimovacs ASA ("Ultimovacs") (OSE ULTI), a clinical stage leader in immune stimulatory vaccines for cancer, today announced that its universal cancer vaccine, UV1, in combination with the checkpoint inhibitor pembrolizumab, demonstrated a 60% objective response rate (ORR) in metastatic malignant melanoma. All patients have been observed for at least 18 months and median observation time is 21 months. The results will be presented as an online poster at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting.

The 60% ORR (6 complete responses (CR); 6 partial responses (PR) from a 20-patient cohort) with 30% CR, clearly exceeds the response rate for pembrolizumab alone in advanced melanoma (33-37% ORR and 5-12% CR)*. The median progression-free survival for the UV1/pembrolizumab combination in the study was 18.9 months compared with 5.5-11.6 months* for pembrolizumab alone in advanced melanoma. The overall survival was 80%, with the median overall survival yet to be reached after 21-months of follow-up.

“These very strong and exciting data further strengthen the foundation for our broad Phase II clinical program for UV1,” said Jens Bjørheim, Chief Medical Officer at Ultimovacs. “To show this level of beneficial clinical response while being safe and well-tolerated in combination with pembrolizumab underscores our development strategy to show that UV1 can provide a significant increase in therapeutic effect in a broad range of indications and combinations.”

The rationale for the use of UV1 is that patients with advanced malignant melanoma often lack the relevant T cells to obtain durable benefits from the use of pembrolizumab alone. UV1 expands T cells that have the potential to increase the breadth and diversity of the immune response towards all parts of the tumor.

The data comes from Ultimovacs’ open-label Phase I study (NCT03538314) and will be shown as a poster presentation at ASCO, to be held virtually Friday, June 4, 2021 through Tuesday, June 8, 2021. The data also shows that the UV1/pembrolizumab combination is well tolerated, with adverse events largely restricted to low grade effects, mainly injection site reactions.

“These data reinforce our conviction that UV1 can play a transformatative role in the treatment of conditions such as malignant melanoma,” said Carlos de Sousa, CEO of Ultimovacs. “It suggests that UV1 in combination with checkpoint inhibitors like pembrolizumab can mobilize the immune system to fight cancer. This is very encouraging for melanoma patients and for those involved with the roll-out of Ultimovacs’ broader programs in solid cancers.”

Webcast
A corporate webcast will be held on Thursday 20 May 2021, 10:00 CEST. Carlos de Sousa, CEO of Ultimovacs and Jens Bjørheim, CMO, will discuss the ASCO abstract. It will be possible to submit written questions during the presentation. [Webcast Link] The webcast will be available subsequently on the company website.

The Poster Presentation
The poster presentation will be available on the Ultimovacs website on 4 June 2021 at 15:00 CEST: [Link]
Title: A Phase I Clinical Trial Investigating the Telomerase Vaccine UV1 in Combination with Pembrolizumab in Patients with Advanced Melanoma


About UV1
UV1 is a peptide-based vaccine inducing a specific T cell response against the universal cancer antigen telomerase. UV1 is being developed as an “off-the-shelf” therapeutic cancer vaccine which may serve as a platform for use in combination with other immunotherapy which requires an ongoing T cell response for their mode of action. To date, UV1 has been tested in four phase I clinical trials in a total of 82 patients and maintained a positive safety and tolerability profile as well as encouraging signals of efficacy.

About UV1 Clinical Programs
As a universal cancer vaccine, UV1’s unique mechanism of action has the potential to be applicable across most cancer types. The clinical development of the UV1 vaccine includes four randomized, multinational, Phase II combination trials: INITIUM, NIPU, DOVACC and FOCUS, recruiting over 500 patients in total. Ultimovacs anticipates announcing data on the primary endpoints for the NIPU and INITIUM studies in 2H2022 and for the DOVACC and FOCUS studies in 2023.

- The INITIUM trial is an Ultimovacs-sponsored clinical trial recruiting 154 patients with metastatic malignant melanoma to evaluate UV1 in combination with ipilimumab and nivolumab as first-line treatment.
- The NIPU study is testing UV1 in combination with checkpoint inhibitors ipilimumab and nivolumab as second-line treatment in 118 patients with advanced malignant pleural mesothelioma, a rare lung cancer. The study is sponsored by Oslo University Hospital and Bristol-Myers Squibb is providing the checkpoint inhibitors for this study.
- The DOVACC study is sponsored by the Nordic Society of Gynecological Oncology. In total, 184 patients with high-grade ovarian cancer will be enrolled to evaluate UV1 in combination with durvalumab and olaparib, both provided by AstraZeneca.
- FOCUS is an investigator-sponsored, randomized clinical trial enrolling 75 patients with metastatic head and neck cancer receiving pembrolizumab as standard of care, and will evaluate the impact of adding UV1 to this regimen.

About Ultimovacs
Ultimovacs seeks to become a leader in developing immune-stimulatory vaccines to treat a broad range of cancers. Ultimovacs’ lead universal cancer vaccine candidate UV1 leverages the high prevalence of the human telomerase (hTERT) to be effective across the dynamic stages of the tumor’s growth and its microenvironment. By directing the immune system to hTERT antigens that are present in over 80% of all cancers, UV1 drives CD4 helper T cells to the tumor with the goal of activating an immune system cascade to increase anti-tumor responses. Ultimovacs’ strategy is to clinically demonstrate UV1’s impact in many cancer types and in combination with other immunotherapies. The Company will expand its pipeline using its novel TET-platform, which is an innovative vaccine technology that can generate multiple vaccine candidates designed to achieve increased T cell responses to a broad range of target antigens.

For further information, please see www.ultimovacs.com or contact:

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