Ultimovacs ASCO Phase I data shows 60% ORR in advanced melanoma with UV1/pembrolizumab, supporting broad Phase II combination program

- UV1/pembrolizumab results in 30% complete responses plus 30% partial responses
- Good safety and tolerability profile supports expanded Phase II combination program
- Data highlighted at ASCO in poster presentation

Oslo, 4 June 2021: Ultimovacs ASA ("Ultimovacs") (OSE ULTI), a clinical stage leader in immune stimulatory vaccines for cancer, announced that data on its universal cancer vaccine, UV1, in combination with the checkpoint inhibitor pembrolizumab will be presented as a poster presentation at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting and available today at 9:00 am ET / 15:00 CEST.

In a twenty patient cohort of patients with advanced melanoma, the combination of UV1 with pembrolizumab as a first-line treatment demonstrated an objective response rate (ORR) of 60% after a minimum of 18 months. Median observation time was 21 months. In addition, 30% of treated patients achieved a complete response (CR), with no signs of tumor detected. These response rates clearly exceed those seen in previous studies for pembrolizumab alone in advanced melanoma of 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 the range of 5.5-11.6 months for pembrolizumab alone*. The overall survival was 80%, with the median overall survival yet to be reached after 21 months of follow-up.

The data also shows that the UV1/pembrolizumab combination is safe and well tolerated, with adverse events largely restricted to low grade effects, mainly injection site reactions.

Principal investigator and presenter of the ASCO data, Yousef Zakharia, MD, Associate Professor of Medicine and Medical Oncologist at the University of Iowa, commented: “These results are encouraging and warrant further investigation. The trial gives a preliminary signal that UV1 vaccine has the potential to increase efficacy and promote durable responses when combined with checkpoint inhibitors and, more importantly, the combination seems to be safe and well tolerable.”

Ultimovacs continues to build on the safety and tolerability profile of UV1 with several ongoing Phase I and Phase II clinical studies of UV1 in combination with checkpoint inhibitors. In the Phase I UV1/pembrolizumab trial, data on a second cohort of 10 patients (given a standard GM-CSF adjuvant dose of 75 µg, twice that for cohort 1) will be reported when one year follow-up is complete in Q4 2021. Two year follow up on the first cohort will also be reported in Q4 2021.
Meanwhile, recruitment continues in Ultimovacs’ expanding Phase II program of randomized multinational trials of UV1 with checkpoint inhibitors in malignant melanoma, malignant pleural mesothelioma, ovarian cancer and metastatic head-and-neck cancer.

“These ASCO data from our Phase I trial in malignant melanoma represent the moving edge of a much broader Ultimovacs clinical program on the safety and effectiveness of UV1 used in combination with checkpoint inhibitors and other therapeutic classes” said Carlos de Sousa, CEO of Ultimovacs. “Across a variety of cancer types and with several different checkpoint inhibitors, we are accumulating a growing body of evidence underpinning our conviction that UV1 can mobilize the immune system and play a transformative role in the treatment of solid tumors.”

Poster Presentation and Webcast
Title: “A Phase I Clinical Trial Investigating the Telomerase Vaccine UV1 in Combination with Pembrolizumab in Patients with Advanced Melanoma”; ASCO abstract 2620
The oral presentation can be accessed on the ASCO website on June 4 at 9.00 a.m ET (15.00 CEST) [ASCO presentation].
The ASCO presentation is also available on the Ultimovacs website from 4 June 2021 at 15:00 CEST: [ADD link on ULTI website] A corporate webcast on the data presented at ASCO is available on the company website.


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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