DPV-001 Vaccine Containing Cancer's "Dark Matter" Yields 2 to >3-fold Increased Response Rate for Head and Neck Cancer

Positive Data from Phase Ib Study Evaluating UbiVac's DPV-001 as Combination Immunotherapy for Head and Neck Squamous Cell Cancer Presented at AACR Meeting

PORTLAND, OR, USA, April 6, 2024 /EINPresswire.com/ -- • UbiVac Announces a 2 to >3-fold increase in objective clinical response rates over anti-PD-1 alone, for patients receiving DPV-001 vaccine containing cancer's "Dark Matter" as combination immunotherapy for recurrent or metastatic HNSCC

> We are encouraged by the bioactivity observed thus far in HPV-agnostic recurrent/metastatic HNSCC. Partial and complete responses have been observed.."
>
> *Rom S. Leidner, MD, Co-director of the Head & Neck Cancer Program*

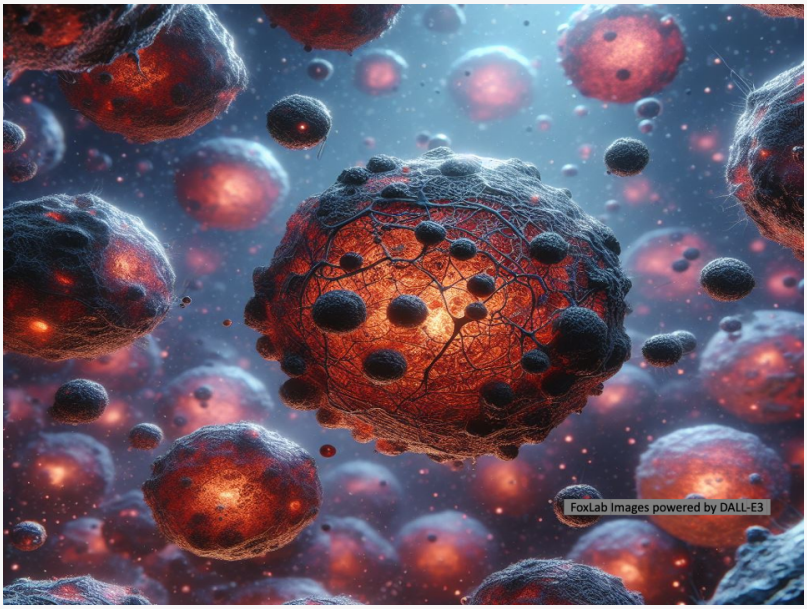
• Responses were observed in patients that had not responded to prior treatment with anti-PD-1/L1

• DPV-001 vaccine is designed as an off-the-shelf combination therapy option for the majority of solid cancers and for patients of all HLA backgrounds

UbiVac, www.ubivac.com, a private, clinical-stage immuno-oncology company today announced the presentation of results from a Phase 1b study evaluating the efficacy and safety of DPV-001, UbiVac's lead cancer vaccine immunotherapy, containing cancer's dark matter, in combination with sequenced checkpoint inhibition (anti-PD-1; retifanlimab, INCMGA00012), with or without anti-GITR agonist (INCAGN01876), in adult patients with recurrent or metastatic head and neck squamous cell cancer (HNSCC) (NCT04470024) at this year's American Association for Cancer Research (AACR) Annual Meeting. The phase Ib study is sponsored by Providence Cancer Institute of Oregon.

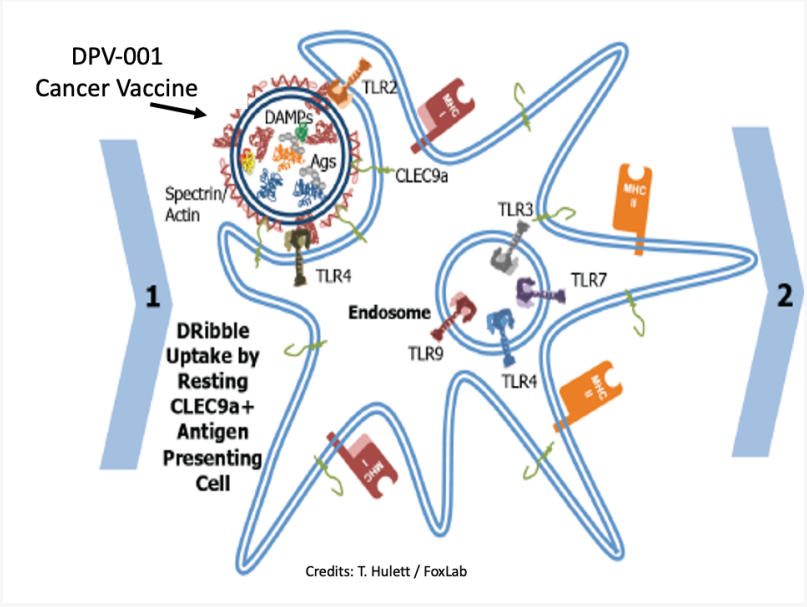
Cancer's dark matter represents a spectrum of previously unknown proteins that have recently

been identified as antigens expressed on the surface of cancer cells but not on normal cells or the thymus. Some of these dark matter proteins appear to be responsible for cancer's malignant properties, making them valuable targets for an anti-cancer immune response. UbiVac believes DPV-001 is the first cancer immunotherapy to include cancer's dark matter in a form that can induce a destructive anti-cancer immune response and established its therapeutic efficacy in more than a decade's worth of preclinical studies.



Scientist's rendering of dark matter on cancer cells. Only recently discovered, dark matter may comprise >10% of the total unique targets on cancer's surface and may be responsible for many of cancer's deadly properties, increasing their relevance as targets.

UbiVac's DRibble Platform Vaccine (DPV) technology is a novel first-in-class cancer vaccine immunotherapy. DPV-001 was developed to be used as combination immunotherapy for most solid cancers, including cancers of the breast, lung, prostate, stomach, colon, pancreas, ovary, brain, and others. DPV-001 contains recently described non-canonical, non-mutated shared alternative neoantigens, also termed "cancer's dark matter", plus more than 300 antigens overexpressed by the average solid cancer. This allows DPV-001 to be available off-the-shelf without having to manufacture a patient specific vaccine. Additionally, DPV-001 can be administered without having to match a patient's HLA tissue antigens.



Cartoon of UbiVac's DPV-001 "off-the-shelf" Dark Matter cancer vaccine, containing dark matter and >300 shared cancer antigens, DAMPs, and 5 immune stimulants, being targeted to a dendritic cell/APC. This starts the process of priming or boosting anti-cancer immunity.

These data will be presented by Principal Investigator Rom S. Leidner, M.D., during the First-in-Human Phase I Clinical Trials Session 1 on April 8 (No. CT112, Poster Section 48, 1:30 to 5pm), at the AACR Annual Meeting held 5-10 April in San Diego, CA. Dr. Leidner is Co-Medical Director, Head and Neck Cancer Program, and Director, Immune

Cell Experimental Therapy, at Earle A. Chiles Research Institute, a division of the Providence Cancer Institute of Oregon.

"We are encouraged by the bioactivity observed thus far in HPV-agnostic recurrent/metastatic HNSCC. Partial and complete responses have been observed in 5 of 9 PD-1 naïve patients, while partial responses have been observed in 3 of 9 PD-1 refractory patients. In most cases, these responses are ongoing, the longest now 20 months duration and continuing. Immune-related adverse events appear to be more frequent than would be expected with PD-1 alone, but have been clinically manageable, and importantly, attest to immuno-efficacy for combinatorial DPV-001 vaccine," said Dr. Leidner.

Dr. Leidner's AACR presentation is entitled, "An Off-the Shelf Multivalent Vaccine Containing Cancer's Dark Matter, DPV-001, Combined with PD-1 +/- GITR in Head & Neck Cancer: Safety, Efficacy, and Immunodynamics from the Phase 1 GITRVax Trial", and will report that patients that had not previously been treated with anti-PD-1 and received DPV-001 as part of their combination immunotherapy had a 55% response rate (ClinicalTrials.gov Identifier: NCT04470024). While patients that had not responded to prior anti-PD-1, and received DPV-001 as part of their subsequent combination immunotherapy, had a 33% response rate.

HNSCC is the sixth most common cancer and accounts for 890,000 cases and 450,000 deaths worldwide annually. UbiVac believes the early data presented here suggests combining DPV-001 with anti-PD-1 and/or other immunotherapies may provide a treatment to further improve patient outcomes for HNSCC and other solid cancers.

About Providence
Providence Cancer Institute, a part of Providence St. Joseph Health, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally renowned research. Providence Cancer Institute is home to the Earle A. Chiles Research Institute, a world-class translational cancer immunotherapy research center located within the Robert W. Franz Cancer Center in Portland, Oregon, and is a recognized leader in the field of cancer immunotherapy since 1993.
Visit www.providenceoregon.org/cancer to learn more.

About UbiVac
UbiVac is a privately held, clinical stage immunotherapy company engaged in the research and development of immune activators and therapeutic vaccines to combat cancer. DPV-001 is UbiVac's lead agent and is a first-in-class platform technology that couples an off-the-shelf DC-targeted microvesicle containing cancer's dark matter plus more than 300 cancer antigens for most adenocarcinomas and squamous cell cancers. DPV-001 also contains multiple TLR/NOD agonists and DAMPs that are effective at supporting anti-cancer immune responses. UbiVac believes that DPV-001 is highly complementary to current and developing immunotherapy, adoptive immunotherapy, chemotherapy and small molecule drug portfolios, and preliminary clinical data suggests it may be effective at increasing response rates in patients that have failed

to respond to anti-PD-1/anti-PD-L1. UbiVac also has a pipeline of agents under development for the treatment of melanoma and thyroid cancer, and to prevent cancer in patients at high risk of developing disease.

UbiVac is currently raising funding from accredited investors. More information about the offering can be found at https://www.ubivac.com/investors.

WATCH NOW: There is a new paradigm for combating cancer at https://www.youtube.com/watch?v=7GTKYbP5fEA

Bernard A Fox, PhD
UbiVac
+1 971-413-7139
press@ubivac.com
Visit us on social media:
Facebook
Twitter
LinkedIn
YouTube
Other
