Promising Phase Ib Data for UbiVac's DPV-001 in Combination Immunotherapy for Head and Neck Squamous Cell Cancer

UbiVac's DPV-001 Dark Matter combo Immunotherapy triples response rate and progression-free survival over PD-1 alone for patients with r/m head and neck cancer

Pioneering the World's 1st Dark Matter Cancer Immunotherapy

HOUSTON, TX, UNITED STATES, November 8, 2024 /EINPresswire.com/ -- UbiVac, www.ubivac.com, a private, clinical-stage immuno-oncology company today announced the presentation of updated results from a Phase 1b study evaluating clinical efficacy and safety of DPV-001, UbiVac's lead investigational 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 Society for Immunotherapy of Cancer (SITC) Annual Meeting. The phase Ib study is sponsored by Providence Cancer Institute of Oregon.

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>
> *Rom S. Leidner, MD*

- 56% objective clinical response rate and a progression-free survival of +9.3 months for patients receiving DPV-001 combination immunotherapy as first line treatment for recurrent or metastatic HNSCC
- Patients that had not responded to prior treatment with anti-PD-1 had a 33% objective clinical response rate and a progression-free survival of +6.2 months
- DPV-001 immunotherapy contains cancer's dark matter and is designed as an off-the-shelf combination therapy option for the majority of solid cancers and for patients of all HLA backgrounds
- A T cell receptor isolated from a responding patient recognized cancers of the lung, head and neck, kidney and melanoma.

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' worth of preclinical studies.

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 patients HLA tissue antigens.

These data will be viewable at the Late-Breaking Abstract Session on November 8, at the Society for Immunotherapy of Cancer Annual Meeting held 8-10 November, in Houston, TX. Poster No. 1481 entitled, "Off-the-shelf dark matter immunotherapy in head & neck cancer: mechanistic insights and clinical efficacy", 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 56% response rate and a progression-free survival of +9.3 months (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 and a progression-free survival of +6.2 months. Consistent with preclinical data, early mechanistic study results suggest that the therapeutic strategy is generating immune cells that can recognize and destroy a wide range of cancer types.

"At the outset of this trial, I was admittedly agnostic about the addition of a broadly targeted, proteosome-blocked DPV-001 vaccine, but the bioactivity that has clinically manifested, in terms of disease response plus in-step irAE - which were readily managed with short-course prednisone - suggested that despite a small sample size, the clinical activity is credible and consistent with the "no free lunch" axiom in immunotherapy: no combinatorial toxicity, no combinatorial efficacy. The still maturing median PFS we are seeing of over 9 months for PD-1 naive 1L r/m HNSCC, compares favorably with the 3.2 month median PFS reported for Keytruda monotherapy in the KN-048 study, but we really need to wait for OS data to mature. Despite receiving a year of serial vaccine injections, patients on this trial have been asking why they can't recieve even more DPV-001, something we really haven't seen before," said Dr. Rom Leidner, Director of Immune Cell Experimental Therapy and Co-director of the Head & Neck Cancer Program at the Earle A. Chiles Research Institute, a division of the Providence Cancer Institute of Oregon.

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 .

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