FDA Grants Approval for UbiVac Manufactured Coronavirus Vaccine to Start Clinical Trial

Providence St. Joseph Health, one of the national's leading non-profit health systems, and the Providence Cancer Institute to run Phase 1 clinical trial

Therapeutic Vaccines for Combination Treatment to Combat Cancer and Infectious Disease

PORTLAND, OREGON, UNITED STATES, October 29, 2020 /EINPresswire.com/ -- UbiVac Inc., a clinical stage immunotherapy company, is pleased to announce that the FDA has granted approval to commence clinical trials of the CorVax vaccine. UbiVac in collaboration with Providence Cancer Institute, a part of Providence St. Joseph Health ("Providence") and OncoSec Medical Incorporated (NASDAQ:ONCS, "OncoSec") developed this vaccine to help prevent the spread of coronavirus. For their part, UbiVac manufactured and tested the SARS-CoV-2 drug product. The trial will evaluate safety and efficacy of the vaccine to induce an immune response against the SARS-CoV-2 spike protein.

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> *Bernard A. Fox, III, Cofounder and COO at UbiVac*

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There is a great unknown with current vaccine strategies for COVID-19: Will they work in the older population and will immunity be durable? According to the World Health Organization there are 17 vaccine trials ongoing in the USA and 44 in the world. The majority of these trials are what UbiVac considers to be trials using "standard" first generation viral vaccine approaches. Unfortunately, natural infection-induced immunity to coronavirus infection appears to be of limited duration and we won't know until late 2021 how effective the "standard" first generation vaccines currently being developed will be at protecting the older population. For these reasons, UbiVac in collaboration with colleagues at Providence and OncoSec moved forward to test a vaccine with DNA encoding both the SARS-CoV-2 spike and interleukin-12 (IL-12).

This combination of DNA encoding SARS-CoV-2 spike and interleukin-12 (IL-12) is what UbiVac considers to be a second-generation vaccine for COVID-19. Preclinical studies from the Earle A. Chiles Research Institute have shown that adding IL-12 can augment the immune response of older subjects. Additionally, OncoSec had already developed, tested and demonstrated the safety of administering IL-12 plasmid in humans and preclinical studies evaluating the effectiveness of this combination immunotherapy to induce an immune response to SARS-CoV-2 will be presented by Dr. Shawn M. Jensen at the 35th Annual meeting of the Society for Immunotherapy of Cancer (SITC). In addition to safety, this clinical trial will evaluate whether older participants receiving DNA encoding both spike and IL-12 will generate a stronger and more durable immune response than participants receiving DNA for spike alone.

A third-generation vaccine for COVID-19 is already in the works, and UbiVac is applying lessons learned from 30+ years of cancer vaccine research and development. In collaboration with UbiVac's Cofounders at the Earle A. Chiles Research Institute, UbiVac is working to support the development and manufacture of microvesicle and virus-like particle vaccines for COVID-19 that take advantage of combination immunotherapy strategies. UbiVac is backing a proposal from the Earle A. Chiles Research Institute to the NIH that would support early testing of this third generation vaccine strategy for COVID-19. Successful testing of these vaccines for COVID-19 could also provide a platform for rapid development of virus-like particle vaccines for other infectious agents.

"As with everything, it was a team effort" said Bernard A. Fox, PhD, Cofounder and CEO at UbiVac and Harder Family Chair for Cancer Research at the Earle A. Chiles Research Institute, a part of the Providence Cancer Institute. "This collaboration was built on the scientific knowledge, clinical experience, and regulatory understanding, of UbiVac, OncoSec and our partners at Providence. Without the dedicated clinical trials and research support teams at Providence and philanthropic support of the Portland area community, this trial would not have been possible."

About UbiVac

UbiVac is a privately held, clinical stage immunotherapy company engaged in the research and development of therapeutic vaccines to combat cancer. With innovative, first-in-class platform technology that couples an off-the-shelf DC-targeted cancer vaccine with more than 100 cancer antigens for most adenocarcinomas and squamous cell cancers, plus multiple TLR/NOD agonists and DAMPs that are effective at inducing anti-cancer immune responses. UbiVac believes that DPV-001 is highly complementary to current and developing immunotherapy, chemotherapy and small molecule drug portfolios. UbiVac also has a pipeline of vaccines under development to prevent cancer in patients at high risk of developing disease and for those that have failed to respond to anti-PD-1/anti-PD-L1. Since mid-March of 2020 UbiVac has redirected substantial resources to address the pandemic caused by SARS-CoV-2. UbiVac has manufactured a vaccine for the second generation phase I trial announced here and has rushed to develop third generation vaccines in collaboration with our academic partners. In June 2020 UbiVac announced a collaboration with Bristol Myers Squibb to perform a triplet immunotherapy for

advanced triple negative breast cancer utilizing DPV-001, UbiVac's lead agent. Founded by Dr. Bernard A. Fox, Dr. Hong-Ming Hu, and Mr. Bernard A. Fox, III, in Portland, Oregon in 2005, UbiVac is a spinout of the Robert W. Franz Cancer Center, Earle A. Chiles Research Institute at Providence Portland Medical Center.

UbiVac raising equity funding

To further the research and clinical development of its DRibble Platform Vaccine technology and its third generation vaccines for COVID-19, UbiVac is currently raising equity funding from accredited investors. More information about the offering can be found at www.ubivac.com/investors.

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