Medigen's COVID-19 Vaccine Combined with Dynavax's CpG 1018 Adjuvant Receives Taiwan Government Subsidy with First Participant Dosed in Early October

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TAPEI, Taiwan and EMERYVILLE, Calif., Oct. 13, 2020 /PRNewswire/ -- Medigen Vaccine Biologics Corporation (MVC) (TPEx: 6547.TWO), a biopharmaceutical company focusing on the development and production of vaccines and biologics, and Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced that MVC has obtained a Taiwan government subsidy for successfully initiating a Phase 1 clinical trial in Taiwan. The first participant in MVC's Phase 1 clinical trial was dosed with MVC's COVID-19 vaccine combined with Dynavax's CpG 1018 adjuvant at National Taiwan University Hospital in early October. The subsidy will be released at agreed upon milestones in the total amount of up to NT$ 472 million (US$ 16.4 million). The grant received by MVC was earmarked by the Taiwan government for purposes of research and development of a locally produced COVID-19 vaccine.

MVC's Phase 1 study is an open-label, single-center, staggered dose-escalation study intended to assess the safety and immunogenicity of the stable prefusion form of SARS-CoV-2 recombinant spike protein S-2P at three dose levels (low, medium and high) adjuvanted with CpG 1018 plus alum, in approximately 45 healthy subjects 20 to 50 years of age. The vaccination schedule consists of two doses for each study participant, administered via intramuscular (IM) injection 28 days apart, on Day 1 and Day 29.

"The pre-clinical study results demonstrated that the combination of our S-2P vaccine candidate and CpG 1018 plus alum provided safety and immunogenicity sufficient to advance to Phase 1 development," said Charles Chen, Chief Executive Officer of MVC. "We are pleased with the pre-clinical data and the potential to demonstrate clinical benefit and have a positive impact fighting this global pandemic motivates our team to undertake the clinical development ahead."

"Dynavax is proud to be working with MVC as they begin the Phase 1 trial for an adjuvanted vaccine candidate to help prevent COVID-19," commented Ryan Spencer, Chief Executive Officer of Dynavax. "Based on the preclinical studies the combination of S-2P and CpG 1018 plus alum has the potential to provide critical enhancements to the immune response to drive increased protection for adults, especially those who are traditionally less responsive to vaccination and are at greatest risk for severe disease from COVID-19."

MVC's subunit vaccine is based on the stable prefusion form of the SARS-CoV2 recombinant spike protein with global technology license from the U.S. Vaccine Research Center at National Institutes of Health (NIH).

About Vaccine Adjuvants
An adjuvant is a pharmacological or immunological agent that modifies the effect of other agents. Adjuvants are added to a vaccine to boost the immune response to produce more antibodies and longer-lasting immunity, thus minimizing the dose of antigen needed. Adjuvants may also be used to enhance the efficacy of a vaccine by helping to modify the immune response by particular types of immune system cells.

About CpG 1018 Adjuvant
CpG 1018 is the adjuvant used in HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 provides a well- developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine.

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also further developing CpG 1018 as an advanced vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

About MVC
MVC is a biopharmaceutical company using cell-based technologies for the development of vaccines and biosimilars. With a goal of national self-sufficiency, MVC also aims to provide vaccines and biopharmaceuticals to meet regional needs and with a desire to help globally against the threats of infectious diseases. MVC's pipeline includes enterovirus EV71 vaccine, dengue vaccine, influenza quadrivalent vaccine which all have entered late clinical stage. MVC's large-scale production facility is state of the art and adherent to international PIC/s and GMP requirements. For more information, visit www.medigenvac.com.

About the Novel Coronavirus SARS-CoV-2 (and COVID-19 Disease)
SARS-CoV-2 is a new coronavirus identified in late 2019 which belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of the respiratory system. The virus causes a disease named COVID-19. Since this outbreak was first reported in late 2019, the virus has infected over 19.9 million people and has caused over 732,000 reported deaths (as of August 11, 2020). It has been declared a pandemic by the World Health Organization (WHO). Currently there is no vaccine available for COVID-19.

Dynavax Forward-Looking Statements

This press release contains "forward-looking" statements, including statements regarding the potential to develop a COVID-19 vaccine containing CpG 1018. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in vaccine research and development, including the timing of completing development, whether CpG 1018 plus aluminum combined with MVC's subunit vaccine will prove to be beneficial in clinical trials, , whether and when the vaccine will be approved for use, and whether sufficient quantities of CpG 1018 will be able to be manufactured, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

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