

DYNAVAX

Medigen Vaccine Biologics COVID-19 Vaccine Adjuvanted with Dynavax's CpG 1018 Announces First Participant Dosed in Phase 2 Clinical Trial in Taiwan

January 25, 2021

TAIPEI, TAIWAN and EMERYVILLE, Calif., Jan. 25, 2021 /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 vaccines, today announced that the first participant has been dosed in the Phase 2 clinical trial evaluating MVC's COVID-19 vaccine candidate, MVC-COV1901. MVC-COV1901 is a subunit vaccine with recombinant S-2P antigen adjuvanted with CpG 1018 supplied by Dynavax.

MVC's Phase 2 clinical trial is a randomized, double-blinded, multi-center clinical trial, expecting to enroll 3,700 healthy subjects, 20 years of age and above. The trial will evaluate MVC-COV1901 safety and endurance of immunogenicity. The proposed dosing regimen is two doses administered intramuscularly one month apart. Based on MVC's Phase 1 interim data, MVC-COV1901 has demonstrated a good safety profile and encouraging immunogenicity performance.

"MVC is delighted to receive the Phase 2 clinical trial IND approval by Taiwan FDA for MVC-COV1901 vaccine" said Charles Chen, Chief Executive Officer at Medigen. "We would like to express our deepest gratitude to all the volunteers, partners and Dynavax for the continued support. MVC will continue with our best efforts to bring MVC-COV1901 vaccine to market to meet our commitment to help the global community in the fight against COVID-19."

"Dynavax is proud to collaborate with MVC and support their commitment to help the global fight against COVID-19," commented [Ryan Spencer](#), Chief Executive Officer of Dynavax. "We are pleased with the results of Phase 1 clinical testing, where the combination of S-2P and CpG 1018 plus alum induced neutralizing antibody levels higher than human convalescent sera and was well tolerated, allowing for the continued development on the path to bringing this product to market to address the global demand for coronavirus vaccines."

About MVC-COV1901

MVC-COV1901 is a subunit vaccine with recombinant S-2P antigen adjuvanted with CpG 1018 supplied by Dynavax plus aluminum hydroxide. The S-2P antigen is a trimeric and prefusion-stable recombinant spike protein developed by U.S. NIH. MVC has obtained a global technology license for S-2P from the U.S. Vaccine Research Center at National Institutes of Health (NIH). Building upon the S-2P platform, MVC conducted large-scale screenings of various adjuvants and finalized the compositions of MVC-COV1901 vaccine to optimize safety and desired immunogenicity properties. MVC established the production platform of MVC-COV1901 and based on MVC's preclinical and phase 1 clinical study data, MVC-COV1901 showed robust safety and promising immunogenicity responses and as a result entered Phase 2 clinical trial in 2020.

About Medigen Vaccine Biologics Corp. (MVC)

MVC is a biopharmaceutical company using cell-based technologies to develop novel 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 GMP requirements. For more information, visit www.medigenvac.com.

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's commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing CpG 1018 as a premier 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 <https://www.dynavax.com> and follow the company on [LinkedIn](#).

MVC's Forward Looking Statements

This press release contains certain forward-looking statements relating to the business of Medigen Vaccine Biologics Corporation (MVC, TPEX: 65470.TWO) including with respect to the progress, timing and completion of research, development and clinical trials for MVC's COVID 19 vaccine candidate, MVC-COV1901, and the ability to manufacture, market, commercialize and achieve market acceptance thereof. These forward-looking statements are based largely on the current expectations of MVC as applicable, as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, such could be affected by, among other things, uncertainties involved in the development and manufacture of MVC's COVID19 vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, changes in global financial markets and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that such forward-looking statements will in fact be realized. MVC and is providing the information in this press release as the date hereof, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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.

Medigen Contact:

Paul Torkehagen
Director, Overseas Business Development
paul@medigenvac.com

Dynavax Contacts:

Nicole Arndt, Senior Manager, Investor Relations
narndt@dynavax.com
510-665-7264

Derek Cole, President

Investor Relations Advisory Solutions
derek.cole@IRadvisory.com

 View original content: <http://www.prnewswire.com/news-releases/medigen-vaccine-biologics-covid-19-vaccine-adjuvanted-with-dynavaxs-cpg-1018-announces-first-participant-dosed-in-phase-2-clinical-trial-in-taiwan-301213721.html>

SOURCE Dynavax Technologies