# **ΔΥΝΛΥΑΧ**

## Medigen Vaccine Biologics Announces Launch of Its COVID-19 Vaccine MVC-COV1901 Adjuvanted with Dynavax's CpG 1018 Adjuvant

August 23, 2021

#### - Approximately 600,000 people are anticipated to receive the Medigen vaccine this week

#### - MVC-COV1901 is a subunit vaccine comprised of recombinant SARS-CoV-2 S-2P antigen adjuvanted with CpG 1018®

adjuvant

### - Medigen received Taiwan Emergency Use Authorization and approval for inclusion in Taiwan's COVID-19 vaccine immunization program in July

TAIPEI, Taiwan and EMERYVILLE, Calif., Aug. 23, 2021 /PRNewswire/ -- <u>Medigen Vaccine Biologics Corporation</u> (MVC) (TPEx: 6547.TWO), a biopharmaceutical company focusing on the development and production of vaccines and biologics, and <u>Dynavax Technologies Corporation</u> (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced the rollout of its COVID-19 vaccine, MVC-COV1901. Approximately 600,000 people are anticipated to receive the Medigen vaccine this week.

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<u>Charles Chen</u>, Chief Executive Officer at Medigen commented, "Medigen is honored to be able to serve the people of Taiwan and participate in the global response to this pandemic. We were grateful to have received emergency use authorization from the Taiwan FDA and greatly appreciate the time and effort of both the TFDA staff and the experts that participated in the risk and benefit analysis meeting. It is heartening to see a productive outcome from the dedicated effort from the team at Medigen."

Ryan Spencer, Chief Executive Officer of Dynavax commented, "We are pleased that Medigen's vaccine is now available for the people of Taiwan. We are very excited for this first, of hopefully multiple, EUAs and approvals for COVID-19 vaccines that include CpG 1018 adjuvant. Considering the limitations of current vaccines and the global vaccine shortage, we believe adjuvanted vaccines can contribute significantly to current vaccination efforts."

In July, MVC received Taiwan Emergency Use Authorization and approval for inclusion in Taiwan's COVID-19 vaccine immunization program, MVC-COV1901. MVC COVID-19 vaccine is indicated for adults over 20 years old and is administered in two doses 28 days apart for prevention of COVID-19. The Advisory Committee recommended that MVC should submit safety monitoring report monthly during the declared EUA period and should submit a vaccine effectiveness report within one year after obtaining EUA approval.

#### About MVC-COV1901

MVC-COV1901 is a subunit vaccine with recombinant S-2P antigen adjuvanted with CpG 1018 supplied by Dynavax and aluminum hydroxide. The S-2P antigen is a trimeric and prefusion-stable recombinant spike protein developed by the 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). MVC-COV1901 vaccine's Phase 1 and 3,815-participant Phase 2 clinical study data has shown robust safety and promising immunogenicity responses and as a result obtained Taiwan's EUA approval on July 19th, 2021. MVC will continue to collaborate with international partners for phase 3 clinical trial development and assist the global community in its fight against the COVID-19 pandemic.

#### About Medigen Vaccine Biologics Corporation (MVC)

MVC is a biopharmaceutical company using cell-based technologies to develop novel vaccines and biosimilars. MVC's pipeline includes EV71 vaccine, dengue vaccine, quadrivalent influenza vaccine and COVID-19 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 <u>www.medigenvac.com</u>.

#### About CpG 1018 Adjuvant

CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 adjuvant 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 first commercial product, HEPLISAV-B<sup>®</sup> [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. and the European Union 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 adjuvant 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 <u>www.dynavax.com</u> and follow the company on <u>LinkedIn</u>.

#### **MVC's Forward Looking Statements**

This press release contains certain forward-looking statements relating to the business of Medigen Vaccine Biologics Corporation (MVC, TPEx: 6547.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 and manufacture a COVID-19 vaccine containing CpG 1018 adjuvant, potential for other collaborators to receive EUAs for their vaccine candidates and recombinant subunit protein vaccines' potential contribution to global vaccination efforts. 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 or receiving EUAs, whether CpG 1018 adjuvant plus aluminum combined with MVC's subunit vaccine will prove to be safe and efficacious in remaining clinical trials and ongoing monitoring, whether and when any vaccine will receive final approval for use, and whether sufficient quantities of CpG 1018 adjuvant 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, 2020, 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 <u>www.dynavax.com</u> is not incorporated by reference in our current periodic reports with the SEC.

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