Dynavax and Medigen Announce Collaboration to Develop a Novel Adjuvanted COVID-19 Vaccine Candidate

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- Collaboration focused on developing an adjuvanted COVID-19 vaccine using Medigen's subunit vaccine candidate with Dynavax's CpG 1018
- In preclinical testing, the combination generated strong virus neutralizing antibody responses
- Medigen anticipates initiating a Phase 1 clinical trial evaluating the combination in September 2020

EMERYVILLE, Calif. and TAPEI, Taiwan, July 23, 2020 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, and Medigen Vaccine Biologics Corporation (MVC) (TPEx: 6547.TWO), a biopharmaceutical company focusing on the development and production of vaccines and biologics, today announced their collaboration to develop an adjuvanted vaccine candidate to protect against COVID-19. The collaboration is evaluating the combination of MVC's stable prefusion form of the SARS-CoV2 recombinant spike protein with Dynavax's advanced adjuvant CpG 1018™, the adjuvant contained in Dynavax's U.S. FDA-approved adult hepatitis B vaccine.

"The COVID-19 pandemic is straining healthcare systems across the globe, making a safe, effective and affordable vaccine an important tool in combatting the disease and protecting patients, especially for low and middle-income countries (LMICs)," said Charles Chen, Chief Executive Officer of Medigen. "In preclinical testing, the combination of Dynavax's proven adjuvant with our recombinant spike protein vaccine candidate generated strong virus neutralizing antibody responses and cellular immunity. These results support advancing evaluation of the combination into Phase 1 human testing, which we expect to begin in September of this year."

"Combining our technology with Medigen's reinforces the collaborative approach needed to address this pandemic," commented Ryan Spencer, Chief Executive Officer of Dynavax. "CpG 1018 is expected to enhance the immune response and may play an important role in developing an effective vaccine, especially for populations traditionally less responsive to vaccination such as older adults who 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). Preclinical studies demonstrated that the vaccine candidate adjuvanted with CpG 1018 generated strong immune responses in experimental animals.

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. In pre-clinical and clinical studies, results demonstrated that the addition of CpG 1018 increases antibody concentrations, stimulates helper (CD4+) and cytotoxic (CD8+) T cell populations and generates robust T and B cell memory responses. Additionally, CpG 1018 strongly favors development of the Th1 subset of helper T cells, the type of helper T cell that is essential for protection from infections with viruses and intracellular bacteria. CpG 1018 targets a single, well defined receptor (TLR9) expressed on only a few key cell types and the mechanisms of action as an adjuvant are quite well understood. 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. Upon completion of on-going scale up activities, the existing equipment capacity for CpG 1018 will be 600 million to 1.2 billion adjuvant doses annually, depending on final dose selected.

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 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 www.dynavax.com and follow the company on LinkedIn.

About Medigen
MVC is a cell-based biopharmaceutical company focusing on the development and production of vaccines and biologics. MVC's business partners include US NIH, US CDC, UCAB, Taiwan CDC, and Taiwan National Health Research Institute. MVC's pipeline includes enterovirus EV71 vaccine, dengue vaccine, influenza quadrivalent vaccine which all entered late clinical stage. 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 14.7 million people and has caused over 612,000 reported deaths (as of July 22, 2020). It has been declared a pandemic by the World Health Organization (WHO). Currently there is no vaccine available for COVID-19.

Forward-Looking Statements

This press release contains "forward-looking" statements, including statements regarding the potential to develop a COVID-19 vaccine containing CpG 1018, and to do so on an accelerated basis. 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 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 and of vaccine 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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