Dynavax and Mount Sinai Announce Collaboration to Develop a Universal Influenza Vaccine Candidate with CpG 1018 Adjuvant

July 16, 2020

- Development funded under contract award from NIAID/NIH as part of the CIVICs program
- Currently no approved universal influenza vaccine
- CDC estimates 35.5 million people were infected with influenza in U.S. during 2018-2019 season
- Collaboration will combine Dynavax's CpG 1018 with influenza antigens designed to protect against all strains of influenza

NEW YORK and EMERYVILLE, Calif., July 16, 2020 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, and the Icahn School of Medicine at Mount Sinai ("Mount Sinai") today announced they have entered into a collaboration to develop a universal influenza (flu) vaccine. Mount Sinai's current work in this area is funded under a contract award from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), as part of the Collaborative Influenza Vaccine Innovation Centers (CIVICs) program established by NIAID. The Mount Sinai CIVICs team will evaluate a novel approach they have developed called chimeric hemagglutinin (cHA) designed to protect against all strains of influenza in combination with Dynavax's CpG 1018™ adjuvant.

The development program will support an Investigational New Drug (IND) application for Phase I clinical trials. Drs. Peter Palese, PhD, Professor and Chair of the Department of Microbiology at Mount Sinai, Adolfo-Garcia-Sastre, PhD, Director of the Global Health and Emerging Pathogens Institute, and the Irene and Dr. Arthur M. Fishberg Professor of Microbiology and Medicine (Infectious Diseases) at Mount Sinai, and Florian Krammer, PhD, Professor of Microbiology at Mount Sinai will be leading the development of the program.

There are no approved universal flu vaccines. The effectiveness of seasonal influenza vaccine ranges between 10% and 60%. A universal vaccine could eliminate the need to update and administer the seasonal flu vaccine annually and could protect against newly emerging flu strains, potentially including those that could cause a flu pandemic.

"We are focused on designing novel vaccine candidates and delivery platforms with an emphasis on cross-protective vaccine strategies that could be used in healthy adults as well as populations at high risk for the most serious outcomes of influenza, such as children, older adults, and pregnant women," said Peter Palese, PhD, Professor and Chair of the Department of Microbiology at the Icahn School of Medicine at Mount Sinai. "Including CpG 1018 in these vaccines gives us an important tool to potentially improve the immune response, especially in populations that need it most like the elderly."

"We are excited to partner with Mount Sinai on this important vaccine development effort that has the potential to significantly reduce the morbidity and mortality caused by influenza viruses every year," commented Ryan Spencer, Chief Executive Officer of Dynavax. "Having seen the benefit of incorporating CpG 1018 in our first commercial vaccine, we believe it has significant potential to enhance the immune response in a universal flu vaccine. This effort directly aligns with Dynavax's goal to leverage the value of CpG 1018 across multiple diseases and vaccine approaches through collaborations with world class researchers like Mount Sinai."

"Drs. Palese, Garcia-Sastre and Krammer are key global opinion leaders in virology. Their collective research programs have resulted in technologies that support the development of a universal flu vaccine," said Erik Lium, PhD, Executive Vice President and Chief Commercial Innovation Officer at Mount Sinai. "In collaboration with Dynavax, we look forward to advancing these technologies to create an effective vaccine that can reduce the 3-5 million severe cases of influenza each year."

Influenza is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or death. Some people, such as older people, young children, and people with certain health conditions, are at high risk of serious flu complications. There are 2 epidemiological forms of influenza, seasonal and pandemic. Seasonal influenza epidemics, caused by influenza A and B viruses, result in 3–5 million severe cases and 300 000–500 000 deaths globally each year. Influenza pandemics caused by influenza A virus emerge at unpredictable intervals. They cause significantly increased morbidity and mortality, compared with seasonal influenza.

The U.S. Centers for Disease Control (CDC) annually estimates the burden of flu to the U.S. health system. CDC estimates that the burden of illness during the 2018–2019 season included an estimated 35.5 million people getting sick with influenza, 16.5 million people going to a health care provider for their illness, 490,600 hospitalizations, and 34,200 deaths from influenza.

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 the Mount Sinai Health System
The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care—from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report's* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians in the top 1% of all physicians nationally by *U.S. News & World Report*.

For more information, visit www.mountsinai.org or find Mount Sinai on Facebook, Twitter and YouTube.

About Collaborative Influenza Vaccine Innovation Centers (CIVICs)
The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has initiated the Collaborative Influenza Vaccine Innovation Centers (CIVICs) program, a new network of research centers that will work together in a coordinated, multidisciplinary effort to develop more durable, broadly protective and longer-lasting influenza vaccines. NIAID will provide up to approximately $132 million funding for the program, which is designed to support the CIVICs program centers over seven years.

The CIVICs network will develop so-called universal influenza vaccines, which could provide longer-lasting protection than current vaccines and against a wider variety of influenza viruses. The CIVICs centers will conduct multidisciplinary research that supports the development of vaccine candidates through testing in preclinical studies, clinical trials and human challenge studies. The CIVICs network also will explore approaches to improve seasonal influenza vaccines, such as by testing alternative vaccine platforms or incorporating new adjuvants (substances added to vaccines to boost immunity). These advances could substantially reduce influenza hospitalizations and deaths in the future.

The CIVICs program will include three Vaccine Centers, one Vaccine Manufacturing and Toxicology Core, two Clinical Cores, and one Statistical, Data Management, and Coordination Center (SDMCC). Additional information about CIVICs may be found at www.niaidcivics.org.

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.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding the potential for CpG 1018 to positively impact the development and immune effect of a universal flu vaccine and other vaccines. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether CpG 1018 will improve immune responses and contribute to decreased morbidity and mortality in a potential universal flu vaccine; whether it will provide benefit in the development of other vaccines, including whether it will accelerate the developmental time lines of other vaccines; and the inherent risks associated with vaccine development, such as those regarding the clinical study process and whether and when actual studies will be conducted and completed and what the results will be and whether they will support further studies; 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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Source: Dynavax Technologies Corporation