Dynavax Announces First Participant Dosed in a Phase 2 Clinical Trial Evaluating an Adjuvanted Plague Vaccine

September 12, 2022

EMERYVILLE, Calif., Sept. 12, 2022 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, in collaboration with the U.S. Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and supported by the DOD's Chemical and Biological Defense Program, today announced that the first participant has been dosed in a Phase 2 clinical trial evaluating the immunogenicity, safety, and tolerability of the JPEO-CBRND's Recombinant Plague (rF1V) vaccine combined with Dynavax's CpG 1018®adjuvant, in adults 18 to 55 years of age.

"We are proud to support the U.S. government in developing an effective adjuvanted plague vaccine that we believe will allow U.S. service members to be protected with fewer doses administered over a shorter period of time," commented Ryan Spencer, Chief Executive Officer of Dynavax. "The development of a CpG 1018 adjuvanted plague vaccine is an important example of the broad utility of our adjuvant which we are leveraging to build our pipeline of new and improved vaccines."

As previously announced, Dynavax and the DOD executed an agreement which provides for approximately $22 million in funding over two and a half years to develop an improved recombinant plague vaccine adjuvanted with CpG 1018 adjuvant. Under the agreement, Dynavax will conduct a Phase 2 clinical trial combining its CpG 1018 adjuvant with the DOD's rF1V vaccine. The trial is assessing a two-dose regimen administered over one month. Previous clinical studies of the rF1V, not including CpG 1018 adjuvant, have evaluated a three-dose regimen over six months. Any future commercial supply agreements would be subject to a separate agreement between Dynavax and the U.S government.

About CpG 1018 Adjuvant

Dynavax developed CpG 1018 adjuvant to provide an increased vaccine immune response with an improved tolerability profile, which has been demonstrated in HEPLISAV-B vaccine for adult hepatitis B and multiple COVID-19 vaccines that have received Emergency Use Authorization outside of the U.S. CpG 1018 adjuvant provides a well-developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of novel or improved vaccines.

About Dynavax

Dynavax is a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines to help protect the world against infectious diseases. The Company has two commercial products, HEPLISAV-B® vaccine [Hepatitis B Vaccine (Recombinant), Adjuvanted], which is approved in the U.S. and the European Union for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older, and CpG 1018® adjuvant, currently used in multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 adjuvant as a premier vaccine adjuvant through global research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, seasonal influenza, universal influenza, plague, shingles and Tdap. For more information about our marketed products and development pipeline, visit www.dynavax.com and follow Dynavax on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to a number of risks and uncertainties. All statements that are not historical facts are forward-looking statements. Forward-looking statements can generally be identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "intend," "will," "may," "plan," "project," "potential," "seek," "should," "think," "will," "would" and similar expressions, or the negatives thereof, or they may use future dates. Forward-looking statements in this document include, without limitation, statements regarding our expectations as to outcomes relating to ongoing contractual relationships, the timing and potential outcomes of trials. These forward-looking statements are subject to assumptions, risks and uncertainties that may change at any time, and readers are therefore cautioned that actual results could differ materially from those expressed in any forward-looking statements. Factors that could cause actual results to differ include, among other things: risks and uncertainties associated with actual results of our clinical trials; whether and when an improved plague vaccine candidate will be approved for use and launched; whether we can manufacture sufficient quantities of CpG 1018 to support this program; and other risks and uncertainties discussed in the Company's filings with the SEC, including the "Risk Factors" sections of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. The Company undertakes no obligation to update any forward-looking statements as a result of new information, future developments or otherwise, except as expressly required by law. All forward-looking statements in this document are qualified in their entirety by this cautionary statement.

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