

DYNAVAX

Dynavax and U.S. Department of Defense Announce Collaboration to Develop an Adjuvanted Plague Vaccine Using Dynavax's CpG 1018 Adjuvant

October 4, 2021

EMERYVILLE, Calif., Oct. 4, 2021 /PRNewswire/ -- [Dynavax Technologies Corporation](#) (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing vaccines, and the U.S. Department of Defense (DOD) today announced Dynavax has executed an agreement for approximately \$22 million over two and a half years to develop a recombinant plague vaccine adjuvanted with [CpG 1018®](#). Under the agreement, Dynavax will conduct a Phase 2 clinical trial combining its CpG 1018 adjuvant with the DOD's rF1V vaccine. The Company anticipates the Phase 2 trial will commence in 2022.

[Ryan Spencer](#), Dynavax's Chief Executive Officer commented, "We are honored to receive this award and to support the U.S. government in developing a plague vaccine to protect the U.S. military members who put their lives at risk every day in service to the country. 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. Our confidence in CpG 1018 is built on the successful development of our FDA-licensed 2-dose adult hepatitis B vaccine and the multiple late-stage COVID-19 vaccine candidates utilizing CpG 1018."

This agreement, funded by the DOD's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical), enables Dynavax to conduct a Phase 2 clinical trial, submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA), and generate additional clinical trial results to add to the existing clinical and non-clinical data. Any future commercial supply agreements would be subject to a separate agreement between Dynavax and the U.S. government.

COL Ryan Eckmeier, the Joint Project Manager for CBRN Medical commented, "Advancing the development of a recombinant plague vaccine supports the JPM CBRN Medical's vision to deliver a full, layered medical countermeasure capability to enable a protected and unencumbered Joint Force to fight and win in any global CBRN battlespace. Incorporating the CpG 1018 adjuvant to the DOD's rF1V vaccine will hopefully allow us to protect our service members with fewer doses administered over a shorter time period."

The planned Phase 2 randomized, placebo-controlled, observer-blind, multicenter clinical trial will evaluate the immunogenicity, safety, and tolerability of the rF1V vaccine antigens provided by the U.S. government combined with Dynavax's CpG 1018 adjuvant in adults 18 to 55 years of age.

About Plague*

Plague is a potentially deadly infectious disease caused by bacteria found in fleas and rodents or by handling an animal infected with plague. It is caused by the bacterium, *Yersinia pestis*. It is possible that Pneumonic plague bacteria could be released intentionally in a biological attack to sicken people.

About CpG 1018 Adjuvant

CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 adjuvant 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® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. and Europe 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 an advanced vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis, universal influenza and plague. 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 expected results for an ongoing contractual relationship and expected business results. 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 they may use future dates. Forward-looking statements in this document include, without limitation, statements regarding our expectations as to outcomes relating to ongoing collaborations and contractual relationships, the timing and potential outcomes of trials, regulatory approvals and product launches. 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 or those conducted by our other collaborators; whether and when any vaccine candidate will be approved for use and launched; whether we can manufacture sufficient quantities of CpG 1018 to support these programs; 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, 2021. 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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*CDC, <https://www.cdc.gov/plague/index.html>

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