Dynavax Initiates Phase 1/2 Study of Novel Shingles Vaccine Program

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EMERYVILLE, Calif., June 27, 2024 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a commercial-stage biopharmaceutical company developing and commercializing innovative vaccines, today announced that the first participant has been dosed in a Phase 1/2 clinical trial evaluating the safety, tolerability, and immunogenicity of Z-1018, the company's investigational vaccine candidate being developed for the prevention of shingles (herpes zoster), a debilitating disease caused by the varicella-zoster virus.

"We believe there is an opportunity to develop an improved shingles vaccine with a significantly better tolerability profile compared to the market-leading shingles vaccine. One of the unique advantages of our vaccine candidate is CpG 1018 adjuvant's established safety and tolerability profile, combined with its ability to induce strong CD4+ T-cell responses, which are thought to be critical in preventing the reactivation of the herpes zoster virus," said Rob Janssen, M.D., Chief Medical Officer of Dynavax.

The Phase 1/2 randomized, active-controlled, dose escalation, multicenter trial is expected to enroll approximately 440 healthy adults aged 50 to 69 years at trial sites in Australia, and will evaluate the safety, tolerability, and immunogenicity of Z-1018 compared to Shingrix®. Key objectives of the trial include selecting the optimal glycoprotein E (gE) protein dose level and dosing schedule for further clinical development. The Phase 1/2 trial will be used to support validation of a Patient Reported Outcome measurement tool to differentiate Z-1018 on tolerability and to support potential label claims. Dynavax anticipates reporting top line immunogenicity and safety data in the second half of 2025, including a comparison of CD4+ T-cells one month after the second of two vaccine doses.

Shingles is an extremely painful consequence of the reactivation of a latent varicella-zoster virus infection, the same virus that causes childhood chickenpox, with attacks leading to potential complications including chronic pain. While there are currently approved vaccines for shingles, there is an unmet medical need for a shingles vaccine with both high efficacy and improved tolerability.

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., the European Union and Great Britain 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 HEPLISAV-B and multiple adjuvanted COVID-19 vaccines. Dynavax is advancing CpG 1018 as a premier vaccine adjuvant used in clinical programs for shingles and Tdap, and in global collaborations currently focused on adjuvanted vaccines for COVID-19, plague, seasonal influenza and universal influenza. For more information about our marketed products and development pipeline, visit www.dynavax.com.

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," "toward," "will," "would" and similar expressions, or the negatives thereof, or they may use future dates. Forward-looking statements made in this document include statements regarding requests for future meetings with the FDA and the potential timing or outcome of those meetings. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including, the availability, time and cost associated with any potential follow up studies or additional trials, availability and willingness of the FDA to meet, and the uncertainty of whether these efforts will achieve our desired results, as well as other risks detailed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the three months ended March 31, 2024 and periodic filings made thereafter, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. These forward-looking statements are made as of the date hereof, are qualified in their entirety by this cautionary statement and 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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