

DYNAVAX

Valneva Initiates Pivotal Phase 3 Clinical Trial for its Inactivated, COVID-19 Vaccine Candidate using Dynavax's CpG 1018™ Adjuvant

April 21, 2021

- Phase 3 clinical trial to enroll approximately 4,000 participants in the U.K.
- Supported by the National Institute for Health Research (NIHR)

EMERYVILLE, Calif., April 21, 2021 /PRNewswire/ -- [Dynavax Technologies Corporation](#) (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced [Valneva SE](#) has initiated a pivotal Phase 3 clinical trial for its inactivated, COVID-19 vaccine candidate, VLA2001, using Dynavax's [CpG 1018](#) adjuvant. The Phase 3 trial "Cov-Compare", (VLA2001-301), will compare Valneva's SARS-CoV-2 vaccine candidate, VLA2001, against AstraZeneca's conditionally approved vaccine, Vaxzevria, in a comparative immunogenicity trial.

The initiation of the Cov-Compare trial follows positive initial [results](#) from Valneva's Phase 1/2 clinical trial, which demonstrated that the safety profile and immunogenicity were supportive of further development.

[Ryan Spencer](#), Chief Executive Officer of Dynavax commented: "We are excited to see the rapid initiation of the comparative Phase 3 clinical trial, providing an opportunity for Valneva's inactivated whole virus vaccine candidate adjuvanted with CpG 1018 to demonstrate superior immunogenicity with respect to the comparator. We are proud to be collaborating with Valneva on the development of this vaccine for COVID-19 and are committed to supporting Valneva in making the vaccine available."

Cov-Compare (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in approximately 4,000 adults. Its primary objective is to demonstrate the superiority of VLA2001 compared to Vaxzevria administered in a two-dose immunization schedule four weeks apart, in terms of Geometric Mean Titer ratio of SARS-CoV-2-specific neutralizing antibodies at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older. It will also evaluate the safety and tolerability of VLA2001 at two weeks after the second vaccination in adults aged 18 years and older.

The trial will be conducted at approximately 25 sites in the U.K. and is supported by the U.K. [National Institute for Health Research](#). Approximately 3,000 participants 30 years of age and older will be randomized in a 2:1 ratio to receive two intramuscular doses of either VLA2001 (n=2,000) or Vaxzevria (n=1,000) at the recommended dose level, 28 days apart, on Days 1 and 29. For immunogenicity analyses, samples from approximately 1,200 participants (600 per group) who have been tested sero-negative for SARS-CoV-2 at screening will be analyzed. Approximately 1,000 participants that are under 30 years of age will be placed in a non-randomized treatment group and receive VLA2001 28 days apart.

Subject to successful Phase 3 data, Valneva intends to make a regulatory submission in the autumn of 2021 for initial approval.

About VLA2001

VLA2001 is intended for active immunization of at-risk populations to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic and potentially later for routine vaccination including addressing new variants. VLA2001 is produced on Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO®. VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018. The process includes inactivation with BPL to preserve the native structure of the S-protein. Valneva expects VLA2001 to conform with standard cold chain requirements (2 degrees to 8 degrees Celsius).

About CpG 1018 Adjuvant

CpG 1018 adjuvant is used in HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency. 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 European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also advancing its CpG 1018 adjuvant 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](#).

Dynavax Forward Looking Statements

This press release contains "forward-looking statements", including statements regarding the potential development (including but not limited to the timing and potential outcome) of the Phase 3 clinical trial of VLA-2001, regulatory submission and importance of a COVID-19 vaccine containing CpG 1018 adjuvant, the potential of the platform to address variants, and the evaluation of the other trials. 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, dose selection, the results of clinical trials, whether and when the vaccine containing CpG 1018 adjuvant will be approved for use, whether and when purchases of CpG 1018 adjuvant will occur, and the ability to manufacture sufficient supply to meet the purchase needs, as well as other risks detailed in the "Risks Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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 obligations 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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