Positive Phase 1/2 Results for Valneva's Inactivated COVID-19 Vaccine Candidate Using Dynavax's CpG 1018™ Adjuvant

April 6, 2021

- VLA2001, an inactivated COVID-19 vaccine candidate with CpG 1018 adjuvant, was highly immunogenic and generally safe and well tolerated

-- 100% seroconversion rate for S-protein binding IgG antibodies in the high dose group

-- Neutralizing antibody titers at or above levels seen in convalescent sera

-- Majority of adverse events were mild to moderate

- Valneva plans to initiate a Phase 3 immunogenicity study in April 2021, subject to regulatory approval

EMERYVILLE, Calif., April 6, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced that Valneva SE reported positive initial results for Part A of the Phase 1/2 clinical trial of Valneva's inactivated COVID-19 vaccine candidate, VLA2001, using Dynavax's CpG 1018™ adjuvant in 153 healthy adults aged 18 to 55 years. Based on these results, Valneva plans to commence a pivotal Phase 3 clinical trial by the end of April 2021, subject to regulatory approval.

In their press release issued April 6th, 2021 (available here), Valneva reported that VLA2001 was generally safe and well tolerated across all dose groups tested and was highly immunogenic with a seroconversion rate for S-protein binding IgG antibodies of 100% in the high dose group. The IgG antibody response was highly correlated with neutralization titers in a micro-neutralization assay. The geometric mean titer of neutralizing antibodies measured two weeks after completion of the two-dose schedule in this group was at or above levels for a panel of convalescent sera.

Ryan Spencer, Chief Executive Officer Dynavax, said, "We are excited to see the positive results Valneva has generated with their inactivated vaccine using Dynavax's CpG 1018 adjuvant. We believe the effect delivered by our CpG 1018 adjuvant combined with Valneva's existing manufacturing process for whole virus inactivated vaccines will result in an important option in the global fight against COVID-19. This platform has potential to allow rapid modifications to the vaccine as needed to address variants using Valneva's existing manufacturing process."

Valneva plans to initiate a pivotal, comparative immunogenicity Phase 3 clinical trial with the high dose formulation by the end of April 2021. Other trials, including booster trials, involving antigen sparing doses will also be evaluated.

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 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 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 the timing for a Phase 3 clinical trial and 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 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 purchasing needs, 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, 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 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.

Dynavax Contacts:
Nicole Arndt, Senior Manager, Investor Relations
narndt@dynavax.com

510-665-7264

Derek Cole, President
Investor Relations Advisory Solutions
derek.cole@IRadvisory.com

View original content to download multimedia:http://www.prnewswire.com/news-releases/positive-phase-12-results-for-valnevas-inactivated-covid-19-vaccine-candidate-using-dynavaxs-cpg-1018-adjuvant-301262647.html

SOURCE Dynavax Technologies