COVID-19 Vaccine Developed by Valneva Using Dynavax's CpG 1018 Adjuvant Meets Both Co-Primary Endpoints in Phase 3 COV-COMPARE Trial

October 18, 2021

- VLA2001 successfully met both co-primary endpoints
- Superior neutralizing antibody titer levels compared to active comparator vaccine, AstraZeneca's AZD1222 (ChAdOx1-S)
- Neutralizing antibody seroconversion rate above 95%
- VLA2001 was well-tolerated, demonstrating a statistically significant better tolerability profile compared to active comparator vaccine

EMERYVILLE, Calif., Oct. 18, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing vaccines, today announced that Valneva SE reported positive topline results from the Phase 3 pivotal trial of VLA2001, their inactivated COVID-19 vaccine candidate using Dynavax's CpG 1018® adjuvant.

Valneva reported the following data from their Phase 3 COV-COMPARE trial in a press release issued October 18, 2021. The trial met its co-primary endpoints: VLA2001 demonstrated superiority against AZD1222 (ChAdOx1-S), in terms of geometric mean titer for neutralization antibodies (GMT ratio=1.39, p<0.0001), (VLA2001 GMT 803.5 (95% CI: 748.48, 862.59)), (AZD1222(ChAdOx1-S) GMT 576.6 (95% CI 543.6, 611.7)), as well as non-inferiority in terms of seroconversion rates (SCR above 95% in both treatment groups) at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older. VLA2001 was generally well-tolerated. The tolerability profile of VLA2001 was significantly more favorable compared to the active comparator vaccine. Participants 30 years and older reported significantly fewer solicited adverse events up to seven days after vaccination, both with regards to injection site reactions and systemic reactions (73.2% VLA2001 vs. 91.1% AZD1222 (ChAdOx1-S), p<0.0001) and systemic reactions (70.2% VLA2001 vs. 91.1% AZD1222 (ChAdOx1-S), p<0.0001). No unsolicited treatment-related serious adverse events (SAE) have been reported. Less than 1% reported an adverse event of special interest in both treatment groups. Participants in the younger age group vaccinated with VLA2001 showed an overall safety profile comparable to the older age group.

Ryan Spencer, Chief Executive Officer of Dynavax commented, "With these results announced by Valneva, our CpG 1018 adjuvant has now been shown to help drive a robust immune response while maintaining a favorable tolerability profile in multiple phase 3 trials across different vaccine platforms. This data further supports the value of CpG 1018 in the global response to the pandemic and as a platform for developing new and improved vaccines. We look forward to continuing to support Valneva in the development and approval of their inactivated COVID-19 vaccine to make it available to those in need."

About Valneva's Phase 3 Trial Cov-Compare (VLA2001-301)
Cov-Compare (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in 4,012 adults and 660 adolescents. Co-Primary immunogenicity endpoints are superiority of GMT ratio of VLA2001 compared to AZD1222 (ChAdOx1-S) as well as non-inferiority of seroconversion rates of neutralizing antibodies administered in a two-dose immunization schedule four weeks apart, measured at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and older. It also evaluates the safety and tolerability of VLA2001 at two weeks after the second vaccination in adults and adolescents aged 12 years and older. The trial is being conducted at 26 sites across the U.K. 2,972 participants 30 years of age and older were randomized in a 2:1 ratio to receive two intramuscular doses of either VLA2001 (n=1,977) or AZD1222 (ChAdOx1-S) (n=995) at the recommended dose level, 28 days apart, on Days 1 and 29. For immunogenicity analyses, samples from 990 participants (492 vaccinated with VLA2001, 498 vaccinated with AZD1222 (ChAdOx1-S)) who tested sero-negative for SARS-CoV-2 at screening were analyzed. 1,040 participants that are under 30 years of age were recruited in a non-randomized treatment group and received VLA2001 28 days apart. Safety data on those participants aged 18-29 years of age are analyzed in parallel to the adults aged 30 years and above. Recently, the trial commenced enrolling the first adolescent participants.

About CpG 1018 Adjuvant
CpG 1018 is the adjuvant used in HEPLISAV-B. Dynavax developed CpG 1018 adjuvant to provide an enhanced vaccine immune response, which has been demonstrated in HEPLISAV-B and in multiple COVID-19 vaccine candidates. CpG 1018 adjuvant provides a well- developed technology and a significant safety database, supporting 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 and universal influenza. 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 of regulatory approvals and product launches, our ability to support Valneva's vaccine development program and our expected financial performance. 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 clinical trials conducted by Valneva as well as our other collaborators; whether and when Valneva's vaccine will be approved for use and launched; whether sufficient quantities of CpG 1018 will be able to be manufactured; whether or how much Gavi or other commercial customers purchase from Valneva; 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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