Dynavax Provides Update on its COVID-19 Collaboration with Valneva

September 13, 2021

EMERYVILLE, Calif., Sept. 13, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing vaccines, today announced that Valneva SE has received a termination notice from the United Kingdom Government in relation to Valneva's supply agreement for its COVID-19 vaccine candidate, VLA2001. Valneva stated that they intend to continue clinical development of VLA2001 and the pivotal Phase 3 trial for VLA2001, Cov-Compare, remains ongoing at Public Health England. Based on its portfolio of COVID-19 collaborations Dynavax reiterates its belief that its CpG 1018 supply contracts continue to represent an approximately $300 - $400 million dollars aggregate revenue opportunity in 2021.

Valneva recently announced that its Phase 3 results for VLA2001 are expected to be available early in the fourth quarter of 2021 and these results are expected to form part of Valneva's planned rolling submission for conditional approval of VLA2001 with the UK's Medicines and Healthcare products Regulatory Agency ("MHRA"). Subject to these data and MHRA approval, Valneva has indicated that it believes initial approval for VLA2001 could be granted in late 2021.

Ryan Spencer, Chief Executive Officer of Dynavax commented, "Valneva is one of a number of companies developing COVID vaccines using CpG 1018 as an adjuvant and we continue to look forward to the upcoming Phase 3 clinical trial results for Valneva's inactivated COVID-19 vaccine adjuvanted with CpG 1018. The first COVID-19 vaccine that uses CpG 1018 was recently authorized by regulatory authorities and we look forward to the potential authorization of additional Dynavax-enabled COVID-19 vaccines in the months and quarters ahead."

Under Dynavax's existing supply agreement for CpG 1018, purchase orders submitted by Valneva are cancellable if the UK Government reduces or terminates its order for VLA2001, in which case, Valneva would not be obligated to pay Dynavax the final portion of an outstanding purchase order. Valneva has not yet cancelled any outstanding purchase orders for CpG 1018. Dynavax has the right to retain any portion of the purchase price for CpG 1018 made in advance by Valneva as well as any CpG 1018 manufactured but not yet delivered.

Dynavax intends to continue to monitor the situation but can make no assurances regarding the outstanding orders. If Valneva's existing purchase orders are cancelled, Dynavax will work to reallocate CpG 1018 inventory to its other COVID-19 collaborators. Dynavax's revenue opportunity associated with its CpG 1018 commercial supply agreements in 2021, as well as its corresponding profit margin, are contingent on many variables including continued success of each of Dynavax's partners' programs and timing of product delivery.

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 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.

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, our ability to reallocate certain quantities of CpG 1018 to different programs 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 Valneva's relationship with the UK Government, results of clinical trials being conducted by Valneva as well as our other collaborators; 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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