

# DYNAVAX

## Valneva and Dynavax Announce Commercial Supply Agreement for Inactivated, Adjuvanted COVID-19 Vaccine

September 14, 2020

**- Dynavax will provide CpG 1018 to produce up to 190 million doses over a five year period to support Valneva's contract with the U.K. government**

**- Inactivated, adjuvanted SARS-COV-2 vaccine candidate scheduled to enter first clinical studies in December 2020**

**- Combines Valneva's proven approach with Dynavax's advanced CpG 1018 adjuvant**

SAINT-HERBLAIN, France and EMERYVILLE, Calif., Sept. 14, 2020 /PRNewswire/ -- [Valneva SE](#) ("Valneva"), a specialty vaccine company focused on prevention of diseases with major unmet needs, and [Dynavax Technologies Corporation](#) (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced a commercial partnership for the supply of Dynavax's CpG 1018 adjuvant for use in Valneva's SARS-CoV-2 vaccine candidate, VLA2001. Valneva separately announced today an agreement with the UK government to provide up to 190 million doses of VLA2001<sup>1</sup> over a five year period. Dynavax will supply CpG 1018 to produce up to 100 million doses of vaccine in 2021. Valneva has the option to purchase up to an additional 90 million doses through 2025.



**Thomas Lingelbach, Chief Executive Officer of Valneva, commented,** "We are pleased to partner with Dynavax on the further development and future commercialization of our COVID-19 vaccine. We believe that CpG 1018 will add significant value to the target product profile of our vaccine including its intended use in at risk populations. This agreement marks another step in our approach to find a safe and effective solution to address the virus that is continuing to have an impact on us all."

**Ryan Spencer, Chief Executive Officer of Dynavax, commented,** "Dynavax is proud to be working with Valneva to support development and commercialization of an adjuvanted vaccine candidate to prevent COVID-19. We are pleased to extend our current partnership to include commercial supply of CpG 1018, our advanced adjuvant. We believe CpG 1018 may play a critical role in the development of a safe and effective vaccine, including potentially enhancing the immune response for those who are traditionally less responsive to vaccination and are at greatest risk for severe disease from COVID-19."

Valneva expects VLA2001 to enter clinical studies by the end of 2020 and to potentially reach regulatory approval in the second half of 2021.

This commercial supply partnership follows Valneva and Dynavax's initial collaboration to advance COVID-19 vaccine development, announced in April 2020<sup>2</sup>.

### About VLA2001

VLA2001 is a Vero-cell based, highly purified inactivated vaccine candidate against the SARS-CoV-2 virus, leveraging the manufacturing technology for Valneva's Japanese encephalitis vaccine. The Company has designed a process that largely uses this platform in regards to upstream- and downstream process steps as plug-and-play with moderate adjustments. The process includes inactivation with BPL to preserve the native structure of the S protein. The combination with CpG 1018 is expected to induce a strong immune response and has the potential to generate high titers of neutralizing antibodies as well as a polarized Th1 response. VLA2001 is expected to conform with standard cold chain requirements (2 degrees to 8 degrees centigrade).

### About Valneva SE

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO<sup>®</sup>/JESPECT<sup>®</sup> indicated for the prevention of Japanese encephalitis and DUKORAL<sup>®</sup> indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has various vaccines in development including unique vaccines against Lyme disease, chikungunya and SARS-CoV-2. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 500 employees. For more information, visit the Company website at [www.valneva.com](http://www.valneva.com) and follow Valneva on [LinkedIn](#).

### About Vaccine Adjuvants

An adjuvant is a pharmacological or immunological agent that modifies the effect of other agents. Adjuvants are added to a vaccine to boost the immune response to produce more antibodies and longer-lasting immunity, thus minimizing the dose of antigen needed. Adjuvants may also be used to enhance the efficacy of a vaccine by helping to modify the immune response by particular types of immune system cells.

### About CpG 1018 Adjuvant

CpG 1018 is the adjuvant used in HEPLISAV-B<sup>®</sup> [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 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 launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also further developing CpG 1018 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](http://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 of a COVID-19 vaccine containing CpG 1018 and the commercial sale of CpG 1018 to be used in the vaccine. 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, the results of clinical trials, whether CpG 1018 will provide an enhanced immune response, whether and when the vaccine containing CpG 1018 will be approved for use, whether and when purchases of CpG 1018 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, 2019 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](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

#### **Valneva Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of their in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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<sup>1</sup> [Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program](#)

<sup>2</sup> [Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19](#)

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