

Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19

- Valneva is leveraging its technical and platform capabilities to develop an inactivated, whole virus vaccine candidate against the current coronavirus threat
- Dynavax is providing CpG 1018, the adjuvant contained in U.S. FDA-approved HEPLISAV-B vaccine, to support the development of Valneva's COVID-19 vaccine candidate
- Valneva will seek grant funding to support the required investment for this program

Saint-Herblain (France), Emeryville (U.S.), April 22, 2020 – [Valneva SE](#), a specialty vaccine company focused on prevention against diseases with major unmet needs, and [Dynavax Technologies Corporation](#) (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced their collaboration to initiate a vaccine program for the current coronavirus, COVID-19.

Valneva's scientific team has tirelessly explored opportunities to rapidly leverage Valneva's existing technology, capabilities and infrastructure to create a SARS-CoV-2 vaccine candidate in response to the current pandemic.

Valneva is leveraging its well-established platform for [IXIARO](#)[®], the Company's commercial vaccine product indicated for active immunization for the prevention of Japanese encephalitis. This platform operates on a highly purified Vero-cell based, inactivated, whole virus strategy for vaccine development.

Dynavax is providing technical expertise and the company's proprietary toll-like receptor 9 (TLR9) agonist adjuvant, CpG 1018, the adjuvant used in HEPLISAV-B[®] [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.

Valneva will use its Biosafety Level 3 laboratory capabilities to rapidly leverage its large scale, Vero-based, viral Good Manufacturing Practice manufacturing facility in Livingston, Scotland, where both IXIARO[®] and VLA1553, the Company's vaccine candidate against chikungunya, are currently manufactured.

Wolfgang Bender, Ph.D., M.D., Chief Medical Officer of Valneva, commented: "Valneva aims to contribute to a world in which no one dies or suffers from a vaccine-preventable disease, such as COVID-19. Although different vaccine technologies are being deployed in the global effort to combat COVID-19, we believe that a proven approach is the best option for rapidly delivering a safe and effective vaccine. The proven approach that we are taking to develop VLA2001 has the potential to yield protection for the general population, as well as high risk groups, including the elderly, immuno-compromised and individuals suffering from other diseases."



[Ryan Spencer](#), Chief Executive Officer of Dynavax commented: “Now more than ever, the world is feeling the crucial role vaccines play in protecting our families, communities, and those at high risk for infectious disease. Dynavax’s mission is to investigate, innovate, and improve vaccines to provide protection for an unpredictable world. We are pleased to partner with Valneva on this important development effort to address the global health crisis spawned by COVID-19.”

Professor George Siber, MD, Member of Valneva’s Scientific Advisory Board commented: “Although many companies are advancing novel vaccine approaches to develop a vaccine against SARS-COV-2, the Scientific Advisory Board strongly supports this approach. There is a high likelihood that a modern, inactivated SARS-CoV-2 vaccine combined with an adjuvant such as CpG 1018 could be effective and safe.”

Valneva and Dynavax will work with regulatory authorities to align on the optimal strategy to execute an expedited clinical development path, with the goal to initiate clinical trials before the end of 2020.

About the Novel Coronavirus SARS-CoV-2 and COVID-19 Disease

SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of respiratory system. The virus, which causes a disease named COVID-19, has never before been found in humans. Since this outbreak was first reported in late-2019, the virus has infected over 2.5 million people and has caused over 170,000 reported deaths (as of April 22, 2020). It has been declared a pandemic by the [World Health Organization \(WHO\)](#). Currently, there is no vaccine available for COVID-19.

About VLA 2001

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.

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®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® 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 and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 500 employees. More information is available at www.valneva.com.

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 advancing CpG 1018 as an advanced vaccine adjuvant through research collaborations and partnerships. 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 to develop a COVID-19 vaccine and to do so on an accelerated basis. 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, and whether and when the vaccine will be approved for use, 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 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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