

VALNEVA SE Campus Bio-Ouest | 6, Rue Alain Bombard 44800 Saint-Herblain, *France* 

## Valneva Provides Business Update on COVID-19 Situation

**Saint Herblain (France), March 24, 2020** – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company, today provided an update on its operations as the COVID-19 situation evolves.

Valneva is actively managing its operations to maintain business continuity while taking measures to protect the health and wellbeing of its employees, their families and the local communities in which they live and work. The Company has instituted a work from home policy and for critical areas of its business that necessitate employees to be onsite, such as certain R&D and manufacturing functions, the Company is implementing strategies to promote additional social distancing. The continuous supply of Valneva's products to its patients and customers is of utmost priority to the Company. Valneva's scientific and commercial teams are in close dialogue with their partners and are providing project-specific information on a real-time basis.

Valneva is cognizant of the impact of the COVID-19 outbreak on the travel market. As the provider of two travel vaccines, one against Japanese encephalitis and one against cholera/ETEC, the Company expects that its 2020 revenues may be adversely affected. The Company estimates that 2020 product sales revenues could be impacted by between €20 million and €40 million (compared to guidance of €125 million to €135 million announced previously). First-quarter sales 2020 will not be materially adversely affected as the impact of the COVID-19 crisis did not affect its major markets until March.

This reduction in product sales revenue, offset by the likely delay in chikungunya Phase 3 initiation and therefore delay of initial Phase 3 costs, may lead to negative EBITDA of up to €50 million in 2020 compared to earlier guidance of negative EBITDA of up to €35 million.

While uncertainty remains around the duration, severity and geographic scope of the COVID-19 outbreak, the Company is well positioned to deal with the crisis. At the end of December 2019, Valneva reported cash of €64.4 million and, in February 2020, the Company announced an \$85 million debt financing arrangement; the Company has drawn \$45 million from this facility to date. Valneva is also well placed to take cost management measures if required and has commenced a review of non-mission critical projects and expenses. Excluding further cost containment measures, national government support mechanisms and Lyme partnering but including full draw down of the \$85 million debt facility, the cash position at the end of 2020 could be in the range of €35 million to €40 million.

Lyme disease vaccine candidate (VLA15): The two Phase 2 studies VLA15-201 and VLA15-202 are fully recruited and all subjects have been fully vaccinated. Valneva continues to closely follow the study monitoring/visits/blood draws within the COVID-19 framework and sees the Phase 2 progress as relatively unaffected. All testing activities relating to the data analysis are proceeding as planned to provide first Phase 2 data mid-2020. The Company also re-affirms its commitment to complete the partnering process for the late stage development and commercialization in the next few months.

Chikungunya vaccine candidate (VLA1553): The Company recently held its End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and has received clearance for an



Accelerated Approval Pathway. Finalization of remaining activities for Phase 3 entry including the alignment on execution plans and protocols with the Company's Contract Research Organization partner and the FDA are progressing. Valneva is advancing all activities to allow Phase 3 initiation as soon as the COVID-19 situation permits. Currently, the Company's assumption is that it may start Phase 3 in the fourth quarter of this year, representing approximately a delay of 3 to 6 months compared to its original plans.

Thomas Lingelbach, Chief Executive Officer at Valneva, commented "Our fully integrated business model combined with a strong balance sheet provides a strong basis for sustainability even in this global crisis. While it is difficult to predict the precise impact, and we feel that there may even be a positive mid to long term effect on the vaccine market leading to an increase in vaccination awareness, we estimate that 2020 product sales in the travelers segment will be significantly impacted, notably in the second and third quarters, with a market recovery in the fourth quarter. We are pleased that the current stage of our two leading, unique development programs against Lyme and Chikungunya largely permits progression according to plan with very moderate impact."

Valneva will continue to monitor the COVID-19 situation carefully and work closely with its partners, customers and the regulatory agencies. The Company plans to provide a complete business update during the publication of its first quarter results on May 7, 2020.

## **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

## **Valneva Investor and Media Contacts**

Laetitia Bachelot-Fontaine Director of Investor Relations & Corporate Communications M +33 (0)6 4516 7099 investors@valneva.com Teresa Pinzolits
Corporate Communications Specialist
T +43 (0)1 20620 1116
communications@valneva.com

## **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 Valneya 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 forwardlooking 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.