

Valneva Announces Mutual Agreement with GSK to End Strategic Alliance Agreement; Regains Control of R&D

Investor/analyst conference call tomorrow at 09:30 CEST

Saint Herblain (France), June 20, 2019 – Valneva SE (“Valneva” or “the Company”), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, today announces that GSK and Valneva have decided, by mutual agreement, to end the Strategic Alliance Agreement (“SAA”), originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively). Valneva will pay €9 million to GSK immediately and up to a further €7 million in milestones relating to marketing approvals of its Lyme vaccine. As a result, Valneva is now fully in control of its main R&D assets including its Lyme vaccine candidate VLA15.

Valneva has the only clinical stage Lyme vaccine candidate worldwide and is fully committed to advancing this asset. The Company is driving the program forward and has recently reported progress of its Phase 2 studies. VLA15 has been awarded Fast Track status by the U.S. Food and Drug Administration (FDA) and is currently undergoing Phase 2 studies. The Lyme vaccine development program is fully funded through Phase 2.

Valneva is also developing a highly differentiated vaccine candidate for chikungunya – VLA1553. Recent positive data support an accelerated development strategy and the Company is also committed to advancing this vaccine candidate as expeditiously as possible. VLA1553 has also been awarded Fast Track status by the FDA.

Thomas Lingelbach, CEO of Valneva, commented, “We would like to thank GSK and, previously, Novartis, for the legacy partnership. I am delighted that Valneva is now solely able to determine its entire development strategy for all vaccine candidates, including Lyme and chikungunya whilst being in the position to capture their entire economic potential. I am confident that we can fully address these very serious threats to public health whilst simultaneously maximising value for our shareholders.”

Emmanuel Hanon, Senior Vice President, Head of R&D, GSK Vaccines, commented, “The partnership between Novartis and Intercell was established with positive intent and has benefited both parties. As part of GSK’s ongoing initiative to allocate capital to fewer, highest priority areas, we have elected to come to an early termination so that both parties can make clear plans for the future. We wish Valneva well and hope that the Lyme vaccine development will be successful.”

Webcast details:

The call will be webcast live at 09:30 CEST on Friday June 21, 2019 and accessible via the following link: <https://edge.media-server.com/m6/p/xyeno5qh>. A recording will also be available on the Company website after the call.



About Valneva SE

Valneva is a biotech company developing and commercializing vaccines for infectious 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 a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with approximately 480 employees. More information is available at www.valneva.com.

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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.