

VALNEVA SE

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Valneva's *Pseudomonas Aeruginosa* Candidate (VLA43) Did Not Confirm Positive Vaccine Effect in Phase II/III trial

- + Phase II/III trial results did not confirm prior Phase II and interim analysis findings which had shown a clinically meaningful vaccine effect of all-cause mortality reduction
- + Complete trial analysis in the coming months may provide additional insights on clinical trial outcomes and secondary endpoints

Lyon (France), June 2, 2016 – Valneva SE (“Valneva” or “the Company”), a leading pure play vaccine company, announced today Phase II/III results for its *Pseudomonas aeruginosa* vaccine candidate (VLA43).

The current Phase II/III study was a randomized, placebo-controlled, double-blind study of VLA43. It was conducted in 800 mechanically ventilated Intensive Care Unit (ICU) patients at 52 trial sites in 6 European countries. Patients were vaccinated twice with either the *Pseudomonas aeruginosa* vaccine candidate or a placebo at a 7-day interval, in conjunction with standard of care treatments for ICU patients.

While the trial confirmed good immunogenicity and an acceptable safety profile of the vaccine candidate, the primary endpoint of the Phase II/III trial was not met. Findings from a previous Phase II study that had shown a strong reduction in all-cause mortality were therefore not confirmed.

Overall survival, a secondary endpoint in the study, also did not differ between the VLA43 treatment group and the placebo group.

Further study results on secondary endpoints, including *Pseudomonas aeruginosa* infection rates and sepsis-related mortality, will become available over the coming months and may provide additional insights into the clinical trial outcome and secondary endpoints.

Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva commented, “We have shared the development risk with our partner in an attempt to find a new way of fighting Hospital-Acquired Infections. The results of this Phase II/III trial, however, did not meet our expectations. This outcome will not affect the key strategic direction we have taken since the creation of Valneva. We will continue to grow our commercial product portfolio with the goal of delivering close to €100 million revenues this year and are targeting operational break-even in the short term. The R&D resources now available will allow us to accelerate product development, focusing on our core development competence including travel vaccines. We expect to bring two vaccine candidates into Phase I in the short term.”

Valneva considers it is unlikely that GSK will exercise its option to the program under the Strategic Alliance Agreement (SAA). The Pseudomonas program, as an acquired intangible asset, represents a book value of approximately €34 million on Valneva's balance sheet. The company may impair all or a substantial part of this book value as a result of the trial outcome.

Valneva preferred shares (ISIN FR0011472943), which were issued in the 2013 merger with Intercell AG, are expected to be redeemed at their nominal value of €0.01 per preferred share in June 2020 as the Company no longer expects approval of the Pseudomonas vaccine within their seven-year term (which would have led to conversion into ordinary Valneva shares at the end of this term).

About Valneva SE

Valneva is a fully integrated vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to protect people from infectious diseases through preventative medicine.

The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

Valneva's portfolio includes two commercial vaccines for travelers: one for the prevention of Japanese Encephalitis (IXIARO[®]/JESPECT[®]) and the second (DUKORAL[®]) indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has proprietary vaccines in development including candidates against Pseudomonas aeruginosa, Clostridium difficile and Lyme Borreliosis. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (EB66[®] vaccine production cell line, IC31[®] adjuvant).

Valneva is listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Scotland, Canada and Sweden with approximately 400 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 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 in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.