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Valneva Announces Continuation of the Phase II/III Clinical Trial for its *Pseudomonas Aeruginosa* Vaccine Candidate

- *Valneva and co-development partner decided to continue ongoing trial following data review of the interim analyses, further internal assessments and discussions with European regulators*
- *Recruitment of patients for clinical trial is expected to resume Q2 / 2014*
- *Preliminary results are expected at the end of 2015 / early 2016*

Lyon (France), March 24, 2014 –European biotechnology company Valneva SE (Valneva) announced today the continuation of the current phase II/III clinical trial of its *Pseudomonas aeruginosa* vaccine candidate IC43.

Valneva and its co-development partner decided to continue the trial following different assessments including analyses conducted by a Data Monitoring Committee (DMC) and consultation with two European regulatory agencies and experts.

The continuation decision was taken since the interim analysis showed a clinically meaningful reduction in all-cause mortality rates for the vaccine group as compared to placebo and no safety concerns were observed. These findings were in-line with previous Phase II results.

Valneva expects to resume recruitment for the trial in the second quarter of 2014. In addition to the 394 patients already enrolled, another 400 ventilated intensive care patients are planned initially to be enrolled in this second phase of the study in 40 different sites. Preliminary results are expected at the end of 2015 / early 2016

Although the difference on all-cause mortality between vaccine and placebo groups on day 28 (primary endpoint) at interim analysis was smaller than initially pre-specified, the development partners concurred to progress with the original sample size to potentially achieve statistical significance in this pivotal trial earlier on a potential route to licensure. The company is however also considering the option to extend the study further if needed and justified.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva, commented, "We are encouraged by the interim results. This study aims to deliver a major improvement for intensive-care unit patients. Continuing the trial gives us the prospect of a potential novel nosocomial vaccine that may save many lives and underpins our ambition to develop groundbreaking innovation to improve patient's health"

Valneva's *Pseudomonas aeruginosa* vaccine candidate is targeted for ventilated intensive care patients, who are vaccinated after ICU admission and are at particular risk of life threatening Pseudomonas infections. Targeted patients include more than 700 000 patients in Europe and US.

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About *Pseudomonas aeruginosa*

Pseudomonas aeruginosa is one of the leading causes of nosocomial infections which patients acquire in hospitals during the course of receiving treatment for other conditions.

Nosocomial infections are becoming a prominent problem as patients admitted to hospitals are on the average older, multimorbid, may have reduced immunocompetence and are increasingly compromised by antibiotic resistant bacteria circulating in hospitals across the world. Of the 2 million nosocomial infections in the U.S. alone per year, 10% are caused by *Pseudomonas aeruginosa*. The bacterium is the number 1 cause of ventilator-associated pneumonia, the number 2 cause of hospital-acquired pneumonia and the number 4 cause of surgical site infections.

In particular for intensive care patients, severe burns patients, cancer and transplant patients who are immunosuppressed, *Pseudomonas aeruginosa* causes the most severe and life threatening infections with a mortality rate of approximately 50%.

Infections caused by *Pseudomonas aeruginosa* are often difficult to treat because of the increasing antibiotic resistance of these bacteria indicating the high medical need for additional treatments or preventive measures. Currently, there is no vaccine against *Pseudomonas aeruginosa* available.

In 2007, Valneva (formerly Intercell) and Novartis announced a major strategic alliance to accelerate innovation in vaccines development in infectious diseases. The partnership is centered around the shared vision of science in vaccines research, development and commercialization. Beside the use of Valneva's adjuvant technology (IC31®) in selected vaccines it focuses on the development of vaccine products for which, upon Novartis' opt in, Valneva has the right at its election either to profit-share with Novartis or to receive potential milestones and royalties tied to sales-performance[1].

About Valneva SE

Valneva is a European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger between Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery, and vaccine development and commercialization, either through in-house programs or in collaboration with industrial partners using innovative technologies developed by the company. Valneva generates diversified revenue from both its marketed product, a vaccine for the prevention of Japanese encephalitis (IXIARO®), commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66® cell line, VIVA|Screen®

[1] Intercell press release, April 1, 2011, "Intercell announces next steps of development for Pseudomonas vaccine"

antibody discovery technology, and the IC31® adjuvant) developed by Valneva that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquartered in Lyon, France, the company employs approximately 280 people in France, Austria, Scotland, the United States, and Japan. The internationally experienced management team has a proven track-record across research, development, manufacturing, and commercialization

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.