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Valneva provides update on Phase II/III interim analysis of its Pseudomonas aeruginosa vaccine candidate

+ Data Monitoring Committee observed clinically meaningful effect on mortality rates although pre-specified futility criterion on primary efficacy endpoint was met
+ Development partners Valneva and Novartis are in discussions on trial continuation
+ Subject to further analysis and regulatory concurrence, the trial could be continued early 2014

Lyon (France), October 30, 2013 – Valneva SE (Valneva) today provided an update on the Phase II/III efficacy study interim analysis of its Pseudomonas aeruginosa vaccine candidate. The development partners – Valneva and Novartis Vaccines & Diagnostics have initiated discussions on trial continuation in agreement with the recommendations of a Data Monitoring Committee (DMC) following their data review on the primary efficacy endpoint and safety data from 394 patients.

Although the stringent pre-specified futility criterion in regards to the primary efficacy endpoint was formally met, the difference in all-cause mortality rates (at Day 28) between the vaccine and placebo group in this randomized, placebo controlled double blind study, was considered clinically meaningful and in line with the trend observed in the previous study. Additionally there were no concerns with regard to the observed safety profile.

Possible protocol modifications, if needed, will be discussed with the DMC to enable re-initiation of the trial, which is anticipated today for early 2014.

IC43 is targeted for ventilated Intensive Care (ICU) patients, who are only vaccinated at hospital admission and are at particular risk of life threatening Pseudomonas infections. The primary endpoint of the Phase II/III trial is the mortality rate from all causes of death (all-cause mortality) on Day 28. The futility analysis for the primary endpoint midway through the study, conducted in critically ill patients *(or people),* was factored into its design to allow early discontinuation , in case it would appear unlikely to see a meaningful vaccine effect when the study has been completed.

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 in this very ambitious study. A continuation of the study could give us the prospect of delivering a novel nosocomial vaccine that has the potential to save many lives."*

Valneva's vaccine candidate IC43 is a recombinant subunit vaccine consisting of two outer membrane proteins (OprF and OprI) of Pseudomonas aeruginosa. These outer membrane proteins have been shown to be disease-relevant targets in numerous preclinical and several early clinical trials.

The current pivotal Phase II/III efficacy trial follows a previous randomized, placebo-controlled exploratory Phase II trial in which lower all-cause mortality rates were observed for the vaccine candidate at several dosage levels compared to placebo.

The pivotal Phase II/III trial is a randomized, placebo-controlled double-blind study of IC43 expected to enrol a total of 800 ventilated intensive-care unit patients in approximately 40 study sites. Patients are

vaccinated twice with either the Pseudomonas aeruginosa vaccine candidate or placebo at a 7-day interval in addition to the standard of care for ICU patients.

The Pseudomonas aeruginosa vaccine candidate is used as a non-adjuvanted product formulation which was found to lead to the highest observed survival rates in the previous Phase II clinical study. The primary objective of the Phase II/III trial is to compare all-cause mortality rates at day 28 after first vaccination between the two study groups. Secondary objectives include comparison of infection-related mortality rates and Pseudomonas aeruginosa infection rates between the groups and to investigate the vaccine candidate's immunogenicity, safety and tolerability.

The study has previously received positive scientific advice from the European Medicines Agency (EMA).

Pseudomonas aeruginosa is a nosocomial pathogen accounting for around 10% of all hospital acquired infections, second only to Staphylococcus aureus. In particular, in 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%. Currently no vaccine exists to prevent the occurrence of the disease, which ascribes a significant market potential to a potential new product. The Pseudomonas aeruginosa program is part of a Strategic Alliance Agreement with Novartis Vaccines and Diagnostics, who is also co-financing the current Phase II/III pivotal efficacy trial.

Valneva will give an update to its share- and stakeholders (including holders of preferred shares, the value of which is exclusively linked to the Pseudomonas vaccine) on next steps, impacts on its R&D strategy and other business implications in due course.

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About Valneva SE
Valneva is a new European biotech company focused on vaccine development and antibody discovery. It was created 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™ antibody discovery technology, and the IC31® adjuvant) developed by Valneva that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquarted in Lyon, France, the company employs approximately 350 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.
www.valneva.com

About*Pseudomonasaeruginosa*

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

Nosocomial infections are becoming more and more 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 in 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.

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.