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Valneva Announces Start of Phase II Clinical Trial of its Clostridium difficile vaccine candidate

+ First Study participant(s) enrolled in Phase II trial which aims to enable Phase III entry upon successful completion
+ Study to enroll 500 healthy subjects aged 50 years and older in the United States and Germany
+ First results are expected in Q4 2015

Lyon (France), December 18, 2014 – European biotechnology company Valneva SE ("Valneva") announced today the initiation of the Phase II clinical trial of its VLA84 prophylactic vaccine candidate against Clostridium difficile (C. difficile), the main cause of nosocomial diarrhea. Data from the Phase I study in healthy elderly and adults showed good safety and immunogenicity of the vaccine candidate, and indicated functionality of induced antibodies, supporting the Company's decision to progress the vaccine candidate into Phase II.

The Phase II study (VLA84-201) will enroll 500 healthy subjects aged 50 years and older. This age group represents the target population for a prophylactic C. difficile vaccine as the risk to contract the infection-associated disease increases with age. The randomized, placebo-controlled, observer-blind study will be conducted in Germany as well as in the United States under an Investigational New Drug application (IND). It aims to confirm the optimal dose and formulation of the vaccine in two different age groups and to generate sufficient additional clinical data to advance the program into Phase III.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva commented, "C. difficile is a growing, difficult-to-treat infection, resulting in approximately 14,000 deaths each year in the US[1], and no vaccine is currently available to prevent this disease. Hence, we are pleased to progress our vaccine candidate in this major area of unmet medical need a step further towards licensure".

Valneva expects to announce the first results of the Phase II study at the end of 2015.

Valneva's C. difficile vaccine is part of the Strategic Alliance Agreement (SAA) which was signed between Valneva Austria GmbH and Novartis in 2007. Following completion of Phase II clinical development and if Novartis opts-in, Valneva will have the right, at its option, to either co-develop and profit-share with Novartis or to receive potential milestones for the remaining development period along with royalties tied to sales-performance[2].

[1]Centers for Disease Control and Prevention (CDC). "Investigating Clostridium difficile Infections Across the U.S." http://www.cdc.gov/features/AntibioticResistanceThreats/index.html
[2] Intercell press release, July 2, 2007, "Intercell and Novartis form world-leading strategic partnership to drive vaccines innovation". http://www.valneva.com/?page=4&Y=2007

About *Clostridium difficile* infection

C. difficile is an anaerobic spore-forming bacterium that causes diarrhea and more serious intestinal conditions such as colitis. *C. difficile* is shed in feces and any surface, device, or material that becomes contaminated with feces may serve as a reservoir for the *C. difficile* spores. When the natural microbial flora of the gut is disturbed (e.g. as a result of antibiotic treatment) and a patient gets in contact with *C. difficile* spores - this can result in a broad range of gastrointestinal symptoms. The symptoms may include diarrhea, cramping, dehydration, fever, nausea and vomiting. In advanced stages it can cause bloody diarrhea and severe inflammation of the gut. *C. difficile* spores are transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item.

C. difficile rarely causes infections in healthy persons but is a significant threat for patients with gastrointestinal surgery, or for subjects in healthcare settings or with immunocompromising conditions.

Currently, no vaccine against *C. difficile* exists, and antibiotic treatment of the established disease has significant limitations. The incidence of nosocomial infections is steadily increasing due to the growing number of medical interventions and antibiotic resistance.

Valneva aims at developing a vaccine for the prevention of recurring *C. difficile* Diarrhea, for hospital prophylaxis, and eventually for community-wide prophylaxis on an age- and risk-based vaccination strategy.

About Valneva SE

Formed in 2013 through the merger of Intercell AG and Vivalis SA, Valneva is a biotechnology company developing, manufacturing and commercializing innovative vaccines with a vision to protect people from infectious diseases.

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 a commercial vaccine for the prevention of Japanese encephalitis (IXIARO®) and proprietary vaccines in development 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 headquartered in Lyon, France, listed on Euronext-Paris and the Vienna stock exchange and operates out of France, Austria and Scotland with approximately 270 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.