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Valneva Announces Positive Phase I Results for its Clostridium Difficile Vaccine Candidate

+ Primary and secondary objectives met in clinical trial in elderly subjects to prevent Clostridium difficile infections
+ Data showed good safety and tolerability profile of vaccine candidate (primary objectives)
+ The vaccine candidate was highly immunogenic in elderly subjects and was able to induce similar immune responses to Clostridium difficile toxins A and B as the ones observed in adults in part Ia of the study (secondary objective)
+ Next development steps will be decided after final study close-out, expected for Q4/2013.

Lyon (France), August 26, 2013 – Valneva SE (Valneva) today announced positive Phase Ia/Ib results for the company's vaccine candidate IC84 to prevent diseases caused by the bacterium *Clostridium difficile* (*C. difficile*). The pathogen is one of the main causes of nosocomial diarrhea.

Valneva's vaccine candidate is a recombinant protein vaccine consisting of two truncated toxins A and B from *C. difficile*. The toxins are known to be disease-causing and anti-toxin immunity can be protective.

IC84 showed a favorable safety and tolerability profile in both study populations, elderly subjects and adults, with local tolerability being even better in elderly subjects.

The investigational vaccine induced antibodies that reacted with both native toxins A and B of *C. difficile* in both study populations. Functionality of IC84-induced antibodies could be shown in toxin-neutralizing assays in both study populations.

Interestingly, immune responses in elderly subjects, where immunosenescence (i.e., lower immune response) is expected, was comparable to adults: similarly high antibody titers with a plateau response could be reached with the non-adjuvanted middle dose after three vaccinations for both toxins in both study populations and were identified as the optimal schedule, dose and formulation both for adults and elderly subjects for future studies.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva, commented: "We are pleased with the successful outcome of this trial which showed better than expected immune responses in elderly people in an area of significant unmet medical need".

The phase Ia/Ib trial consisted in a first-in-man study to obtain safety and immunogenicity data.

The first part of the study, phase Ia, enrolled 60 healthy adults (18-65 years). Three different alum-adjuvanted vaccine candidate doses were tested in a 3 times-vaccination schedule; two of the three vaccine doses were additionally tested without adjuvant.

The second part of the study, phase Ib, enrolled 81 healthy elderly subjects (≥65 years), this age group representing the main target population for a *C. difficile* vaccine, and tested the two higher vaccine doses as adjuvanted and non-adjuvanted formulations in a 4 times-vaccination schedule to potentially further optimize the immune response in the elderly.

Analysis of long-term safety and immunogenicity data (up to 6 months after last vaccination of a subgroup of elderly subjects) is still ongoing and is expected to be available in Q4 2013.

Next development steps will be decided after final study close-out and in agreement with Valneva's strategic alliance partner.

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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 faeces and any surface, device, or material that becomes contaminated with faeces 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

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

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.