VALNEVA SE
World Trade Center Lyon
Tour Oxygène
10-12 boulevard Marius Vivier Merle
69007 Lyon, *France*

Valneva Receives FDA and European Approvals to Start Clinical Testing of Lyme Disease Vaccine Candidate

Investor Meeting and Live Webcast on Lyme Disease, December 12th at 12pm ET

Lyon (France), December 9, 2016 – Valneva SE ("Valneva" or "the Company"), a fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines, today announced that its vaccine candidate VLA15 against Lyme disease is now progressing into clinical testing (Phase I) following the Investigational New Drug application (IND) clearance from the Food & Drug Administration (FDA) and the approval of the Clinical Trial Application (CTA) in Europe (Belgium).

Currently, there is no licensed vaccine available to protect humans against Lyme disease, a multi systemic tick-transmitted infection that can cause serious health problems and disabilities. Each year, an estimated 300,000 Americans and 85,000 Europeans develop Lyme disease and according to the CDC (Centers for Disease Control and Prevention), it is the fastest growing vector-borne infectious disease in the United States.

Valneva is developing a new hexavalent, protein subunit-based vaccine targeting the Outer Surface Protein A (OspA) of Borrelia. OspA is, one of the most dominant proteins expressed by the bacteria when present in a tick. Pre-clinical data showed that Valneva's vaccine candidate can provide protection against the majority of Borrelia species pathogenic for humans[1].

Thomas Lingelbach, President and CEO, and Franck Grimaud, Deputy CEO of Valneva, commented, "We are very pleased to be able to advance our Lyme vaccine candidate which is intended to address such an important unmet medical need. We are committed to finding ways to accelerate the clinical development path to licensure, given that we are conducting the only active vaccine program in the industry."

Valneva´s Phase I trial VLA15-101 is being conducted at two sites – one in the U.S. and one in Europe (Belgium) and will enroll 180 subjects, aged 18-40 years. The primary objective of the single-blind, partially randomized, dose escalation study will be to evaluate the product candidate´s safety and tolerability. Immunogenicity, measured by observing IgG antibodies specific against six OspA serotypes, will also be monitored for different dose groups and formulations at different time-points.

Investor Meeting and Live Webcast in New York, December 12th, 12pm Eastern Time

Considering the strong interest shown on the disease by investors, shareholders and the general public, Valneva is hosting a conference on Lyme disease in New York on December 12, 2016 to provide more detailed information on the disease and the opportunity to develop

[1] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294

a vaccine. The conference will be co-presented by Prof. Stanley A. Plotkin, Emeritus Professor, University of Pennsylvania, and Valneva's Lyme R&D experts led by CEO Thomas Lingelbach. To register for the conference, please visit Valneva's website (http://www.valneva.com/en/)

About Valneva SE

Valneva is a fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines.

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: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and 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 *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, Great Britain, Sweden, Canada and the US with over 400 employees. More information is available at www.valneva.com.

Contacts

Laetitia Bachelot-Fontaine
Head of Investor Relations
& Corporate Communications
T +02-28-07-14-19
M +33 (0)6 4516 7099
investors@valneva.com

Teresa Pinzolits
Corporate Communications Specialist
T +43-1-206 20-1116
M +43-676-84 55 67 357
communications@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.