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Valneva Announces Successful Generation of a Highly-purified Zika Vaccine Candidate Using its FDA-EMA Approved Japanese Encephalitis Platform

Lyon (France), July 7, 2016 – Valneva SE ("Valneva" or "the Company"), a leading pure play vaccine company, today announced that it successfully generated a highly purified inactivated vaccine candidate against the Zika virus (ZIKV). The candidate was developed using the same manufacturing platform as the Company's Japanese encephalitis vaccine, a vaccine which has already been approved by the American (FDA, Health Canada), European (EMA) and other regulatory agencies and is today commercialized in the US, Europe, Canada, and other territories under the tradenames IXIARO®/ JESPECT®.

In response to the international health emergency declared by the World Health Organization (WHO), Valneva announced on February 2, 2016 the initiation of research work on Zika based on the Company´s Japanese Encephalitis ("JE") vaccine which Valneva developed from bench to market.

The Company´s JE vaccine is a Purified, Inactivated Vaccine ("PIV") based on an original technology which Valneva exclusively in-licensed from the Walter Reed Army Institute of Research (WRAIR) and others.

Health authorities, including WHO, have expressed a preference for the PIV approach over other vaccine technologies, such as live attenuated approaches, in the initial target product profile for emergency use. The emergency target population is expected to be women of child-bearing age, including those who may be pregnant. There is a theoretical risk that live attenuated or replication competent viral vaccines given to pregnant women may be capable of crossing the placenta and infecting the foetus, and for this reason, live vaccines are not recommended during pregnancy.

By working on a type of vaccine that the regulatory agencies have seen and licensed before, Valneva believes that regulatory risk can be mitigated, resulting in the most efficient path to market.

Generated on the IXIARO® (JESPECT®) platform, Valneva's Zika vaccine candidate demonstrated excellent purity and overall had a biological, chemical and physical profile comparable to the commercially produced JE vaccine.

Given the manufacturing process proximity, Valneva´s Zika vaccine candidate could be produced rapidly and at attractive costs in the clinical and commercial JE vaccine facilities.

Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented “We are glad that by building on our proven technology and leveraging on our strong capabilities in arthropod-borne flaviviruses, we have been able to generate a Zika vaccine candidate quickly. Valneva´s existing manufacturing platform represents a unique asset that could enable rapid production of a significant number of doses for an emergency use”.

Valneva was recently invited to participate to the global consultation on research related to Zika virus infection convened by WHO in Geneva and conducted discussions with WHO, BARDA and WRAIR to potentially join forces in accelerating the Zika vaccine development. Subject to regulatory approvals, Valneva could be in a position to move into clinical investigations in the coming months.

About IXIARO®/JESPECT®

Valneva’s Japanese encephalitis vaccine is indicated for active immunization for the prevention of Japanese encephalitis for adults who travel to, or live in, endemic areas. It has received marketing approval in the U.S., Europe, Canada, Hong Kong, Singapore, and Israel under the trade name IXIARO® and in Australia and New Zealand where it is marketed as JESPECT®. It is the only vaccine being marketed to the U.S. military for Japanese encephalitis. IXIARO® is approved for use in individuals 2 months of age and older in the US and EU member states, Norway, Liechtenstein, Iceland, Singapore, Hong Kong and Israel. In all other licensed territories, IXIARO®/JESPECT® is indicated for use in persons 18 years of age and above.

About Valneva SE

Valneva is a fully integrated vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to protect people from infectious diseases through preventative medicine.
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: one for the prevention of Japanese Encephalitis (IXIARO®/JESPECT®) and the second (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, Scotland, Canada and Sweden with approximately 400 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.