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# Valneva Announces Approval of its Japanese Encephalitis Vaccine through Commercial Partner Adimmune in Taiwan

**Lyon (France), January 11, 2016** – Valneva SE ("Valneva" or "the Company"), a leading pure play vaccine company, announced today that vaccine manufacturer Adimmune was granted marketing approval for Valneva's Japanese encephalitis (JE) vaccine by the Taiwanese Food & Drug Administration (TFDA). The product is expected to be marketed in Taiwan under the trade name JEVAL®.

This approval follows the agreement signed in 2014 between Valneva and Adimmune granting Adimmune the right to commercialize JEVAL® in Taiwan, including the right to locally fill and pack JEVAL® by using bulk product delivered by Valneva.

Thomas Lingelbach, President and CEO, and Franck Grimaud, Deputy CEO of Valneva commented, "The JEVAL® approval is an important step forward in our JE vaccine expansion strategy into endemic markets. Given Adimmune's leading position as a commercial vaccine manufacturer in Taiwan, we expect strong product supplies in this market, allowing us to leverage our existing manufacturing capacities and significantly contribute to our product profitability."

JE is recognized as a major public health issue in Asia and Adimmune has worked with the Taiwanese Center for Disease Control and Prevention for decades to ensure supply of its mouse-brain derived JE vaccine. Public tenders have historically reached a level of 600,000 doses per year. However, the Taiwanese Advisory Committee on Immunization Practices recently recommended the introduction of a cell culture-derived vaccine and the first tender for supply in 2017 is expected to be issued in the short-term. Valneva and Adimmune will carefully review any publicly issued tender in order to determine their ability to respond based on tender specifications.

In order to supply large quantities of  $\mathsf{JEVAL}^{@}$  for Taiwan's national immunization program at a competitive cost base, Adimmune intends to establish a local fill-and-finish of the vaccine within the next two years.

## **About Japanese Encephalitis**

Japanese Encephalitis (JE) is a deadly infectious disease found mainly in Asia. 67,900 cases of JE are estimated to occur in Asia each year, although the actual number of cases is likely much higher due to underreporting in rural areas and other factors. JE is fatal in approximately 30% of those who show symptoms, and leaves half of survivors with permanent brain damage. The disease is endemic in Southeast Asia, a region with more than 3 billion inhabitants. In 2005, Japanese Encephalitis killed more than 1,200 children in only 1 month during an epidemic outbreak in Uttar Pradesh, India, and Nepal.





# About JEVAL®

Adimmune's JE vaccine is indicated against Japanese encephalitis for individuals of 2 months of age and older who live in Taiwan. It received marketing approval for the vaccine, under the trade name JEVAL®. The vaccine is based on bulk product delivered by Valneva and is the only inactivated vaccine against Japanese encephalitis approved in Taiwan.

#### **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 LT-ETEC. The Company has proprietary vaccines in development including candidates 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 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 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 in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.