

VALNEVA SE Campus Bio-Ouest | 6, Rue Alain Bombard 44800 Saint-Herblain, *France* 

# Valneva Announces FDA Approval of IXIARO<sup>®</sup> Shelf Life Extension to 36 Months; New US Military RFP Issued

**Saint Herblain (France), March 8, 2020** – Valneva SE ("Valneva" or "the Company"), today announced that the Food and Drug Administration (FDA) has approved the extension of the shelf life of its Japanese encephalitis vaccine IXIARO<sup>®</sup> from 24 months to 36 months.

Separately, the US Department of Defense ("DoD") has issued a Request for Proposal ("RFP") for Japanese Encephalitis Vaccine. This RFP covers a period of three years comprising one year plus two years of options. Valneva will respond to this RFP expeditiously and, if successful, expects to enter into a new supply contract during the first half of 2020.

**Franck Grimaud, Valneva's Chief Business Officer**, commented, "We are pleased to receive this valuable shelf life extension for IXIARO<sup>®</sup> in the US. We also look forward to continuing to work closely with the DoD and to meeting their requirements. The U.S. military has been using IXIARO<sup>®</sup> for the past ten years and we look forward to continuing to help protect US troops, their families, military retirees, and government service personnel from this potentially deadly disease."

# About IXIARO®/JESPECT®

Valneva's Japanese encephalitis vaccine is indicated for active immunization for the prevention of the disease for people 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<sup>®</sup> and in Australia and New Zealand where it is marketed as JESPECT<sup>®</sup>. IXIARO<sup>®</sup> was developed through a cooperative research and development agreement with the Walter Reed Army Institute of Research. Valneva markets and distributes IXIARO<sup>®</sup> directly to the U.S. military and U.S. private market. It is the only vaccine available to the U.S. military for Japanese Encephalitis. IXIARO<sup>®</sup> is approved for use in individuals two months of age and older in the U.S. and EU member states, Canada, Norway, Liechtenstein, Iceland, Singapore, Hong Kong, and Israel. In all other licensed territories, IXIARO<sup>®</sup>/JESPECT<sup>®</sup> is indicated for use in persons aged 18 years or more.

#### **About Japanese Encephalitis**

Japanese encephalitis is a deadly infectious disease found mainly in Asia. About 70,000 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. JE is fatal in approximately 30 percent of those who show symptoms, and leaves half of survivors with permanent brain damage. The disease is endemic in Southeast Asia, India and China, a region with a population of more than three billion. In 2005, JE killed more than 1,200 children in only one month during an epidemic outbreak in Uttar Pradesh, India, and Nepal.

### **About Valneva SE**

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO<sup>®</sup>/JESPECT<sup>®</sup> indicated for the prevention of Japanese encephalitis and DUKORAL<sup>®</sup> indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by



ETEC. The Company has various vaccines in development including unique vaccines against Lyme disease and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with approximately 500 employees. More information is available at <u>www.valneva.com</u>

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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 forwardlooking 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.

