

Valneva Announces FDA Approval of Accelerated IXIARO® Vaccination Schedule

Saint Herblain (France), October 5, 2018 – Valneva SE (“Valneva” or “the Company”), a commercial stage biotech company focused on developing innovative lifesaving vaccines, announced today that the U.S. Food and Drug Administration (FDA) has approved an alternate IXIARO® immunization schedule of two doses administered seven days apart for adult travelers aged 18-65 years old. This accelerated schedule comes in addition to the previously approved schedule.

IXIARO® is the only Japanese encephalitis (JE) vaccine licensed and available in the United States (U.S.). The vaccine was approved with a two-dose primary immunization with the two vaccinations administered 28 days apart. The newly-approved accelerated vaccination schedule allows rapid immunization in adults with the two doses given seven days apart. This rapid schedule has already been approved and is used in Europe and Canada.

Franck Grimaud, Valneva’s Chief Business Officer, commented, “Many people make their travel plans at the last minute, so being able to receive IXIARO®’s two shots within seven days makes it easier for travelers, ultimately enhancing the value proposition of our product. The U.S. is IXIARO®’s largest market and we expect that this new schedule will encourage more U.S. travelers to seek prevention against this devastating disease.”

The FDA’s revised schedule follows previous approvals by Health Canada and the European Medicines Agency, who authorized accelerated IXIARO® vaccination schedules for adult travelers in March 2018 and April 2015, respectively.

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® and in Australia and New Zealand where it is marketed as JESPECT®. It is the only vaccine available to the U.S. military for Japanese encephalitis. IXIARO® is approved for use in individuals two months of age and older in the U.S. 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 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 fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines. 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 various vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 450 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.