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ACIP Unanimously Votes to Extend the Recommendations for Use of IXIARO®Vaccine

Lyon (France), June 21, 2013 – Valneva SE today announced that the U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) approved by unanimous vote on June 19, 2013 to extend the current JE vaccination recommendations for use of IXIARO® to include travelling individuals aged 2 months and above.

The ACIP's last recommendations for vaccination against JE were issued in June 2009 and published by CDC in Morbidity and Mortality Weekly Report (MMWR) in March 2010. At that time, IXIARO® was only approved by the U.S. Food and Drug Administration (FDA) for use in person 17 years of age and older.

The ACIP's new recommendations follow the marketing approval for IXIARO® in individuals aged 2 months and above from the FDA which Valneva received on May 17, 2013. IXIARO® is developed by Valneva SE and the rights to market and distribute the vaccine to the private sector in the United States are held by Novartis Vaccines.

"Valneva is pleased that the ACIP has extended the JE vaccination recommendations for IXIARO® to include infants, children and adolescents. Following FDA's recent approval for pediatric use of IXIARO®**,** this marks a successful conclusion of a major step in supporting vaccination of traveling children against a potentially devastating disease. We hope that ACIP and CDC will extend the JE vaccination recommendations for use of IXIARO® even further and we trust, in accordance with the new May 2013 JE guidance issued by the Assistant Secretary of Defense for Health Affairs, that the U.S. military will follow these new ACIP recommendations for immunizing military dependents residing in endemic countries of Asia", Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva stated.

The ACIP vote followed a presentation by Valneva of clinical trial data showing that IXIARO®, administered at a dose of 0.25 mL in children aged ≥2 months to <3 years and 0.5 mL in children aged 3 years and older, induced a seroprotection rate exceeding 99% and had a safety profile that was comparable to that of routinely used pediatric vaccines against other diseases (7-valent pneumococcal conjugate vaccine and inactivated Hepatitis A virus vaccine).

The ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U.S. Department of Health and Human Services to provide advice and guidance on the control of vaccine-preventable diseases. ACIP develops written recommendations for the routine administration of

vaccines to children and adults in the civilian population. The ACIP is the only entity in the federal government that makes such recommendations.

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About Valneva SE
Valneva is a new European biotech company focused on vaccine development and antibody discovery. It was created in 2013 through the merger between Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery, and vaccine development and commercialization, either through in-house programs or in collaboration with industrial partners using innovative technologies developed by the company. Valneva generates diversified revenue from both its marketed product, a vaccine for the prevention of Japanese encephalitis (IXIARO®),commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66®cell line, VIVA|Screen™ and IC31®)developed by Valneva that are becoming widely adopted by the biopharmaceutical industry.
www.valneva.com

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 percent 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. Only within 1 month in the year 2005, Japanese Encephalitis killed more than 1,200 children during an epidemic outbreak in Uttar Pradesh, India, and Nepal.

About IXIARO®/JESPECT®
Valneva's Japanese Encephalitis vaccine is a purified, inactivated vaccine for active immunization against the Japanese Encephalitis virus. The total development time of this vaccine was more than 10 years. The vaccine was developed under a Collaborative Research and Development Agreement with the Walter Reed Army Institute of Research, a biomedical research laboratory of the U.S. Department of Defense.
Valneva's Phase III trials for the approval of the vaccine in adults found that the vaccine demonstrated excellent immunogenicity against Japanese Encephalitis and an overall clinical safety profile similar to the control arm, combined with an excellent local tolerability profile.

These data were published in *The Lancet* in December 2007:

- The immunogenicity was comparable to that of the, then still marketed, U.S. licensed product, JE-VAX®.
- Valneva's vaccine demonstrated an overall clinical safety profile similar to the control arm.

Further, Valneva's Japanese Encephalitis vaccine had a more favorable local tolerability profile in the head-to-head study with JE-VAX®.

In pediatric studies, the JE vaccine showed to be highly immunogenic in children aged 2 months to <18 years with a safety profile comparable to pediatric vaccines licensed for other diseases.

Novartis distributes the vaccine to North America and Europe as well as Hong Kong and Singapore (IXIARO®), whereas bioCSL distributes the vaccine in Australia and New Zealand (JESPECT®).Please refer to the Product / Prescribing information (PI) / Medication Guide approved in your respective countries for complete information including safety about this vaccine and details for reporting adverse events or inadvertent use in pregnant women/nursing mothers.

Important Safety Information
IXIARO is a vaccine indicated for the prevention of disease caused by Japanese encephalitis virus (JEV). IXIARO is approved for use in individuals 2 months of age and older in the US and EU member states, Norway, Liechtenstein and Iceland. In all other licensed territories, IXIARO®/JESPECT® is indicated for use in persons 18 years of age and above.
You should not receive this vaccine if you have had an allergic reaction to IXIARO®/JESPECT® or any other Japanese Encephalitis Virus vaccine. This vaccine contains protamine sulfate, which may cause allergic reactions in some people. Tell your doctor if you have had an allergic reaction to protamine sulfate or any other JE vaccine before you receive this vaccine. After you are vaccinated, tell your doctor if you have any of the following problems because these may be signs of an allergic reaction: difficulty breathing, hoarseness or wheezing, hives, dizziness, weakness, or fast heartbeat.
IXIARO®/JESPECT® may not fully protect everyone who gets the vaccine. IXIARO®/JESPECT® does not protect against encephalitis caused by other viruses/pathogens. IXIARO®/JESPECT® does not protect against other diseases transmitted by mosquitoes.
This vaccine is given in 2 doses. Dose 2 is scheduled 28 days after Dose 1. Make sure you receive both doses. It is very important that you receive the 2nd dose of the vaccine at least 7 days before potential exposure to the virus. If you had been previously vaccinated with IXIARO®/JESPECT®, consult with your doctor if you need a booster dose.
Make sure your doctor knows if you have a weakened immune system or are using medicines that may weaken the immune system. Tell your doctor if you are pregnant.
The most common side effects in adolescents >12 years of age and adults are headache, muscle pain and injection site reactions (e.g., pain, swelling, tenderness, redness). Nausea, skin rash, fatigue, flu-like illness, fever, irritability and loss of appetite may also occur.
The most common side effects in children below the age of 12 years are fever, irritability, diarrhea, vomiting, loss of appetite, injection site pain and injection site redness.

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 achievement 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 nor otherwise.