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Valneva Wins FDA Market Exclusivity for the Pediatric Indication of IXIARO® in the United States

Following approval by the U.S. Food and Drug Administration (FDA) of the pediatric indication for Valneva's Japanese encephalitis vaccine IXIARO® in May 2013, the vaccine has now been also granted orphan drug market exclusivity by FDA.

Lyon (France), October 18, 2013 – Valneva SE (Valneva) today announced that the U.S. FDA's Office of Orphan Drug Development (OOPD) granted a 7 years orphan drug market exclusivity period for IXIARO® for prevention of disease caused by Japanese encephalitis virus in children 2 months to less than 17 years of age.

During this 7-year exclusivity period, the FDA will not approve another vaccine for the prevention of JE in children less than 17 years of age, unless such competitive JE vaccine can be shown to be clinically superior to IXIARO® in this pediatric population. The 7-year exclusivity period began on May 17, 2013, which coincides with the date of FDA's approval of the pediatric indication for IXIARO®.

"We are very pleased that the FDA acknowledges the development and profile of IXIARO® and granted the 7-years market exclusivity", **Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva stated.**

Orphan drug market exclusivity is one of the mechanisms put in place by FDA to encourage the pharmaceutical industry to invest in drugs and vaccines that target niche markets. Another major incentive is the waiving by the FDA of the approximately 1 Million U.S. Dollars review fee for submitting a Biologics License Application (BLA) or subsequent changes to the indication.
FDA granted orphan drug status for IXIARO® pediatric indication in September 25, 2012 as the use in this niche group of pediatric travelers to Asia is expected to remain below the maximum annual number of 200,000 patients.

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.

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About Valneva SE

Valneva is a 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.

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.