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Valneva Provides Update on ACIP Recommendation for its Chikungunya Vaccine IXCHIQ® Among U.S. Travelers

Saint Herblain (France), April 18, 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that during its regular meeting on April 16, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) updated its recommendation for use of Valneva's single-dose chikungunya vaccine IXCHIQ® for the prevention of disease caused by the chikungunya virus (CHIKV). ACIP maintained its current recommendation for IXCHIQ® for persons aged ≥18 years traveling to a country or territory where there is a chikungunya outbreak. Additionally, it may be considered for persons aged ≥18 years traveling or taking up residence in a country or territory without an outbreak but with elevated risk for U.S. travelers if planning travel for an extended period of time e.g., six months or more.

The ACIP also voted to recommend a precaution related to the use of IXCHIQ® in persons aged ≥65 years. This precaution is a response to an ongoing investigation by the CDC of six cases of serious adverse events (SAEs), including five hospitalizations, among persons aged 67-86 years after vaccination with IXCHIQ®. These SAEs were reported through the Vaccine Adverse Event Reporting System (VAERS), which is intended to be an early warning system to identify potential safety issues but generally cannot determine if adverse events are caused by a vaccine.

All of the individuals who were hospitalized had pre-existing comorbidities, and ACIP concluded that while plausible, no causal association with IXCHIQ® could be determined for all cases and that further investigation is warranted.

ACIP also noted that for individuals aged ≥65 years, vaccination with IXCHIQ® might be indicated in certain higher-risk settings (e.g., outbreak), given the known risks for severe chikungunya disease and hospitalization in this age group. For example, earlier this month Valneva supplied 40,000 doses of IXCHIQ® to France's Island of La Réunion where the local public health agency, the *Agence Régionale de Santé* (ARS), is prioritizing vaccination of adults aged 65 and over, especially those with comorbidities, to protect residents during the ongoing chikungunya outbreak. Valneva recently received confirmation from ARS for an order of 50,000 additional doses of IXCHIQ® as part of its ongoing effort to manage this outbreak.

To date, Valneva has supplied approximately 80,000 doses of IXCHIQ® in the United States, Canada and Europe. No further SAEs have been reported since January 2025 globally, and Valneva has not identified any safety signal concerns that are inconsistent with the U.S. product label through its ongoing post-marketing safety monitoring, including its periodic safety reports and routine signal detection activities, which are shared with the U.S. Food and Drug Administration (FDA).

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, commented, "Valneva is committed to the highest standards of safety, and the safety profile of IXCHIQ® remains unchanged and positive. We respect the ACIP recommendation and agree on the importance of continuing the stringent safety surveillance protocols that are in place. We encourage providers to assess the benefit/risk of vaccination based on the individual's medical history and upcoming travel, in line with the current recommendation."

The recommendation from ACIP is pending final approval by the Director of the CDC and the U.S. Department of Health and Human Services.

About Chikungunya

Chikungunya virus (CHIKV) is a mosquito-borne viral disease spread by the bites of infected *Aedes* mosquitoes which causes fever, severe joint and muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can persist for weeks to years[1].

In 2004, the disease began to spread quickly, causing large-scale outbreaks around the world. Since the re-emergence of the virus, CHIKV has now been identified in over 110 countries in Asia, Africa, Europe and the Americas[2]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[3] and the economic impact is considered to be significant. The medical and economic burden is expected to grow with climate change as the mosquito vectors that transmit the disease continue to spread geographically. As such, the World Health Organization (WHO) has highlighted chikungunya as a major public health problem.[4]

About Valneva SE

We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.

We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market three proprietary travel vaccines, including the world's first chikungunya vaccine, as well as certain third-party vaccines.

Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats.

More information is available at www.valneva.com.

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[1] https://jvi.asm.org/content/jvi/88/20/11644.full.pdf
[2] https://cmr.asm.org/content/31/1/e00104-16
[3] *PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2023 and Cases per year 2013-2017). https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 01 Aug 2023.*
[4] *Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)*

Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to potential product sales and regulatory review of existing products. 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 sustained 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 and delays 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. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. 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 this information 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.