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U.S. CDC Advisory Committee (ACIP) Recommends Use of Valneva's Single-Dose Chikungunya Vaccine IXCHIQ®

- Recommendation for use in travelers and laboratory workers follows U.S. Food and Drug Administration (FDA) approval in November 2023[1]
- IXCHIQ® is the first and only vaccine approved to address this unmet medical need in adults aged 18 years and older who are at increased risk of exposure to the chikungunya virus

Saint-Herblain (France), February 29, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, announces today that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend use of Valneva's single-dose chikungunya vaccine IXCHIQ® for the prevention of disease caused by the chikungunya virus (CHIKV).

ACIP recommends 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 traveling to a country or territory without an outbreak but with evidence of CHIKV transmission within the last five years, who are aged >65 years and likely to have at least moderate exposure to mosquitos (at least two weeks, cumulatively) or who are traveling for a longer duration (six months or more, cumulatively). ACIP also recommended chikungunya vaccination for laboratory workers with potential for exposure to CHIKV.

Juan Carlos Jaramillo, MD, Chief Medical Officer of Valneva, commented, "Chikungunya poses a significant risk to individuals journeying to or residing in regions where the chikungunya virus and its mosquito vectors thrive. IXCHIQ offers advantages to travelers on vacation and visiting family and to people engaged in business ventures, missions, or laboratory duties. We embrace the ACIP endorsement, marking IXCHIQ® as the only approved and recommended vaccine for the target population. We will continue collaborating with regulatory authorities worldwide to increase the accessibility of IXCHIQ® across regions."

The ACIP recommendations will be forwarded to the director of the CDC and the U.S. Department of Health and Human Services for review and approval. Once approved, the final recommendations will be published in a future Morbidity and Mortality Weekly Report (MMWR) to advise healthcare providers on appropriate use of the vaccine.

About Chikungunya

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. Infection leads to symptomatic disease in up to 97% of humans after four to seven days following the mosquito bite[2]. While mortality with CHIKV is low, morbidity is high, and the global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[3]. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea, rash and chronic arthralgia. Chikungunya virus often causes sudden large outbreaks with high attack rates, affecting one-third to three-quarters of the population in areas where the virus is circulating. The high-risk areas of infection for travelers are places where

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[1] *Valneva Announces U.S. FDA Approval of World's First Chikungunya Vaccine, IXCHIQ® - Valneva*
2 *Staples, J.E. Hills, S.L. Powers, A.M. "Chikungunya." In CDC Yellow Book 2020: Health Information for International Travel, by Centers for Disease Control and Prevention. New York: Oxford University Press, 2020*
3 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020

chikungunya virus-carrying mosquitos are endemic, including the Americas, parts of Africa, and Southeast Asia, and the virus has spread to more than 110 countries[4]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[5] and the economic impact is considered to be significant. The medical and economic burden is expected to grow as the CHIKV primary mosquito vectors continue to spread geographically. Before IXCHIQ®, there were no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat.

To make the vaccine more accessible to Low- and Middle-Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement in January 2021 for the development, manufacturing and marketing of VLA1553[6]. The collaboration falls within the framework of the agreement signed between CEPI and Valneva in July 2019[7], which provides funding of up to $23.4 million with support from the European Union's Horizon 2020 program. Regulatory review by the Brazilian authority ANVISA is ongoing.

About IXCHIQ®

In the U.S., IXCHIQ® is a live-attenuated vaccine indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. As for all products approved under FDA's accelerated approval pathway, continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory studies.
Please click here for full Prescribing Information for IXCHIQ®.

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 as well as certain third-party vaccines leveraging our established commercial infrastructure.

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, as well as vaccine candidates against the Zika virus and other global public health threats.

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4 https://www.who.int/news-room/fact-sheets/detail/chikungunya
5 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.
6 Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries
7 CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the approval and use of products and product candidates. 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 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.