VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

Valneva Provides Update on Recommended Use of IXCHIQ® by Elderly Individuals in the United States

Saint Herblain (France), May, 12 2025 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced that the U.S. Food and Drug Association (FDA) and the U.S. Centers for Disease Control and Prevention (CDC), in a joint communication to the medical community, have recommended a pause in the use of Valneva's single-dose live attenuated chikungunya vaccine IXCHIQ® in elderly individuals while ongoing investigations into reported serious adverse events (SAEs) are completed. This update follows an earlier recommendation from the U.S. Advisory Committee on Immunization Practices (ACIP) to include a precaution related to the use of IXCHIQ® in persons aged 65 and over and a similar decision by the European Medicines Agency (EMA) to temporarily suspend the use of the vaccine for individuals over 65 years old pending investigation.

Valneva is committed to upholding the highest safety standards and has engaged proactively with health authorities in all territories where IXCHIQ® is licensed to provide timely information about all known SAEs, most of which have been reported to the Vaccine Adverse Event Reporting System (VAERS) and have been in elderly individuals with significant underlying medical conditions and/or co-medications.

As highlighted by FDA/CDC, adverse events may not be causally related to vaccination, yet thorough evaluation of these cases is critical to ensure the safe use of IXCHIQ®, of which over 40,000 doses are estimated to have been utilized to date, worldwide. Valneva is working with the health authorities and anticipates formal reviews of the post-marketing safety reports in all territories where IXCHIQ® is approved. The Company will provide further updates as these evaluations are concluded.

Juan Carlos Jaramillo, M.D., Chief Medical Officer of Valneva, said: "We reiterate our support for the precautionary measures that have been taken as well as our commitment to continue monitoring all reported serious adverse events, particularly from the active chikungunya vaccination campaign in La Réunion, as there have not been any further SAEs reported outside of this public vaccination effort to combat this ongoing outbreak. We will continue engaging proactively with the global regulatory authorities while these important investigations continue over the coming months".

The Company continues to see a positive risk-benefit in the vast majority of people with potential exposure to the disease. The FDA and CDC maintain their recommendations for use of IXCHIQ® foin individuals aged 18 to 60 years. The EMA continues to recommend IXCHIQ® for individuals aged 12 to 64 years. Additionally, France's national public health agency, the Haute Autorité de Santé (HAS), continues to vaccinate people aged 18 to 64 years of age in its campaign to combat the current chikungunya outbreak in La Réunion.

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].

[1] https://jvi.asm.org/content/jvi/88/20/11644.full.pdf

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.

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.

Media and Investor Relations Contacts

Laetitia Bachelot-Fontaine
VP Global Communications & European Investor Relations
M +33 (0)6 4516 7099
laetitia.bachelot-fontaine@valneva.com

Joshua Drumm, Ph.D.
VP Global Investor Relations
M +001 917 815 4520
joshua.drumm@valneva.com

Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to use 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

[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)*

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 or new adverse events, 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.