VALNEVA SE
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Valneva Announces Sale of Priority Review Voucher for $103 Million

Saint-Herblain (France), February 5, 2024 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today announced it sold the Priority Review Voucher (PRV) it received from the U.S. Food and Drug Administration (FDA) for $103 million (€95 million).

The Company was awarded a tropical disease PRV in November 2023[1] following U.S. FDA approval of IXCHIQ®, Valneva's single-dose, 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. With this approval, IXCHIQ® became the world's first licensed chikungunya vaccine available to address this unmet medical need.

Valneva will invest proceeds from the sale of the PRV into its R&D projects, including the co-development of its Phase 3 vaccine candidate against Lyme disease, additional clinical trials for its chikungunya vaccine IXCHIQ® and the expansion of the Company's clinical pipeline.

Thomas Lingelbach, Chief Executive Officer of Valneva, said, "This non-dilutive capital provides an important source of additional funding to advance the continued development of our clinical pipeline. As shown with the recent approval of our chikungunya vaccine, we remain committed to growing our portfolio of vaccines addressing unmet medical needs which have the potential to transform people's lives."

Under the tropical Disease Priority Review Voucher Program, FDA awards priority review vouchers to sponsors of tropical disease product applications that meet certain criteria. The program is intended to encourage development of new drugs and biologics for the prevention and treatment of tropical diseases. PRVs can be redeemed to receive priority review of a subsequent marketing application for a different product, sold or transferred.

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 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

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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
4 https://www.who.int/news-room/fact-sheets/detail/chikungunya

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.

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, including the world's first and only 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, as well as vaccine candidates against the Zika virus and other global public health threats.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates, to regulatory approval of product candidates and 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,"

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.

“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.