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Valneva Hosts Investor Day in New York City

Live event and webcast TODAY at 10 AM – 12 PM ET

Saint-Herblain (France), December 06, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, is hosting an in-person investor day today in New York City to discuss the Company's current vaccine pipeline, commercial products, and future directions. Valneva's Chief Executive Officer Thomas Lingelbach, Chief Financial Officer Peter Bühler, and other members of the Company's senior leadership team will highlight Valneva's core near- and mid-term value drivers, including its early- and late-stage development pipeline and commercial vaccine business.

Presentations will begin at 10am Eastern Time. The event will also be webcast live and archived on the Events and Presentations page in the Investors section of Valneva's website. A live Q&A session will follow the formal presentations with opportunity for virtual attendees to participate. To register for the event, please click here.

Valneva will highlight its late-stage clinical and select preclinical vaccine candidates:

- VLA15, a Lyme Borreliosis (Lyme disease) vaccine candidate that is partnered with Pfizer for global development and commercialization, currently enrolling a pivotal Phase 3 study
- VLA1553, a chikungunya virus vaccine candidate for which rolling submission of a Biologics License Application (BLA) is nearing completion
- VLA1554, a proprietary recombinant protein subunit candidate comprised of stabilized pre-fusion F peptide as a potential prophylactic vaccine against the respiratory pathogen human metapneumovirus (hMPV)
- VLA2112, a recombinant protein subunit candidate comprised of a mix of relevant antigens as a potential second-generation prophylactic vaccine against Epstein-Barr virus (EBV)

Valneva will also provide a detailed overview of its current commercial products and the factors driving continued recovery and potential growth of this part of the business as the COVID-19 pandemic slows, followed by a brief financial overview.

Thomas Lingelbach, Chief Executive Officer of Valneva, said, "As we look ahead over the next 12 to 36 months, we anticipate substantial growth for Valneva, driven by the potential commercialization of two additional vaccine products. This key strengthening of our commercial portfolio, combined with initiatives designed to fuel our current and future R&D pipeline, is part of a broader vision to transform Valneva into a globally recognized leader in the vaccines industry. To achieve this vision, we will continue to rely on our core strengths in vaccine development and manufacturing, as well as our experience and track record for bringing new vaccines from discovery and early development to commercialization."

Select Investor Day Highlights:

VLA15, Lyme disease
VLA15 is the only Lyme vaccine program in advanced clinical development worldwide. It leverages an established mechanism of action against Lyme borreliosis infection by targeting the six most

prevalent serotypes of the *Borrelia* outer surface protein A (OspA). Pre-clinical proof-of-concept studies showed that VLA15 was protective against tick-transmitted *Borrelia* infection, and in clinical studies in more than 1000 adults and children (age ≥5 years), VLA15 was generally well tolerated and showed strong immunogenicity including anamnestic response to a booster dose twelve months after primary vaccination[1]. Recently reported antibody persistence results from study VLA15-221 in adults and children further validate the use of the three-dose vaccination schedule, which is also included in the Phase 3 protocols for all participants. Antibody levels remained above baseline six months after completing primary vaccination, and no vaccine-related serious adverse events (SAEs) and no safety concerns were observed in this six-month observational follow up[2]. Pfizer and Valneva are currently executing the Phase 3 field efficacy study for VLA15 called VALOR (Vaccine Against Lyme for Outdoor Recreationists)[3]. Enrollment completion is anticipated in the second quarter 2023. Pending successful Phase 3, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2025.

VLA1553, chikungunya virus

VLA1553 is a live-attenuated vaccine candidate targeting long-lasting immunity against mosquito-transmitted chikungunya virus infection with a single shot. It is currently the only chikungunya vaccine candidate to successfully complete pivotal Phase 3 studies and the first for which a regulatory filing process has been initiated with the U.S. FDA[4]. The sponsor of the first chikungunya vaccine approved in the U.S. may be eligible to receive a Priority Review Voucher (PRV), which Valneva intends to monetize upon receipt. The pivotal Phase 3 study of VLA1553 met its primary efficacy endpoint, with a seroresponse rate (SRR) that exceeded the threshold established with the FDA based on an immunological surrogate of protection, including in older adults (age ≥65 years)[5]. The high SRR was maintained after six months[6] and, as recently reported, after twelve months[7], further highlighting the potential for long-lasting immunity from a single shot of VLA1553.

While completion of the BLA submission is expected by year end, Valneva is focused on pre-commercial and market access preparations. Upon potential approval, the Company expects to market VLA1553 globally across multiple market segments, leveraging its existing commercial infrastructure, which spans North America, Europe, the Nordics and other key territories, as well as its strategic partner in Brazil, Instituto Butantan, who will market in low- and middle-income countries (LMICs) where chikungunya is currently endemic[8].

The recommendation process is ongoing with the Advisory Committee on Immunization Practices (ACIP), which governs vaccine policy in the U.S. This is a well-defined process and the ACIP vote on the specific recommendation(s) for VLA1553 is tentatively scheduled for the February 2024 meeting, pending approval by the FDA. In parallel, market access for ACIP-recommended vaccines is improving. Recent passage of the Inflation Reduction Act now requires that the 49 million-and-growing population of Americans enrolled in Medicare Part D be covered without cost

[1] Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate
[2] Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate
[3] https://www.valorlymestudy.com/
[4] Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate
[5] Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate
[6] Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate
[7] Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate - Valneva
[8] Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries

sharing for all ACIP-recommended vaccines. This is important as the number of outbound travelers to chikungunya endemic countries is projected to exceed pre-COVID-19 levels by 2025 according to the International Air Transport Association (IATA)[9].

VLA1554, human metapneumovirus

Valneva's hMPV vaccine program leverages recent advances in the development of vaccines against related Respiratory Syncytial Virus (RSV), where discovery of the pre-fusion form of the F protein, which mediates viral entry into human cells, led to major recent breakthroughs. Valneva successfully generated a stabilized pre-fusion F protein antigen, which forms the basis of the proprietary vaccine candidate VLA1554. In key pre-clinical studies, low doses of the vaccine candidate generated hMPV-neutralizing responses that protected mice from challenge with hMPV virus. Adjuvant evaluation is currently in progress.

VLA2112, Epstein-Barr virus

Valneva's EBV vaccine candidate is based on adjuvanted, subunit viral glycoproteins designed to elicit high titers of EBV-neutralizing antibodies and block EBV infection of both B cells and epithelial cells. Vaneva is utilizing structural information to design potently immunogenic antigens. Evaluation of external and internal antigens is ongoing, with the ultimate vaccine candidate comprised of an adjuvanted combination of antigens that best neutralizes EBV infection.

Commercial portfolio

Valneva's current commercial portfolio includes proprietary travelers' vaccines IXIARO® and DUKORAL®, for which Valneva owns global rights, as well as a number of vaccines that Valneva markets on behalf of third parties in select markets, leveraging its commercial infrastructure. Since 2016, Valneva has established a strong track record of adding additional third-party products to its portfolio, most recently adding VBI Vaccines' PreHevbri® in 2022[10]. The portfolio also includes VLA2001, the Company's vaccine against COVID-19, for which the Company is now solely focused on deploying remaining vaccine inventory. In parallel, the current shelf-life of VLA2001 was recently extended to 18 months and the Company is continuing to work to gradually extend the shelf-life to at least 24 months.

Financial Overview

Valneva remains well capitalized to execute on its strategic objectives, with €261 million in cash at the end of September 2022, excluding an additional €102.9 million in gross proceeds from a recent follow-on Global Offering. The Company reiterates its 2022 financial guidance, which includes total revenues of €340 million to €360 million and lowered R&D expenses of €95 million to €110 million (previously €120 million to €135 million)[11].

[9] https://www.iata.org/
[10] Valneva and VBI Vaccines Announce European Partnership for Marketing and Distribution of PreHevbri®
[11] Valneva Reports Nine-Month 2022 Results and Provides Corporate Updates

About Valneva SE
Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to commercialize three vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease and the chikungunya virus.

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Valneva Forward-Looking Statements
This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to its product candidates and estimates for future performance. 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 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.