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Valneva Reports Nine Month Results Marked by Further Major Corporate Achievements

Q3 milestones included

- **Major COVID-19 vaccine partnership with U.K. government**
  - **Pre-clinical and industrialization activities on track**
- **Positive top-line results for Lyme Phase 2 studies**
- **First company to initiate Phase 3 study for chikungunya vaccine; EMA PRIME Designation granted**
- **New US military / DoD contract for IXIARO®**

Cash position of €156 million at end of Q3, year-end outlook expected to exceed €180 million

Operating financial results impacted by second wave of COVID-19 pandemic

- **Limited product sales in Q3**
- **Gross Margin impacted**
- **US military orders and supply rephased into Q4**

Thomas Lingelbach, Chief Executive Officer, commented "We have seen a quarter marked by excellent progress for the Company – positive results from our Lyme Phase 2 studies, the start of a potentially pivotal Phase 3 trial for chikungunya and we signed a very important agreement to provide COVID-19 vaccines to the U.K. government. It is also true, however, that our commercial business has continued to suffer from the ongoing COVID-19 impact on the travel industry. Nonetheless, we continue to focus on building shareholder value, as reflected in our share price performance in 2020 to date, and to build on our strengths."

Financial highlights

- **Cash position of €156 million at end of September; FY 2020 cash outlook expected at between €180 million and €200 million.**
  - UK COVID vaccine partnership deal executed in September, advance payments invoiced in September create high Q3 receivables position
    - In excess of €100 million of receivables paid in October
  - UK Government COVID-19 vaccine partnership will continue to provide funding for the Livingston site capacity expansion and the UK VLA2001 clinical trials
  - No further drawing from $85 million debt financing arrangement with leading US funds expected for the rest of 2020 ($60 million drawn in Q1 and Q2 2020)

- **Total revenues of €58.8 million in the first nine months of 2020 compared to €81.4 million in the first nine months of 2019; Overall FY 2020 revenue guidance now expected at around €120 million**
  - Product sales revenue of €45.9 million in the first nine months of 2020 adversely affected by the COVID-19 pandemic (€86.4 million in the first nine months of 2019) and the US military phasing in Q4.
    - FY 2020 product sales revenue now expected at around €70 million

- FY 2020 total revenue to include €35 million to €40 million resulting from the Lyme vaccine partnership with Pfizer and approximately €10 million of Service and Technology revenues.
- No revenue associated with the UK COVID-19 partnership booked in Q3; IFRS accounting treatment being assessed during Q4.

- **EBITDA[1] loss of €45.2 million in the first nine months of 2020 compared to an EBITDA profit of €3.0 million in the first nine months of 2019;**
  - Nine-month EBITDA includes planned increase in R&D investment of €51.7 million in the first nine months of 2020 compared to €23.2 million in the first nine months of 2019
    - Notwithstanding potential revenue recognition, €5.2 million of COVID-19 R&D investment were included in the nine-month 2020 results
    - Lyme, chikungunya and COVID-19 vaccine programs progressed well as reflected in the level of R&D investments
  - Gross margin adversely affected by inventory provisions and idle capacity costs in manufacturing plants caused by the impact of the ongoing COVID-19 pandemic
  - G&A costs include additional share option costs given share price appreciation during 2020 as well as one-off costs related to corporate partnership deal expenses
- **FY EBITDA guidance remains highly dependent on the ongoing impact of the COVID-19 pandemic on the travel industry including demand for travel vaccines, revenue recognition of the Pfizer collaboration, the UK COVID vaccine partnership, the chikungunya-CEPI agreement as well as on other non-cash related items, and is therefore subject to significant variance.**
  - FY EBITDA loss currently is expected to be in the range of minus €40 million to minus €50 million

David Lawrence, Valneva's Chief Financial Officer, commented, "During these first nine months, Valneva has managed to deliver strong returns to its shareholders despite the adverse impact of the COVID-19 pandemic on our commercial business. The ongoing excellent execution in R&D combined with the important partnerships that we have struck this year ensure that the Company is in a strong financial position as we look forward."

Nine-month 2020 Financial Information

(unaudited, consolidated under IFRS)

€million	**9 months ending September 30**	
	2020	**2019**
Total revenues	58.8	81.4
Product sales	45.9	86.4
Net profit / (loss)	(62.3)	(2.4)
EBITDA	(45.2)	3.0
Cash	156.2	67.4

[1] *Nine-month 2020 EBITDA was calculated by excluding €7.3 million of depreciation and amortization (€6.2 million in the first nine months of 2019) from the €52.5 million operating loss (€3.2 million in the first nine months of 2019) as recorded in the consolidated income statement under IFRS*

Saint Herblain (France), November 3, 2020 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on prevention against diseases with major unmet needs, reported today its nine-month financial results ending September 30, 2020. The condensed and consolidated interim financial results are available on the Company's website www.valneva.com.

Valneva will provide a live webcast of its nine-month 2020 results conference call beginning at 3 p.m. CET today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/6xazaoyo

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In the first nine months of 2020, revenues from IXIARO®/JESPECT® product sales reached €30.8 million compared to €64.2 million in the first nine months of 2019. Sales were affected by the impact of the COVID-19 pandemic on the travel market and the phasing of the US Department of Defense (DoD) contract.

At the beginning of September 2020, Valneva announced the signing of a new contract with the US DoD for the supply of its Japanese encephalitis (JE) vaccine, IXIARO®[2]. This new contract spans a total of three years (one base year, plus two option years) with a base-year value of $61 million. The DoD has the possibility to purchase a total of $76 million – $105 million worth of IXIARO® across the two option years. Deliveries for the base-year will commence in the fourth quarter of 2020.

CHOLERA / ETEC[3]-DIARRHEA VACCINE (DUKORAL®)

In the first nine months of 2020, revenues from DUKORAL® sales reached €13.2 million compared to €19.8 million in the first nine months of 2019. DUKORAL® sales were also adversely impacted by the COVID-19 pandemic effect on the travel market.

OVERALL SALES OUTLOOK

Taking into account the ongoing COVID-19 situation, Valneva's sales could return to 2019 levels in 2023 with the expected sales recovery of its two commercial products and the marketing and distribution partnership with Bavarian Nordic announced in June 2020[4]. The successful development of a SARS-CoV-2 vaccine could accelerate that timeline.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15

Partnering deal with Pfizer; **Positive initial results reported for the two Phase 2 studies**

Valneva has developed a multivalent vaccine candidate, VLA15, which is currently the only active vaccine program in clinical development against Lyme disease. The program was granted Fast

[2] *Valneva Announces New IXIARO® Supply Contract with the US Government worth up to $166 million*
[3] *Indications differ by country -Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.*
[4] *Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership*

Track designation by the US Food and Drug Administration (FDA) in July 2017[5] and, in April 2020, the Company signed an exclusive, worldwide partnering deal with Pfizer Inc. for the late stage development and future commercialization of VLA15[6].

During the first nine months of the year, Valneva reported positive initial results for the two Phase 2 studies of its Lyme disease vaccine candidate (VLA12-201 in July 2020[7] and VLA15-202 in October 2020[8]). Both studies met their endpoints.

The two studies, conducted in the EU and US, were investigating similar doses of the vaccine but with two different vaccination schedules (Month 0-1-2 for VLA15-201 and Month 0-2-6 for VLA15-202) in a total of approximately 800 healthy adults aged 18 to 65 years.

In both studies, the vaccine was generally safe across all doses and age groups tested and no related Serious Adverse Events (SAEs) were observed in any treatment group. Reactogenicity decreased following the first vaccination.

Compared to study VLA15-201, immunogenicity was further enhanced in VLA15-202 using a Month 0-2-6 schedule. SCRs (Seroconversion Rates) after completion of primary vaccination series, were equally distributed and ranged from 93.8% (Serotype 1) to 98.8% (Serotypes 2 and 3). Antibody responses were comparable in the two dose groups tested in both studies.

The immunological response in older adults, one of the main target groups for a Lyme disease vaccine, was particularly encouraging in the two studies. Results in both studies did not indicate that prior exposure to Borrelia spirochetes (sero-positivity) has an impact on immunogenicity or safety, as observed in VLA15-201.

A Serum Bactericidal Assay (SBA), assessing the functional immune response against Lyme disease after vaccination with VLA15, was conducted for the first time in VLA15-202 and demonstrated functionality of antibodies against all OspA serotypes. Assays, such as SBAs, are commonly used to enable a potential prediction of vaccine efficacy via the measurement of vaccine-induced functional immune responses.

VLA15-202 safety and immunogenicity data at Day 208 support advancing the program with the Month 0-2-6 schedule. Valneva and Pfizer will finalize dosage analysis and prepare for the next development steps in the coming months.

According to the US Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans[4] are infected with Lyme disease annually with at least an additional further 200,000 cases in Europe[9].

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[5] *Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15*
[6] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[7] *Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate*
[8] *Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15*
[9] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.*

VLA15 is a multivalent, protein subunit vaccine that targets the outer surface protein A (OspA) of Borrelia and is intended to protect against the majority of human pathogenic Borrelia species. VLA15 is designed to confer protection by raising antibodies that prevent Borrelia from migrating from ticks to humans after a bite.

Peak revenue potential for a Lyme disease vaccine in the US and EU is estimated at more than $1 billion[10] annually.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Phase 3 initiated; EMA PRIME designation granted

Valneva has developed VLA1553, a single-shot vaccine candidate against chikungunya. The program entered Phase 3 in September 2020[11] and is currently the most advanced chikungunya vaccine program worldwide. The sponsor of the first chikungunya vaccine Biologics License Application (BLA) to be approved in the US will be eligible to receive a Priority Review Voucher (PRV)[12]. VLA1553 was granted Fast Track designation by the FDA in December 2018[13] and received PRIME designation by the European Medicine Agency (EMA) in October 2020[14]. Valneva plans to take VLA1553 to market with the prospect of leveraging major manufacturing and commercial synergies, primarily focusing on the traveler vaccine market.

In September 2020, Valneva initiated a pivotal Phase 3 study, VLA1553-301. Conducted in the US, VLA1553-301 is a double-blinded, placebo-controlled, multi-center study in approximately 4,000 healthy adults aged 18 or above. Participants will be randomized into two study groups to receive either vaccine or placebo. The primary endpoint will be to demonstrate safety and immunogenicity 28 days after a single-shot vaccination with VLA1553. A subset of participants will be tested for sero-protection based on an immunological surrogate under the Accelerated Approval pathway. Participants will be followed for a total of six months. The total duration of the study is expected to be nine to twelve months and the outcome, if positive, shall provide the basis for licensure of the vaccine. Seroprotection threshold is subject to FDA approval and the Phase 3 study duration is subject to COVID-19 pandemic related impact on clinical operations.

To make VLA1553 also accessible to Low and Middle Income Countries, Valneva and the Butantan Institute in Brazil signed a binding term sheet in May 2020 for the development, manufacturing and marketing of VLA1553[15]. The collaboration will be effective upon the signing of definitive agreements and will fall within the framework of the $23.4 million funding which Valneva received from the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019[16].

Chikungunya is considered a major public health threat with no preventive vaccines or effective treatments available. Chikungunya is a mosquito-borne viral disease caused by the chikungunya

[10] *Lyme Disease research and analysis conducted by an independent market research firm*
[11] *Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553*
[12] *https://priorityreviewvoucher.org/*
[13] *Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate*
[14] *Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation*
[15] *Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle- Income Countries*
[16] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. As of September 2020, there have been more than 3 million reported cases in the Americas[17] and the economic impact is considered to be significant (e.g. Colombia outbreak 2014: $73.6 million[18]). The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically.

The global market for vaccines against chikungunya is estimated to exceed $500 million annually by 2032[19].

SARS-CoV-2 VACCINE CANDIDATE – VLA2001
Major COVID-19 Vaccine Partnership with U.K. Government

In April 2020, Valneva initiated a program aiming to rapidly develop a vaccine against SARS-CoV-2, the pathogen that causes COVID-19[20].

In September 2020, Valneva announced a major COVID-19 vaccine partnership with the U.K. government potentially worth up to €1.4 billion. Under the agreement, if vaccine development is successful, Valneva will provide the UK government with 60 million doses in the second half of 2021, representing €470 million in revenues. UK Government then has options over 40 million doses in 2022 and a further 30 million to 90 million doses, in aggregate, across 2023 to 2025. Revenue from these options could amount to almost €900 million. Valneva's inactivated SARS-CoV-2 vaccine is expected to have a two dose regimen. UK government is also investing up-front in the scale up and development of the vaccine, with the investment being recouped against the vaccine supply under the partnership. The agreement follows the initial intent to participate in the UK Government's COVID-19 vaccine response announced in July 2020[21].

As part of its broader COVID-19 response, Valneva plans to further invest in its manufacturing facility in Livingston, Scotland and also in Solna, Sweden. Valneva is also in discussions with further potential customers for the vaccine.

Valneva is leveraging its technical and platform capabilities derived from IXIARO®, the Company's commercial vaccine product indicated for active immunization for the prevention of Japanese encephalitis, to develop an inactivated, whole virus vaccine candidate. The Company is collaborating with Dynavax to evaluate the adjuvant CpG 1018, which is a component of the US FDA-approved HEPLISAV-B® vaccine.

Valneva is in the process of industrializing the potential commercial manufacturing process for VLA2001 and has already produced first Clinical Trial Material. Assuming that preclinical activities are successful, Valneva plans to commence clinical studies by the end of 2020 with the objective to achieve a first regulatory approval in the second half of 2021, subject to the appropriate regulatory authority requirements.

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[17] *PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas. https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 13 Oct 2020.*
[18] *Cardona-Ospina et al. 2015, Trans R Soc Trip Med Hyg 109:793-802.*
[19] *VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020*
[20] *Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19*
[21] *Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program*

SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of respiratory system. The virus, which causes a disease named COVID-19, has never before been found in humans. To date, there has been over one million COVID-19 related deaths reported worldwide[22]. It has been declared a pandemic by the World Health Organization (WHO). Currently, there is no vaccine available for COVID-19.

Nine-Month 2020 Financial Review
(Unaudited, consolidated under IFRS)

Revenues
Valneva's total revenues in the first nine months of 2020 were €58.8 million compared to €81.4 million in the first nine months of 2019.

Product sales revenues in the first nine months of 2020 declined to €45.9 million compared to €86.4 million in the same period of 2019. On a CER basis[23], product sales declined by 47.6% compared to the first nine months of 2019 with both commercial vaccines impacted by COVID-19 related consequences on the travel market. The sales decline was primarily driven by a 52.8% decrease at CER in IXIARO®/JESPECT® sales while DUKORAL® sales declined by 34.0% at CER compared to the first nine months of 2019.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €13.0 million in the first nine months of 2020 and included revenues related to the Lyme R&D collaboration agreement with Pfizer amounting to €4.0 million. In the comparator period of 2019, negative Other Revenues amounting to €5.0 million were reported, including the effect of the termination of the SAA with GSK. Excluding the termination effect, other revenues would have amounted to €5.7 million in the first nine months of 2019.

Operating result and EBITDA
Costs of goods and services sold (COGS) were €35.1 million in the first nine months of 2020. Gross margin on product sales was 37.4% compared to 65.2% in the first nine months of 2019, with the decline mainly related to provisions taken for excess stock driven by reduced demand (due to the COVID-19 pandemic), idle capacity costs in both of Valneva's manufacturing sites as well as lower sales to US military prior to the execution of the new IXIARO® supply agreement. COGS of €16.2 million were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 47.5%. €11.1 million of COGS were related to DUKORAL® sales, yielding a product gross margin of 15.4%. Of the remaining COGS in the first nine months of 2020, €1.4 million were related to the Third Party Product distribution business and €6.4 million were related to cost of services. In the first nine months of 2019, overall COGS were €33.4 million, of which €30.1 million related to cost of goods and €3.3 million related to cost of services.

[22] *https://www.worldometers.info/coronavirus/*
[23] *CER: Constant Exchange Rate; Nine-months 2019 actuals restated to Nine-months 2020 average exchange rates*

Research and development investments in the first nine months of 2020 continued to increase as planned, more than doubling to €51.7 million compared to €23.2 million in the first nine months of 2019. This was driven by investments into Valneva's clinical stage vaccine candidates, notably Lyme and chikungunya, and was also impacted by spending related to Valneva's SARS-CoV-2 vaccine candidate. Marketing and distribution expenses in the first nine months of 2020 amounted to €13.8 million compared to €17.1 million in the first nine months of 2019. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity further to the COVID-19 pandemic. In the first nine months of 2020, general and administrative expenses increased to €19.3 million from €13.0 million in the first nine months of 2019, mainly driven by increased costs to support corporate transactions and projects as well as costs related to Valneva's employee share option program. Amortization and impairment charges of fixed assets/intangibles in the first nine months of 2020 remained unchanged compared to the same period of 2019 and amounted to €2.2 million.

Other income, net of other expenses in the first nine months of 2020 increased to €10.7 million from €4.2 million in the first nine months of 2019. This increase was mainly driven by increased R&D tax credit directly resulting from increased R&D spending along with income from the CEPI funding for Valneva's chikungunya R&D program.

Valneva recorded an operating loss of €52.5 million in the first nine months of 2020 compared to €3.2 million in the first nine months of 2019. EBITDA loss in the first nine months of 2020 was €45.2 million compared to an EBITDA profit of €3.0 million in the first nine months of 2019.

Net result

In the first nine months of 2020, Valneva generated a net loss amounting to €62.3 million compared to a net loss of €2.4 million in the first nine months of 2019.

Finance costs and currency effects in the first nine months of 2020 resulted in a net finance expense of €10.8 million, compared to a net finance expense of €0.4 million in the first nine months of 2019. The increase of expenses was the result of increased interest charges related to the newly entered financing arrangement with the US Healthcare Funds Deerfield and OrbiMed as well as foreign currency losses.

Cash flow and liquidity

Net cash generated by operating activities in the first nine months of 2020 amounted to €77.6 million compared to €5.0 million in the first nine months of 2019 mainly driven by the $130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement.

Cash outflows from investing activities in the first nine months of 2020 amounted to €8.1 million, compared to €8.0 million in the first nine months of 2019 mainly as a result of purchases of equipment.

Cash inflows from financing activities amounted to €22.4 million in the first nine months of 2020 and consisted mainly of €48.8 million net proceeds from the financing arrangement with US Healthcare Funds Deerfield and OrbiMed, offset by €20 million repayments of borrowings to the

European Investment Bank (EIB). Cash outflows from financing activities amounted to €6.8 million in the first nine months of 2019, which included the repayment of the Biopharma (Pharmakon) loan of €11.3 million in early 2019.

Liquid funds on September 30, 2020 strongly increased and stood at €156.2 million compared to €64.4 million on December 31, 2019. The main change was driven by the $130.0 million upfront payment related to the Lyme collaboration agreement with Pfizer and proceeds from the new debt line net of loan repayment to the EIB in March 2020. Liquid funds by September 30, 2020 did not include any payments made by the UK government within the framework of the UK COVID-19 partnership. These payments were received in October.

About Valneva SE

Valneva is a specialty vaccine company focused on prevention against diseases with major unmet needs. Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has various vaccines in development including unique vaccines against Lyme disease, COVID-19 and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with over 500 employees. For more information, visit www.valneva.com and follow the Company on LinkedIn.

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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 and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. 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 indicative of future performance. 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. 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.