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Valneva Reports H1 2021 Financial Results and Provides Business Update

Key R&D Milestones Achieved

- Positive topline Phase 3 results for single-shot chikungunya vaccine candidate VLA1553
  - Protective neutralizing antibodies induced in 98.5% of trial participants
- Recruitment completed for Phase 2 trial VLA15-221 of Lyme disease vaccine candidate including pediatric age group
- Recruitment completed for pivotal Phase 3 trial of inactivated, adjuvanted COVID-19 vaccine candidate VLA2001
  - Phase 3 topline data now expected early in fourth quarter 2021

Strong financial position

- $107.6 million of gross proceeds raised in a US initial public offering and a concurrent private placement in Europe
- Cash and cash equivalents of €329.8 million at June 30, 2021

2021 financial guidance (excluding COVID) reconfirmed

- Total revenues, excluding VLA2001, of €80 million to €105 million
- R&D expenses, excluding VLA2001, of €65 million to €75 million

Thomas Lingelbach, Valneva's Chief Executive Officer, commented, *"Valneva is continuing to hit its major R&D objectives. We have just reported great results in the world's first ever Phase 3 trial for a chikungunya vaccine alongside excellent progress for our unique COVID and Lyme disease programs. Our successful Nasdaq listing marked a significant strategic step for Valneva as we look to continue to build our Company. Our team has delivered phenomenally well this year already and I would like to thank them for their continued commitment and dedication."*

Financial Information

(unaudited results, consolidated under IFRS)

€ in million	**6 months ending June 30**	
	2021	**2020**
Total revenues	47.5	47.9
Product sales	31.8	40.9
Net profit/(loss)	(86.4)	(25.6)
EBITDA	(80.1)	(17.2)
Cash (at end of period)	329.8	200.0

Saint Herblain (France), August 10, 2021 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical needs, today reported its consolidated financial results for the first half of the year, ended June 30, 2021. The half year financial report, including the condensed consolidated interim financial report and the half year management report, is available on the Company's website www.valneva.com.

Valneva will provide a live webcast of its first half financial results conference call beginning at 3 p.m. CEST today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/gror7sgm

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Acceleration of Pediatric Development

Valneva is developing VLA15, a vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. VLA15 is currently the only vaccine undergoing clinical trials against Lyme disease.

Valneva has previously announced a collaboration with Pfizer for late phase development and, if approved, commercialization of VLA15[1]. Valneva has reported positive initial results for two Phase 2 clinical trials of VLA15 in over 800 healthy adults.

To accelerate VLA15's pediatric development, Valneva and Pfizer initiated an additional Phase 2 trial in March 2021, VLA15-221. In July 2021, Pfizer and Valneva announced recruitment completion for VLA15-221 with a total of 625 participants, 5 to 65 years of age, randomized in the trial. The objective of the trial is to show safety and immunogenicity down to 5 years of age and to evaluate the optimal vaccination schedule for use in Phase 3. Topline results for VLA15-221 are expected in the first half of 2022.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Positive Phase 3 Results reported

VLA1553 is a live-attenuated, single-dose vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further. There are currently no preventive vaccines or effective treatments for the chikungunya virus available and, to Valneva's knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials worldwide.

At the beginning of August 2021, Valneva announced positive topline results for the Phase 3 pivotal trial of VLA1553. The trial, involving 4,115 adults, aged 18 years and above, across 44 sites in the U.S., met its primary endpoint inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot (264 of 268 subjects from the per-protocol subgroup tested for immunogenicity, 95%CI: 96.2-99.6). The seroprotection rate result of 98.5%

[1] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*

exceeded the 70% threshold (for non-acceptance) agreed with the FDA. The seroprotective titer was agreed with the FDA to serve as a surrogate of protection that can be utilized in a potential FDA submission of VLA1553 under the accelerated approval pathway. The vaccine candidate was highly immunogenic with a Geometric Mean Titer of approximately 3,270, confirming the immunogenicity profile seen in the Phase 1 trial.

Additionally, VLA1553 was also highly immunogenic in elderly study participants, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.

VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety. An independent Data Safety Monitoring Board continuously monitored the study and identified no safety concerns. The safety profile is consistent with results from the Phase 1 clinical trial. The majority of solicited adverse events were mild or moderate and resolved within 3 days. 1.6% of study participants reported severe solicited adverse events, most commonly fever. Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia (seen in more than 20% of subjects). The local tolerability profile showed that approximately 15% of participants experienced solicited local adverse events. The trial will continue towards final analysis including the six-month safety data. Final trial results are expected within the next six months.

Valneva's chikungunya program was awarded Breakthrough Therapy Designation by the FDA in July 2021. This new milestone came in addition to the FDA Fast Track designation and the European Medicines Agency (EMA)'s PRIME designation which the Company received in December 2018 and in October 2020, respectively. The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

To make VLA1553 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[2]. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019[3], which provides funding of up to $23.4 million with support from the European Union's Horizon 2020 program.

SARS-CoV-2 VACCINE CANDIDATE – VLA2001
Recruitment Completed for Pivotal Phase 3 Trial

VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe. It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO®.

At the beginning of June 2021, Valneva announced that recruitment had been completed for VLA2001's pivotal Phase 3 trial "Cov-Compare" (VLA2001-301) with over 4,000 randomized

[2] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[3] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

participants. In the Phase 1/2 clinical trial, VLA2001 showed high immunogenicity and was generally well tolerated, with no safety concerns identified[4]. Cov-Compare phase 3 topline data are expected early in the fourth quarter of 2021. Valneva expects to commence rolling submission with the UK Medicines and Healthcare products Regulatory Agency in the coming weeks and, subject to the Phase 3 data, believes that initial approval may be granted by the end of 2021.

In parallel to the Cov-Compare trial, Valneva is studying COVID-19 variants to be in a position to manufacture variant-based vaccines. Valneva is also participating in a UK Government-funded clinical trial looking at different COVID-19 "booster" vaccines. The COV-Boost trial, led by University Hospital Southampton NHS Foundation Trust, looks at seven different COVID-19 vaccines, including VLA2001, as potential boosters, and is also evaluating dosage levels. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus. The COV-Boost trial is fully recruited. Valneva has also commenced production of VLA2001 at its facilities in Scotland and Sweden in order to optimize the timeline for potential deliveries of the vaccine.

Although vaccines against SARS-CoV-2 have already been approved, given the potential advantages often associated with inactivated whole virus vaccines, Valneva believes its vaccine candidate could play a role in the overall portfolio of SARS-CoV-2 vaccines that will address the global need during the pandemic and in the future.

In September 2020, Valneva announced a collaboration with the UK Government, which has the option to purchase up to 190 million doses through 2025[5]. So far, the UK Government has ordered 100 million doses for supply in 2021 and 2022.

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

IXIARO® is the only Japanese encephalitis vaccine licensed and available in the United States, Canada and Europe.

Sales of IXIARO® were €25.4 million in the first half of 2021 compared to €28.4 million in the first half of 2020. While the COVID-19 pandemic is continuing to adversely impact the travel industry and vaccine sales to the private market, the impact on IXIARO® sales during the first half of 2021 was mitigated by the Company's contract with the U.S. Government's Department of Defense (DoD).

CHOLERA / ETEC[6]-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by Vibrio cholerae and/or heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. DUKORAL® is authorized for

[4] *Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001*
[5] *Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program*
[6] *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.*

use in the European Union and Australia to protect against cholera and in Canada, Switzerland, New Zealand and Thailand to protect against cholera and ETEC.

DUKORAL® recorded sales of €0.4 million in the first half of 2021 compared to €12.1 million in the first half of 2020. First half 2021 sales continued to be significantly affected by the COVID-19 pandemic's impact on the travel industry.

First Half 2021 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €47.5 million in the first half of 2021 compared to €47.9 million in the first half of 2020. Product sales declined by 22.4% to €31.8 million in the first half of 2021 compared to €40.9 million in the first half of 2020. On a constant exchange rate (CER) basis, product sales declined by 18.6% in the first half of 2021 compared to the first half of 2020 due to the impact of the COVID-19 pandemic on the travel industry. IXIARO®/JESPECT® sales declined by 10.6% (3.5% at CER) to €25.4 million and DUKORAL® sales by 96.5% (96.6% at CER) to €0.4 million in the first half of 2021 compared to €28.4 million and €12.1 million respectively in the first half of 2020. Third Party product sales grew to €5.9 million in the first half of 2021 from €0.4 million in the first half of 2020. The increase in Third Party product sales was driven by incremental sales related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur®/RabAvert® and Encepur® in certain territories that commenced in 2021.
Other Revenues, including revenues from collaborations, licensing and services, amounted to €15.7 million in the first half of 2021 compared to €7.0 million in the first half of 2020. This increase was attributable to higher revenues related to the Lyme R&D collaboration agreement with Pfizer, incremental revenues related to the collaboration with Instituto Butantan for providing VLA1553 in LMICs as well as higher revenues generated in the CTM Manufacturing unit in Sweden.

Operating Result and EBITDA

Costs of goods and services sold (COGS) were €34.8 million in the first half of 2021. Gross margin on product sales was 39.2% compared to 55.7% in the first half of 2020. The decline was mainly related to idle capacity costs combined with compressed product sales, both impacting gross margin as a percentage of sales. COGS of €11.7 million were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 54.1%. COGS of €3.6 million were related to DUKORAL® sales, causing a negative product gross margin. Of the remaining COGS in the first half of 2021, €4.1 million were related to the Third-Party product distribution business, €4.2 million to start-up costs of the COVID-19 business and €11.3 million to cost of services. In the first half of 2020, overall COGS were €22.5 million, of which €18.1 million related to cost of goods and €4.4 million related to cost of services.
Research and development investments continued to increase in the first half of 2021, growing to €78.7 million compared to €33.1 million in the first half of 2020. This was mainly driven by investments in Valneva's COVID-19 vaccine candidate VLA2001 as well as Phase 3 clinical study costs for Valneva's chikungunya vaccine program VLA1553. Excluding COVID-19, research and development investments amounted to €32.6 million in the first half of 2021 compared to €31.5 million in the first half of 2020. Marketing and distribution expenses in the first half of 2021

amounted to €9.6 million compared to €10.0 million in the first half of 2020. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity as a result of the COVID-19 pandemic. Marketing and distribution expenses in the first half of 2021 notably included €2.0 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first half of 2020). In the first half of 2021, general and administrative expenses increased to €20.9 million from €10.6 million in the first half of 2020, mainly driven by increased costs to support corporate transactions and projects including increased resources in support of incremental COVID activities.
Other income, net of other expenses, increased to €10.4 million in the first half of 2021 from €6.5 million in the first half of 2020. This increase was mainly driven by increased R&D tax credits directly resulting from increased R&D spending.
Valneva recorded an operating loss of €86.2 million in the first half of 2021 compared to an operating loss of €21.9 million in the first half of 2020. EBITDA loss in the first half of 2021 was €80.1 million compared to an EBITDA loss of €17.2 million in the first half of 2020.

Net Result

In the first half of 2021, Valneva generated a net loss amounting to €86.4 million compared to a net loss of €25.6 million in the first half of 2020.
Finance costs and currency effects in the first half of 2021 resulted in a net finance income of €0.5 million, compared to a net finance expense of €5.6 million in the first half of 2020. This was mainly a result of foreign exchange gains amounting to €8.7 million in the first half of 2021 primarily driven by revaluation gains of non-Euro denominated balance sheet positions compared to a net foreign exchange loss (net of gains on derivative financial instruments) of €1.7 million in the first half of 2020. Interest charges increased to €8.4 million in the first half of 2021 compared to €3.9 million in the same period of 2020. This growth was driven by increased interest charges related to refund liabilities as well as increased interest charges related to the financing agreement with U.S. healthcare funds Deerfield & OrbiMed entered into in 2020.

Cash Flow and Liquidity

Net cash generated by operating activities amounted to €84.2 million in the first half of 2021 compared to €113.2 million in the first half of 2020 mainly derived by milestone payments related to the COVID supply agreement concluded with the UK Government in September 2020. The net cash generated by operating activities in the first half of 2020 mainly derived from the $130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement.
Cash outflows from investing activities amounted to €39.9 million in the first half of 2021 compared to €1.8 million in the first half of 2020 mainly as a result of purchases of equipment related to the site expansion activities for COVID vaccine manufacturing in both Scotland and Sweden.
Net cash generated from financing activities amounted to €78.7 million in the first half of 2021 which was mainly a result of proceeds from issuance of new shares in the U.S. initial public offering and European private placement (Global Offering). Cash inflows in the first half of 2020 amounted to €24.5 million and mainly consisted of net proceeds from the financing arrangement with U.S. healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the European Investment Bank.
Liquid funds increased to €329.8 million as of June 30, 2021 compared to €204.4 million as of December 31, 2020. The main changes related to payments made by the UK Government within

the framework of the UK COVID-19 partnership as well as the proceeds from the Global Offering in May 2021.

Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful as an aid to further understand Valneva's current performance, performance trends, and financial condition.

EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

A reconciliation of EBITDA to operating loss, the most directly comparable IFRS measure, is set forth below:

€ in million	**6 months ending June 30**	
	2021	**2020**
Operating Loss	(86.2)	(21.9)
Add:		
Amortization	3.1	3.0
Depreciation	3.0	1.7
EBITDA	**(80.1)**	**(17.2)**

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, beginning with the identification of deadly and debilitating infectious diseases that lack a prophylactic vaccine solution and for which there are limited therapeutic treatment options. It then applies its deep understanding of vaccine science, including its expertise across multiple vaccine modalities, as well as its established vaccine development capabilities, to develop prophylactic vaccines to address these diseases. Valneva has leveraged its expertise and capabilities to successfully commercialize two wholly owned vaccines and rapidly advance multiple vaccine candidates into late-stage clinical development, including candidates against Lyme disease (partnered with Pfizer), the chikungunya virus and COVID-19.

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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 expected total revenues and R&D expenses for full fiscal year 2021, 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 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 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, as well as those risks and uncertainties discussed or identified in Valneva's public filings with the Autorité des Marchés Financiers (AMF) in France, including those listed in the Company's 2020 Universal Registration Document filed with the AMF on April 9, 2021, which is available on the Company's website and on the website of the AMF (www.amf-france.org), and public filings and reports filed with the U.S. Securities and Exchange Commission. 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 the information in these materials as 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.