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

Valneva Reports Q1 Results and Updates 2020 Guidance Following Major Lyme Partnering Deal

- **Limited business impact of COVID-19 crisis during Q1**
- **Unprecedented partnering deal signed for Phase 2 Lyme vaccine candidate**
- **2020 full-year financial guidance updated with improved EBITDA**
- **SARS-CoV-2 vaccine development program for COVID-19 initiated**

Solid financial results in Q1 2020, with limited COVID-19 impact

- Product sales revenue of €32.7 million in Q1 2020, similar to Q1 2019 (€32.8 million)
- Total revenues of €35.2 million in Q1 2020, similar to Q1 2019 (€34.9 million)
- Gross margin on product sales revenues of 69.4% in Q1 2020 driven by geographical mix and strong operational performance in manufacturing
- EBITDA[1] of €2.4 million in Q1 2020, lower than Q1 2019 (€8.2 million) due to increased R&D investments
- Positive operating cash flow of €3.0 million in Q1 2020
- Strong cash position of €80.8 million at the end of March 2020
    - Supported by an $85 million debt financing arrangement with leading U.S. funds in February 2020 (the Company has drawn $45 million from this facility to date)

2020 full-year financial guidance updated reflecting continuing COVID-19 impact and Lyme collaboration, with improved EBITDA

- Total revenues now estimated to be between €95 million and €135 million in 2020
    - Revised guidance includes €10 million to €30 million revenues recognized from the Lyme disease vaccine collaboration to be reported in "Other Revenues"[2]
        - Non-Lyme "Other Revenues" guidance maintained at ~ €10 million
    - Product sales revenue guidance revised to €75 million to €95 million noting the continuing impact of the COVID-19 pandemic
- R&D investments of up to €80 million including:
    - A potential three month delay in the initiation of the chikungunya Phase 3 trial driven by the COVID-19 pandemic situation, as previously announced
    - Lyme-related costs noting the new Lyme collaboration
    - Initial investment in the Company´s SARS-CoV-2 vaccine candidate (VLA2001)
- Valneva now expects improved negative EBITDA of €10 million to €30 million in 2020 (compared to previous guidance of up to €50 million negative EBITDA)
    - Cost containment measures are being implemented across the Company and government support mechanisms are being used where possible

[1] *Q1 2020 EBITDA was calculated by excluding €2.3 million of depreciation and amortization from the €0.1 million operating profit as recorded in the consolidated income statement under IFRS.*
[2] *The Pfizer deal revenue recognition under IFRS is complex and is being evaluated by the Company's accountants and auditors.*

Significant milestones reported for R&D programs since the beginning of the year

- Signing of an unprecedented collaboration with Pfizer for Phase 2 Lyme disease vaccine candidate VLA15[3]
  - $130 million upfront and $35 million development milestones
  - Up to a further $143 million in early commercialization milestone payments
  - Tiered royalties on sales starting at 19%
- No change to timelines of current VLA15 Phase 2 trials despite COVID-19 pandemic. First Phase 2 results expected in July 2020
- Positive End of Phase 2 meeting granted by the FDA for chikungunya vaccine candidate VLA1553[4]
- Chikungunya Phase 3 to be initiated as soon as the COVID-19 situation permits (currently planned for Q4 2020)
- Initiation of VLA2001 – a SARS-CoV-2 vaccine development program for COVID-19[5]
  - Collaboration with Dynavax leveraging Valneva´s technical and platform capabilities to develop an inactivated, adjuvanted whole virus vaccine candidate
  - Existing BSL3 laboratories recommissioned to undertake pre-clinical activities
  - Resources from other early stage programs reallocated to support the project; grant funding also sought for clinical development and manufacturing
  - Valneva and Dynavax to align with regulatory authorities on the optimal strategy for an expedited clinical development program, with the goal to initiate clinical trials before the end of 2020 (subject to successful preclinical work and receipt of appropriate funding)
  - Production of clinical trial material expected in Valneva's FDA approved plant in Livingston, Scotland

David Lawrence, Valneva's Chief Financial Officer, commented, "Considering the current pandemic situation, we are very pleased with our first-quarter financial results. We have also delivered an unprecedented collaborative deal with Pfizer to advance our Lyme disease program in response to a major unmet medical need. Given the global COVID-19 crisis and its significant impact on our travelers vaccine business, we are pleased with our ability to balance employee welfare with business continuity, and would like to thank our employees for their ongoing commitment and flexibility."

Financial Information

(Q1 2020 unaudited results, consolidated under IFRS)

€ in million	**3 months ending March 31**	
	2020	**2019**
Product sales	32.7	32.8
Total revenues	35.2	34.9
Net profit/loss	(1.2)	4.9
EBITDA	2.4	8.2
Cash	80.8	68.1

[3] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[4] *Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study*
[5] *Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19*

Saint Herblain (France), May 7, 2020 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on prevention against diseases with major unmet needs, reported today its first quarter financial results ending March 31, 2020. The condensed consolidated interim financial results are available on the Company's website www.valneva.com.

Valneva will provide a live webcast of its first-quarter 2020 financial results conference call beginning at 3:00 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/5i6xunqx

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In the first quarter of 2020, revenues from IXIARO®/JESPECT® product sales reached €22.9 million, representing year-on-year growth of 2% (0% at CER). The increase was largely driven by demand in North America, both in the public and private markets. During the first quarter of 2020, the U.S. government Department of Defense (DoD) issued a Request For Proposal (RFP) for the supply of Japanese encephalitis vaccines to the U.S. military. As sole supplier of the only U.S. Food and Drug Administration (FDA) approved Japanese encephalitis vaccine, Valneva has responded to this RFP and expects to enter into a new contract with the DoD in the second quarter of this year. This expected contract will drive IXIARO® sales in the second half of 2020 and beyond. In addition, the FDA granted a 36 month shelf-life extension for – IXIARO® in March[6], an important achievement supporting supply management flexibility.

CHOLERA / ETEC[7]-DIARRHEA VACCINE (DUKORAL®)

In the first quarter of 2020, revenues from DUKORAL® sales increased to €9.7 million compared to €9.6 million in the first quarter of 2019.

TRAVEL VACCINES MARKET

The Company expects the travel market for IXIARO®/JESPECT® and DUKORAL® to be significantly impacted, notably in the second and third quarters of 2020, with a gradual market recovery anticipated in the fourth quarter. Although it may take some years for travel-related businesses to return to previous levels, the Company believes that the current crisis may have a positive effect on the vaccine market in the mid-to-long term due to an increase in vaccination awareness.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Strategic alliance with Pfizer; **First Phase 2 results expected mid 2020**

[6] *Valneva Announces FDA Approval of IXIARO® Shelf Life Extension to 36 Months; New US Military RFP Issued*
[7] *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.*

Valneva´s Lyme disease vaccine candidate, VLA15, is the only clinical development stage program in the world and addresses the most common tick-transmitted infection in the Northern hemisphere. The Company recently announced that it has signed a major partnering deal with Pfizer for the late stage development and future commercialization of VLA15[8].

Valneva and Pfizer will work closely together throughout the development of VLA15. Valneva is eligible to receive a total of $308 million in cash payments consisting of a $130 million upfront payment, $35 million in development milestones and $143 million in early commercialization milestones. Under the terms of the agreement, Valneva will fund 30% of all development costs through completion of the development program, and in return Pfizer will pay Valneva tiered royalties starting at 19%. Pfizer will lead late-stage development and have sole control over commercialization.

Valneva has completed patient enrolment and most follow-up visits for the two ongoing Phase 2 studies in more than 800 people. Valneva expects to report first Phase 2 results from study VLA15-201 (0-1-2 month vaccination schedule) in July 2020 followed, in the third quarter, by first results from study VLA15-202 (0-2-6 month vaccination schedule). The results of these studies, comprising immunogenicity and safety data, will support the dose and vaccination schedule to be advanced into Phase 3.

According to the U.S. 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].

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. The program was granted Fast Track designation by the FDA in July 2017[10].

Peak revenue potential for a Lyme disease vaccine in the U.S. and EU is estimated at more than $1 billion[11].

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Phase 3 initiation preparation proceeding

Valneva´s single shot chikungunya vaccine candidate, VLA1553, is unique and addresses a highly prevalent mosquito transmitted infection in the tropical and subtropical regions.
The Company plans to take this vaccine to market with the prospect of leveraging major manufacturing and commercial synergies primarily focusing on the traveler vaccine market. Valneva and the Butantan Institute in Brazil recently announced the signing of a binding term sheet for a collaboration for the development, manufacturing and marketing of Valneva's single-shot

[8] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[9] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.*
[10] *Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15*
[11] *Lyme Disease. L.E.K. interviews, research and analysis*

chikungunya vaccine VLA1553 in Low and Middle Income Countries (LMIC)[12]. The collaboration will be effective upon the signing of definitive agreements and will fall within the framework of the $23.4 million funding Valneva received from the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019[13].

During the first quarter of 2020 Valneva held an End-of-Phase 2 meeting with the U.S. FDA[14]. Valneva is currently advancing all activities, including its Contract Research Organization (CRO), to allow Phase 3 initiation as soon as the COVID-19 situation permits. As previously announced, the Company's assumption is that it may start Phase 3 clinical studies in the fourth quarter of this year, which is three months later than originally planned.

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 virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. As of 2017, there have been more than one million reported cases in the Americas[15] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[16]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically.

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya. It was granted Fast Track designation by the FDA in December 2018[17].

The global market potential for chikungunya vaccines is estimated at up to $500 million and the traveler market at around $250 million [18].

The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

SARS-CoV-2 VACCINE CANDIDATE – VLA2001
Inactivated vaccine program recently initiated

Valneva recently initiated a research program aiming to develop a vaccine against SARS COV-2, the COVID-19 pathogen[19].
The Company is taking advantage of its well-established IXIARO® technology platform to develop an inactivated, whole virus, adjuvanted vaccine candidate, in collaboration with Dynavax.
Dynavax is providing its adjuvant CpG 1018, which is also incorporated in U.S. FDA-approved HEPLISAV-B vaccine.

Valneva is conducting pre-clinical development work in its Biosafety Level 3 laboratories and has reallocated resources from other early stage research and development (R&D) programs, without

[12] *Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle- Income Countries*
[13] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[14] *Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study*
[15] *PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[16] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*
[17] *Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate*
[18] *Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market*
[19] *Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19*

affecting the clinical development of its vaccine candidates for Lyme disease and chikungunya. Valneva and Dynavax will work with regulatory authorities to agree on the optimal strategy to execute an expedited clinical development program, with the goal to initiate clinical studies before the end of 2020, subject to successful pre-clinical work and receipt of appropriate funding.

Valneva has core manufacturing competences in its GMP manufacturing facility in Livingston, UK for such a virus-based vaccine candidate and expects to produce clinical trial material at that facility.

Valneva is seeking non-dilutive funding, in particular grant funding, to support clinical development and manufacturing investments. If the program is successful and obtains appropriate funding, Valneva estimates that its initial manufacturing capacity could exceed 30 million doses per year.

First Quarter 2020 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues in the first quarter of 2020 were €35.2 million compared to €34.9 million in the first quarter of 2019.

Product sales revenues in the first quarter of 2020 amounted to €32.7 million compared to €32.8 million in the same period of 2019. On a CER basis, product sales declined by 2% compared to the first quarter of 2019. Revenues from collaborations, licensing and services amounted to €2.5 million in the first quarter of 2020 compared to €2.1 million in the first quarter of 2019.

Operating result and EBITDA

Costs of goods and services sold (COGS) were €12.1 million in the first quarter of 2020. Gross margin on product sales amounted to 69.4% compared to 66.1% in the first quarter of 2019. COGS of €6.7 million related to IXIARO®/JESPECT® sales, yielding a product gross margin of 70.8%. €3.2 million of COGS related to DUKORAL® sales, yielding a product gross margin of 66.8%. Of the remaining COGS in the first quarter of 2020, €0.1 million related to the Third Party Product distribution business and €2.1 million were related to cost of services. In the first quarter of 2019, overall COGS were €12.2 million, of which €11.1 million related to cost of goods and €1.1 million related to cost of services.

R&D expenses in the first quarter of 2020 amounted to €13.3 million compared to €6.3 million in the first quarter of 2019. This was driven by planned increased investments into Valneva's clinical stage vaccine candidates. Marketing and distribution expenses in the first quarter of 2020 amounted to €6.0 million, compared to €5.6 million in the first quarter of 2019. In the first quarter of 2020, general and administrative expenses increased to €5.2 million from €4.5 million in the first quarter of 2019 mainly driven by increased costs to support corporate project activities as well as costs related to a new employee share option program. Amortization and impairment charges of fixed assets/intangibles in the first quarter of 2020 remained unchanged compared to the same period of 2019 and amounted to €0.7 million.

Other income, net of other expenses in the first quarter of 2020 increased to €2.2 million from €0.8 million in the first quarter of 2019. This increase was driven by increased R&D tax credit and income from the CEPI funding related to Valneva's chikungunya R&D program.

Valneva realized an operating profit of €0.1 million in the first quarter of 2020 compared to €6.2 million in the first quarter of 2019. EBITDA in the first quarter of 2020 was €2.4 million compared to an EBITDA of €8.2 million in the first quarter of 2019.

Net result

In the first quarter of 2020, Valneva generated a net loss of €1.2 million compared to a net profit of €4.9 million in the first quarter of 2019.

Finance costs and currency effects in the first quarter of 2020 resulted in a net finance expense of €2.2 million, compared to a net finance income of €0.5 million in the first quarter of 2019. The decline was the result of increased interest charges as well as foreign currency losses both largely related to the newly entered USD denominated debt facility.

Cash flow and liquidity

Net cash generated by operating activities in the first quarter of 2020 amounted to €3.0 million compared to €5.3 million in the first quarter of 2019.

Cash outflows from investing activities in the first quarter of 2020 amounted to €0.6 million, compared to €0.8 million in the first quarter of 2019.

Cash inflows from financing activities amounted to €14.5 million in the first quarter of 2020 and consisted mainly of €35.5 million net proceeds from the financing arrangement with U.S. healthcare funds, Deerfield and Orbimed, and €20.0 million repayments of borrowings to the European Investment Bank (EIB). Cash outflows from financing activities amounted to €13.5 million in the first quarter of 2019, which included the repayment of the Biopharma (Pharmakon) loan.

Liquid funds on March 31, 2020 stood at €80.8 million compared to €64.4 million on December 31, 2019. The main change was driven by proceeds from the new debt line net off re-paying the loan to the EIB in March 2020.

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 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.

Valneva Investor and Media Contacts
Laetitia Bachelot-Fontaine
Director of Investor Relations &
Corporate Communications
M +33 (0)6 4516 7099
investors@valneva.com

Teresa Pinzolits
Corporate Communications Specialist
T +43 (0)1 20620 1116
communications@valneva.com

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.