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Valneva Reports Strong Q1 Results and Continues to Advance Key R&D Programs

Strong sales and EBITDA performance in Q1 2018

- Product sales of €28.9 million in Q1 2018, representing 11.5% year on year growth, in line with Company guidance of double-digit product sales growth in FY 2018.
  - Total revenues were €32.1 million in Q1 2018 (vs. €28.4 million in Q1 2017)[1].
- EBITDA of €4.9 million in Q1 2018 (vs. €3.4 million in Q1 2017); R&D investment to progress its Lyme and Chikungunya vaccine candidates will increase during the year.
- Gross margin of 59.4% in Q1 2018 (vs. 53.2% in Q1 2017) driven by Q1 country and product sales mix.
- Positive operating cash flow of €4.5 million in Q1 2018 resulting in cash position of €36.2 million at the end of March 2018.

Q1 Pipeline Highlights

- Phase 2 consultation and preparation activities ongoing for Valneva's FDA fast-tracked Lyme vaccine candidate VLA15. The study is expected to commence in the second half of 2018.
- Recruitment for the Company's Chikungunya vaccine candidate VLA1553 Phase 1 progressing according to plan.
- Recruitment for Zika vaccine candidate VLA1601 Phase 1 has been completed. Initial results expected at the end of 2018 or early 2019.

David Lawrence, Valneva's Chief Financial Officer, commented, "The first quarter of 2018 marked a robust start to the year. For IXIARO®, in the US Private market, we can begin to see early, positive results from our newly established in-house sales and marketing team. We remain focused on the execution of our commercial products and investing in the progression of our valuable vaccine candidates to maintain the sustainable longer-term growth of the Company."

[1] *For greater clarity, reporting of grants has been re-classified and will, as of 2018, be included in the company's Other Income / Expense line. The comparator period of 2017 was adjusted accordingly.*

Key Financial Information
(Unaudited)

€ in million	3 months ending March 31	
	2018	2017
Product Sales	28.9	25.9
Total Revenues	32.1	28.4[2]
Net profit/(loss)	1.5	(1.7)
EBITDA[3]	4.9	3.4
Cash, short-term deposits and marketable securities, end of period	36.2	45.2

Lyon (France), May 17, 2018 – Valneva SE ("Valneva" or "the Company"), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, reported today its first quarter financial results ending March 31, 2018. The condensed consolidated interim financial results are available on the Company's website www.valneva.com.

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)
Strong sales growth driven by the US private market

In the first quarter of 2018, IXIARO®/JESPECT® sales reached €18.2 million compared to €15.5 million in the first quarter of 2017, representing 17.3% year-on-year growth. This increase was largely driven by growth in the US private market where Valneva took direct control of sales and marketing at the end of November 2017. Additional growth in the UK, Nordics and Canadian private markets also drove the sales.

In 2018, Valneva expects continued double-digit growth in IXIARO®/JESPECT® revenues through increased market penetration via the development of its commercial network, notably in the US private market.

2 For greater clarity, reporting of grants has been re-classified and will, as of 2018, be included in the Company's Other Income / Expense line. The comparator period of 2017 was adjusted accordingly.
3 EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets (Q1 2018: €1.7m, Q1 2017: €2.9m) from operating profit (Q1 2018: €3.2m, Q1 2017: €0.5m).

CHOLERA / ETEC-DIARRHEA VACCINE (DUKORAL®)

In the first quarter of 2018, DUKORAL® sales reached €9.5 million compared to €9.8 million in the first quarter of 2017. The slight decline in sales was attributable to negative exchange rate movements and supply phasing in certain European markets. The Company expects this effect to even out over the course of the year and confirms it expects DUKORAL® revenues to continue to grow healthily in 2018 through continued market penetration.

Clinical Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Phase 2 study to be initiated in the second half of 2018

After reporting positive Phase 1 interim data for VLA15 in March 2018[4], Valneva expects to launch a Phase 2 study in the second half of 2018, subject to regulatory clearances.

Phase 2 is intended to be conducted in Lyme-endemic regions in the US and Europe and will include subjects previously infected with *Borrelia*, the bacteria that causes Lyme disease. Further dose and schedule optimizations are being considered.

As part of its development acceleration strategy, the Company has elected to augment the Phase 1 study with a booster dose, to gather additional data expeditiously.

A subset of subjects in the higher dose groups who received a complete primary immunization schedule (three vaccinations), will be included in a booster extension to investigate the safety and immunogenicity of a booster dose of VLA15 administered approximately thirteen months after the first immunization. An analysis on safety and immunogenicity will be performed after the last subject has completed the last study visit six months after booster vaccination. In addition, an interim analysis on immunogenicity data one month post booster will be performed.

Lyme disease is the most common and one of the fastest growing vector-borne illnesses in the Northern Hemisphere for which there is no other clinical vaccine candidate in development worldwide. The systemic infection is caused by *Borrelia* bacteria transmitted to humans by infected *Ixodes* ticks. According to the US Centers for Disease Control and Prevention (CDC), approximately 300,000[5] Americans are infected with Lyme disease each year with at least a further 200,000 cases in Europe[6]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called Erythema migrans or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system.

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[4] *http://www.valneva.com/download.php?dir=News_2018&file=2018_03_19_VLA15_Phase_I_Results_PR_ENG.pdf*
[5] *As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article*
[6] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.*

Valneva's vaccine candidate VLA15, under Fast Track Designation by the FDA, 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.

Vaccination with OspA was already proven to work in the 1990s and VLA15 pre-clinical data showed that the vaccine has the potential to provide protection against the majority of the *Borrelia* species pathogenic for humans[7].

The global market for a vaccine against Lyme disease is currently estimated at approximately €700 - €800 million annually[8].

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Phase 1 study (VLA1553-101) progressing according to plan

Recruitment for Phase 1, VLA1553-101, which was initiated in March 2018[9], to evaluate Valneva's single-shot vaccine candidate against Chikungunya is progressing according to plan.

VLA1553-101 is a randomized, observer-blinded, dose-escalation, multi-center study investigating three different dose levels of VLA1553 in approximately 120 healthy adults vaccinated with a single-shot immunization.

The trial design includes the investigation of antibody persistence and an additional vaccination with the highest dose of the live-attenuated vaccine candidate at 6 or 12 months. This re-vaccination serves as an intrinsic human viral challenge demonstrating that subjects are protected from vaccine-induced viremia and thereby potentially indicating efficacy of VLA1553 early in clinical development.

Chikungunya is a mosquito-borne viral disease caused by the Chikungunya virus (CHIKV), a Togaviridae virus, transmitted by *Aedes* mosquitoes. Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash potentially developing into long-term, serious health impairments[10]. Chikungunya outbreaks were reported in Asia, Africa, the Americas and recently (2017) in Europe. As of December 2017, there have been more than 1 million reported cases in the Americas[11] and the economic impact can be considered significant (e.g. Columbia outbreak 2014: $73.6 million)[12]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to further spread geographically.

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[7] *New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017*
https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/
[8] *Company estimate supported by independent market studies*
[9] *http://www.valneva.com/download.php?dir=News_2018&file=2018_03_13_Chikungunya_Phase_I_initiation_EN.pdf*
[10] *WHO, PAHO*
[11] *PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[12] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*

There are no preventive vaccines or effective treatments available and as such Chikungunya can be considered a major public health threat.

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against various Chikungunya virus outbreak phylogroups and strains aiming for a long-lasting protection conferred by neutralizing antibodies in adults and children[13]. The target populations are travelers, military personnel or individuals at risk who live in endemic regions.

In pre-clinical development, a single-vaccine shot was highly immunogenic with a strong, long lasting neutralizing antibody response and vaccinated Non-Human Primates (NHP) (cynomolgus macaques) showed no signs of viremia after challenge[14].

First data from the Phase 1 trial are expected to be available by early 2019.

The global market for vaccines against Chikungunya is estimated at up to €500 million annually[8].

ZIKA VACCINE CANDIDATE – VLA1601
Phase 1 study fully recruited, Partnered with Emergent BioSolutions

After initiating Phase 1 in the US in February 2018[15], Valneva has finalized the recruitment of study participants for this clinical trial under the partnership agreement with Emergent BioSolutions.

The Phase 1 study of VLA1601-101 is a randomized, observer-blinded, placebo-controlled, single center study investigating two dose levels with two different vaccination schedules in 67 healthy adults.

First data from the Phase 1 trial are expected to be available in late 2018 or early 2019. Upon availability of Phase 1 data, Emergent will have the option to continue the development arrangement with Valneva for a milestone payment of €5 million. The agreement also provides Valneva potential additional milestone payments of up to €44 million related to product development, approval, commercialization and product sales, as well as future royalties on annual net sales[16].

Zika Virus infection is a mosquito-borne viral disease caused by the Zika Virus (ZIKV), a flavivirus transmitted by *Aedes* mosquitoes[17]. Disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, since 2015, in the Americas. According to the World Health Organization, there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome[18]. Between 2015 and beginning of January 2018, over 500,000 cases of suspected Zika infection and many cases of the

[13] *Hallengärd et al. 2013 J. Virology 88: 2858-2866*
[14] *Roques et al. 2017JCI Insight 2 (6): e83527*
[15] *http://www.valneva.com/download.php?dir=News_2018&file=2018_02_26_Phase_1_Initiation_VLA1601_EN.pdf*
[16] *http://www.valneva.com/download.php?dir=News_2017&file=2017_07_26_VLA_Emergent_ZIKA_PR_EN.pdf*
[17] *https://www.cdc.gov/zika/transmission/index.html*
[18] *http://www.who.int/mediacentre/factsheets/zika/en/*

congenital syndrome associated with the ZIKV had been reported by countries and territories in the Americas, according to the World Health Organization[19]. Today there is no specific treatment available.

VLA1601 is a highly purified inactivated whole virus vaccine candidate developed using Valneva's proven and licensed inactivated JE vaccine platform. In pre-clinical development VLA1601 demonstrated excellent purity, in-vivo neutralization and overall a biological, chemical and physical profile comparable to IXIARO®.

First Quarter 2018 Financial Review
(Unaudited)

Revenues
Product sales in the first quarter of 2018 increased by 11.5% to €28.9 million from €25.9 million in the same period of the previous year.
Valneva's aggregate first quarter 2018 revenues were €32.1 million compared to €28.4 million in the first quarter of 2017.
Revenues from collaborations and licensing amounted to €3.2 million compared to €2.5 million in the first quarter of 2017. For greater clarity, reporting of grant income has been re-classified in 2018 and is included in the Company's other income and expenses, net. The comparator period of 2017 has been adjusted accordingly.

Operating result and EBITDA
Cost of goods and services sold (COGS) were €13.0 million in the first quarter of 2018, representing an overall gross margin of 59.4% compared to 53.2% for the same period in 2017. €7.2 million of COGS were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 60.6%. €3.8 million of COGS were related to DUKORAL® sales, yielding a product gross margin of 59.6%. Of the remaining COGS for the first quarter of 2018, €0.8 million were related to the Third Party product distribution business and €1.3 million were related to cost of services. In the comparative period of 2017, COGS were €13.3 million, of which €11.5 million were related to cost of goods and €1.8 million to cost of services.
Research and development expenses in the first quarter of 2018 increased to €5.8 million from €5.2 million in the first quarter of the previous year. This was driven by increased investments into Valneva's clinical stage vaccine candidates. Distribution and marketing expenses in the first quarter of 2018 amounted to €6.0 million, compared to €4.3 million in the first quarter of 2017, reflecting increased direct commercial efforts. In the first quarter of 2018, general and administrative expenses equalled the first quarter of 2017, at €4.0 million. Amortization and impairment charges in the first quarter of 2018 amounted to €0.8 million compared to €1.8 million in the first quarter of 2017. The reduction is resulting from the re-

[19] http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en

assessment of the lifetime of IXIARO®/JESPECT® related intangible assets driven by extension of patents in both Europe and the USA.
In the first quarter of 2018, Valneva realized an operating profit of €3.2 million compared to €0.5 million in the first quarter of 2017. Valneva's Q1 2018 saw a positive EBITDA of €4.9 million compared to €3.4 million in the first quarter of 2017. First quarter 2018 EBITDA was calculated by excluding depreciation and amortization amounting to €1.7 million from the operating profit of €3.2 million as recorded in the condensed consolidated income statement under IFRS.

Net result
Valneva achieved in the first quarter of 2018 a net profit amounting to €1.5 million compared to a net loss of €1.7 million in the first quarter of 2017.
Finance costs and currency effects in the first quarter of 2018 amounted to a net finance expense of €1.3 million compared to a net finance expense of €2.0 million in the first quarter of 2017.

Cash flow and liquidity
Net cash generated by operating activities in the first quarter of 2018 was €4.5 million compared to €12.1 million in the same period in 2017.
Cash outflows from investing activities in the first quarter of 2018 amounted to €0.6 million, compared to €1.1 million in the first quarter of 2017, and resulted primarily from purchase of equipment.
Cash outflows from financing activities in the first quarter of 2018 amounted to €3.8 million compared to €4.9 million in the first quarter of 2017 and were mainly related to re-payment of borrowings and interest payments.
Liquid funds on March 31, 2018 stood at €36.2 million compared to €38.1 million on December 31, 2017 and consisted of €33.2 million in cash and cash equivalents and €3.0 million in restricted cash.

From the first quarter of 2018 onwards, Valneva will only present quarterly primary statements based on IFRS with the same accounting principles applied as for the IFRS financial statements. Full results, in line with IAS34, will be issued for Half Year 2018.

About Valneva SE
Valneva is a fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines.
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 proprietary 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 450 employees. More information is available at www.valneva.com.

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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 their 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. 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.