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Valneva Reports Strong Q1 2019 Operating Results and Advances Key R&D Programs towards Major Milestones

Repeated significant growth in IXIARO® revenues; Lyme disease and chikungunya programs advancing towards major data points; R&D investor day planned for July in New York

Strong financial results in Q1 2019

- Product sales revenue of €32.8 million in Q1 2019, representing 9% growth at constant exchange rate (CER[1])
  - Significant growth in IXIARO® revenues (growth of 17% (CER)) in Q1 2019
- Total revenues were €34.9 million in Q1 2019
- EBITDA[2] of €8.2 million in Q1 2019
- Net profit of €4.9 million in Q1 2019
- Positive operating cash flow of €5.3 million
- Strong cash position of €68.1 million at the end of March 2019

Two significant R&D milestones reported in Q1 2019

- Final Phase 1 data and first booster data for Lyme disease vaccine candidate, VLA15[3]
- Positive Phase 1 interim results for chikungunya vaccine candidate, VLA1553[4]

David Lawrence, Valneva's Chief Financial Officer, commented, "We are very pleased with our excellent first-quarter financial results and the continued growth of our business. Sales growth of IXIARO® exceeded 15% at constant exchange rates. We are also extremely pleased that our two leading clinical programs are advancing and we are looking forward to key milestones within the next few months. We continue to execute on our growth strategy and remain confident in our ability to continue driving both profitable growth as well as value inflection via our key R&D programs."

Financial Information

(Q1 2019 unaudited results, consolidated per IFRS)

€ in million	**3 months ending March 31**	
	2019	**2018**
Product sales	32.8	28.9
Total revenues	34.9	32.1
Net profit	4.9	1.5
EBITDA	8.2	4.9
Cash	68.1	36.2

[1] CER% represents growth at constant exchange rates.
[2] Q1 2019 EBITDA was calculated by excluding €2.0 million of depreciation and amortization from the €6.2 million operating profit as recorded in the consolidated income statement under IFRS.
[3] Valneva press release: Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate
[4] Valneva press release: https://www.valneva.com/en/investors-media/news/2019#305

Saint Herblain (France), May 2, 2019 – Valneva SE ("Valneva" or "the Company"), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, reported today its first quarter financial results ending March 31, 2019. 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 2019 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/m6/p/5du5i8vm

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In the first quarter of 2019, revenues from IXIARO®/JESPECT® product sales reached €22.4 million, representing year-on-year growth of 17% (CER). The increase was largely driven by demand in North America, both in the public and private markets. During the first quarter of 2019, Valneva announced the signing of a new $59 million contract with the U.S. government Department of Defense (DoD) to supply IXIARO® doses in 2019 and 2020. The DoD also has an option to purchase a further $11million of IXIARO®.

This contract award and further penetration of the U.S. private market will continue to drive growth in 2019. Valneva projects that revenues from IXIARO®/JESPECT® sales will grow at a minimum of 15% (CER) in 2019.

CHOLERA / ETEC[5]-DIARRHEA VACCINE (DUKORAL®)

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

Valneva expects DUKORAL® revenues to grow by up to 5% (CER) in 2019, through continued market penetration in key markets.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Enrolment for Phase 2 run-in phase completed

Valneva's vaccine candidate, VLA15, is currently in Phase 2 clinical development[6]. The overall objective of the Phase 2 study is to determine the final dose and schedule for use in Phase 3.

In the first quarter of 2019, Valneva reported final Phase 1 data and initial booster data. Overall, the final data confirmed conclusions from the interim data, and the booster evaluations showed a very significant increase in immunogenicity.

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[5] 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.

[6] Valneva press release: https://www.valneva.com/en/investors-media/news/2018#303

As circulating antibody levels are important for OspA-based vaccines, higher dosages are being tested in Phase 2, aiming to induce an earlier, higher and more durable immune response.

The ongoing Phase 2 study (VLA15-201) involves 120 subjects and testing of three dosage levels of VLA15, or placebo. Enrolment of subjects for the run-in phase has been completed. Based upon a final review of the run-in safety data by a Data Safety Monitoring Board (DSMB), the two highest safe doses will be taken further into the main study phase. This dose decision is expected in the second quarter of 2019.

In the main study phase, 450 subjects will receive one of two dose levels of VLA15 (180 subjects each) or placebo (90 subjects).
The DSMB recommendation will also trigger the start of an additional Phase 2 study (VLA15-202) assessing an alternative schedule (0-2-6 months compared to 0-1-2 months). In this study, approximately 250 healthy volunteers, 18 to 65 years, will receive two selected dose levels, chosen after run-in phase, or placebo, on the alternative schedule.

The first interim Phase 2 results supporting further progression into Phase 3 are expected mid-2020.

Lyme disease is the most common vector-borne illness in the northern hemisphere for which there is no other clinical vaccine candidate in development worldwide. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 300,000[7] Americans are infected with Lyme disease annually with at least a further 200,000 cases in Europe[8].

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.

VLA15 has been awarded Fast Track Designation by the U.S. Food and Drug Administration (FDA)[9].

[7] As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article
[8] As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.
[9] Valneva press release: Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Positive initial Phase 1 results reported

Valneva reported positive Phase 1 interim results for, VLA1553, its chikungunya vaccine candidate[10], in the first quarter of 2019.

The interim results showed an excellent immunogenicity profile after a single vaccination with a 100% seroconversion rate[11] achieved at Day 28 in a pooled analysis[12] of all vaccinated groups. Results also showed that 96.5% of subjects achieved at least a 16-fold increase in antibody titres and a high geometric mean titre, fully supporting VLA1553's differentiated target product profile.

The pooled safety profile of all groups was considered acceptable, supporting further development. No serious adverse events nor adverse events of special interest were reported up to Day 28 and the local tolerability was considered excellent.

Valneva is committed to advance its chikungunya vaccine candidate as quickly as possible into pivotal trials, after dialogue and alignment with the authorities. The Company expects unblinded safety and immunogenicity data at dose group level by mid-2019, which will include additional information on whether subjects are protected from chikungunya viremia. This may allow Valneva to determine a future development pathway to licensure.

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[13] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[14]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically. 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 aiming for protection against various chikungunya virus outbreak phylogroups and strains designed for long-lasting protection conferred by neutralizing antibodies in adults and children[15]. The target populations for vaccines against chikungunya are travelers, military personnel or individuals at risk who live in endemic regions.

VLA1553 has been awarded Fast Track Designation by the FDA[16].

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[10] Valneva press release: https://www.valneva.com/en/investors-media/news/2019#305
[11] SCR was defined as the proportion of subjects achieving a CHIKV specific neutralizing antibody titre of NT50≥20
[12] Since the Phase 1 study continues blinded with re-vaccinations to potentially obtain a first indication of efficacy, the interim results were not analyzed by dose group but through a pooled analysis of all dose groups.
[13] PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)
[14] Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015
[15] Hallengärd et al. 2013 J. Virology 88: 2858-2866
[16] Valneva press release: Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate

ZIKA VACCINE CANDIDATE – VLA1601
Final Phase 1 results confirming positive interim data

Valneva has concluded Phase 1 for its vaccine candidate against the Zika virus, VLA1601. The final results overall confirm the interim Phase 1 data reported by Valneva and its partner, Emergent Biosolutions, at the end of 2018[17].

The highly purified inactivated vaccine candidate, VLA1601, met the study's (VLA1601-101) primary endpoint as it showed an excellent safety profile in all tested doses and schedules during the entire study. The safety profile of all tested doses and schedules is comparable to IXIARO® and other clinical stage ZIKV vaccines.

VLA1601 was immunogenic in all tested doses and schedules. The immune response was dose- and schedule-dependent with kinetics expected for an inactivated, alum-adjuvanted whole-virus vaccine. Seroconversion rates (SCRs) of up to 85.7% were reached for the highest dose level tested. Antibodies declined during six-month follow-up, as expected for this vaccine class, with SCRs remaining up to 40%.

Further development considerations will include measures to optimize the primary immune response.

Emergent BioSolutions has an option for an exclusive worldwide license for Valneva's Zika vaccine technology. A decision of the parties on any further development step is expected later in the year.

Zika virus infection is a mosquito-borne viral disease caused by the Zika virus (ZIKV), a flavivirus transmitted by *Aedes* mosquitoes[18]. Disease outbreaks have been reported in tropical Africa, South-East Asia, the Pacific Islands, and, since 2015, in the Americas. According to the World Health Organization (WHO), there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome[19]. Between 2015 and January 2018, over 500,000 cases of suspected Zika infection and many cases of the congenital syndrome associated with the ZIKV were reported by countries and territories in the Americas, according to the WHO[20]. There is currently no specific treatment available.

VLA1601 is a highly purified inactivated whole virus vaccine candidate developed using Valneva's proven and licensed inactivated Japanese encephalitis (JE) vaccine platform.

[17] *Valneva press release: https://www.valneva.com/en/investors-media/news/2018#300*
[18] *https://www.cdc.gov/zika/transmission/index.html*
[19] *http://www.who.int/mediacentre/factsheets/zika/en/*
[20] *http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en*

First Quarter 2019 Financial Review
(Unaudited, consolidated under IFRS)

Revenues
Valneva's total revenues (on an AER basis) in the first quarter of 2019 were €34.9 million compared to €32.1 million in the first quarter of 2018.
Product sales revenues (on an AER basis) in the first quarter of 2019 increased to €32.8 million from €28.9 million in the first quarter of 2018, representing year over year growth of 13.4%.
Revenues from collaborations and licensing amounted to €2.1 million in the first quarter of 2019 compared to €3.2 million in the comparator period of 2018.

Operating result and EBITDA
Costs of goods and services sold (COGS) were €12.2 million in the first quarter of 2019, representing an overall gross margin of 64.9% compared to 59.4% in the first quarter of 2018. €6.9 million of COGS related to IXIARO®/JESPECT® sales, yielding a product gross margin of 69.2%. €3.6 million of COGS related to DUKORAL® sales, yielding a product gross margin of 62.7%. Of the remaining COGS in the first quarter of 2019, €0.6 million related to the Third Party Product distribution business and €1.1 million were related to cost of services. In the first quarter of 2018, overall COGS were €13.0 million, of which €11.8 million related to cost of goods and €1.3 million related to cost of services.
Research and development expenses in the first quarter of 2019 increased to €6.3 million from €5.8 million in the comparator period of 2018. This was driven by planned increased investments into Valneva's clinical stage vaccine candidates. Marketing and distribution expenses in the first quarter of 2019 amounted to €5.6 million, compared to €6.0 million in the first quarter of 2018. In the first quarter of 2019, general and administrative expenses amounted to €4.5 million compared to €4.0 million in the same period of 2018. Amortization and impairment charges in the first quarter of 2019 amounted to €0.7 million compared to €0.8 million in the first quarter of 2018.
As a result of sales growth and improved margins, Valneva realized an operating profit of €6.2 million in the first quarter of 2019 compared to an operating profit of €3.2 million in the comparator period of 2018. EBITDA in the first quarter of 2019 was €8.2 million, compared to an EBITDA of €4.9 million in the first quarter of 2018.

Net result
In the first quarter of 2019, Valneva generated a net profit amounting to €4.9 million compared to a net profit of €1.5 million in the first quarter of 2018.
Finance costs and currency effects in the first quarter of 2019 resulted in a net finance income of €0.5 million, compared to a net finance expense of €1.3 million in the first quarter of 2018. The improved net finance result compared to the first quarter of the prior year was partly the result of foreign currency gains incurred during the first quarter of 2019, as well as lower interest expenses following the re-payment of the Biopharma (Pharmakon) loan in early January 2019.

Cash flow and liquidity

Net cash generated by operating activities in the first quarter of 2019 amounted to €5.3 million compared to €4.5 million in the first quarter of 2018.

Cash outflows from investing activities in the first quarter of 2019 amounted to €0.8 million, compared to €0.6 million in the first quarter of 2018, and resulted primarily from the purchase of equipment (€0.8 million).

Cash outflows from financing activities amounted to €13.5 million in the first quarter of 2019 and consisted of €9.7 million repayments of the Biopharma (Pharmakon) loan, €2.5 million of fees related to the private placement of new shares in October 2018 as well as payments of lease liabilities and interest. Cash outflows from financing activities amounted to €3.8 million in the first quarter of 2018.

Liquid funds on March 31, 2019 stood at €68.1 million compared to €81.7 million on December 31, 2018.

IFRS16 - Lease Accounting

As of January 1, 2019, Valneva adopted the new standard IFRS16 – Leases using the modified retrospective approach. This means that the comparative figures have not been restated. The balance sheet as of March 31, 2019 included €50.3 million of 'right of use assets', of which €25.4 million were related to a re-classification of a finance lease agreement for a building in Vienna, which was previously included in 'property, plant and equipment'. €23.3 million related to a long-term lease contract on the Solna manufacturing site was recognized as of January 1, 2019, in accordance with the new lease standard. Non-current and current liabilities were adjusted accordingly and include €2.2 million of current finance lease liabilities and €57.9 million related to non-current finance lease liabilities.

About Valneva SE

Valneva is a biotech company developing and commercializing vaccines for infectious 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 a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the U.S. with approximately 480 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.