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Valneva Reports H1 2019 Results Marked by Strong Operational Performance and Major Corporate Progress

Valneva regains control of key R&D assets, Strengthens financial outlook with $23 million CEPI chikungunya grant

Strong product sales and financial performance in H1 2019

- Product sales revenue of €61.6 million in H1 2019, representing year on year growth of 15% at AER / 12% at CER[1]
  - Significant growth in IXIARO® revenues to €45.1 million (20% at AER / 15% at CER) in H1 2019
  - Growth in DUKORAL® revenues (7% at AER and CER) in H1 2019
- Total revenues of €54.5 million in H1 2019
  - €65.2 million excluding the effect of the termination of the GlaxoSmithKline (GSK)[2] Strategic Alliance Agreement (SAA)
- Gross Margin (on Product sales revenue) of 66.1% in H1 2019 (compared to 60.0% in H1 2018)
- Positive EBITDA of €2.4 million in H1 2019
  - €13.1 million excluding the effect of the GSK SAA termination
- Net loss of €2.4 million in H1 2019
  - Net profit of €8.3 million excluding the effect of the GSK SAA termination
- Strong cash position of €69.9 million at the end of June 2019
  - Excludes €9 million GSK SAA termination settlement and European Investment Bank (EIB) drawdown of further €10 million

Key R&D milestones reported in H1 2019

- Final Phase 1 data and first booster data for Lyme disease vaccine candidate, VLA15[3]
- Successful outcome of Lyme Phase 2 Run-in[4] and initiation of second Phase 2 study VLA15-202[5]
- Further Phase 1 results for single-shot chikungunya vaccine candidate, VLA1553[6]
- Up to $23.4 million awarded by the Coalition for Epidemic Preparedness Innovations (CEPI) in July for the late-stage development of VLA1553[7]

David Lawrence, Valneva's Chief Financial Officer, commented, "The first half of the year has once again been marked by excellent operational performance. We have delivered strong product sales growth and are on track to meet our FY guidance of 15%-20% CER growth. Margins continue to improve and we continue to advance our two leading clinical programs against Lyme disease and the chikungunya virus. We recently regained full control of these assets through the

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[1] *CER % represents growth at constant exchange rates.*
[2] *Valneva PR: Valneva Announces Mutual Agreement with GSK to End Strategic Alliance Agreement; Regains Control of R&D*
[3] *Valneva PR: Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate*
[4] *Valneva PR: Valneva Reports Successful Outcome of Phase 2 Run-In for its Lyme Disease Vaccine Candidate*
[5] *Valneva PR: Valneva Initiates Second Phase 2 Study for its Lyme Disease Vaccine Candidate VLA15*
[6] *Valneva PR: Valneva Reports Further Positive Results for Its Chikungunya Vaccine Candidate*
[7] *Valneva PR: CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*

termination of the GSK agreement and are now well positioned to capture their full economic potential. Q3 is off to a great start with the recent $23 million chikungunya award from CEPI."

Financial Information

(unaudited, consolidated per IFRS)

€million	6 months ending June 30	
	2019	2018
Product sales	61.6	53.5
Total revenues	54.5	59.0
Net profit/(loss)	(2.4)	(0.2)
EBITDA	2.4	5.8
Cash	69.9	37.7

Saint Herblain (France), August 1, 2019 – Valneva SE ("Valneva" or "the Company"), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, reported today its consolidated financial results for the first half of the year, ended June 30, 2019. 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 2019 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/s4vksxwf

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In the first half of 2019, revenues from IXIARO®/JESPECT® product sales reached €45.1 million, compared to €37.6 million in the first half of 2018. The 20% increase at AER (15% at CER) was largely driven by demand in North America, both in the public and private markets. During the first half of 2019, Valneva announced the signing of a new $59 million contract with the U.S. Department of Defense (DoD) to supply IXIARO® doses in 2019 and 2020[8]. The DoD also has an option to purchase a further $11 million of IXIARO®.

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

[8] *Valneva Press Release: Valneva Announces New $59 Million IXIARO® Supply Contract with US Government*

CHOLERA / ETEC[9]-DIARRHEA VACCINE (DUKORAL®)

In the first half of 2019, revenues from DUKORAL® sales reached €15.2 million, compared to €14.2 million in the first half of 2018. The 7% increase (both at AER and CER) was largely driven by a solid sales performance in Canada in the first half of 2019.

Based on first half sales, Valneva reaffirms that it expects revenues from DUKORAL® sales to grow by up to 5% (at CER) in 2019, through continued market penetration in key markets.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Ongoing Phase 2 studies

As part of the Phase 2 studies, two higher, alum-adjuvanted formulations (135µg and 180µg) have been selected for further development[10]. In the first Phase 2 study, VLA15-201, the vaccine is administered intramuscularly at Day 1, Month 1 and Month 2 while in the second Phase 2 study, VLA15-202, an alternative immunization schedule is being tested with injections at Day 1, Month 2 and Month 6.

Subjects will be followed up to 18 months, with the main immunogenicity readout for both studies one month after completion of the primary immunization with three vaccinations (primary endpoint). The overall Phase 2 objectives for VLA15 are to determine the optimal dosage level and vaccination schedule for use in Phase 3 pivotal field efficacy studies, based on immunogenicity and safety data.

Phase 2 is expected to include 820 subjects and last approximately two years with initial data (primary endpoint) expected mid-2020.

Lyme disease is the most common vector-borne illness in the northern hemisphere with a rapidly growing disease footprint. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 300,000[11] Americans are infected with Lyme disease annually with at least a further 200,000 cases in Europe[12].

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 Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[13].

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[9] 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.
[10] Valneva press release: Valneva Initiates Second Phase 2 Study for its Lyme Disease Vaccine Candidate VLA15
[11] As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article
[12] As estimated from available national data. Case reporting is highly inconsistent in Europe and many LD infections still go undiagnosed.
[13] Valneva press release: Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Further Phase 1 results reported

At the end of May 2019, Valneva announced further positive Phase 1 results for its chikungunya vaccine candidate[14].

VLA1553 was generally safe in all dose groups. The low and medium dose groups were well tolerated and showed a superior safety profile, including viremia, compared to the high dose. No adverse events of special interest (e.g. chikungunya infection related) were reported up to Month 7 and the product candidate's local tolerability profile was excellent.

The results showed an excellent immunogenicity profile in all vaccinated dose groups after a single vaccination, with a 100% seroconversion achieved at Day 14 after a single vaccination in all dose groups and fully sustained at 100% at Month 6.

A subset of study subjects were re-vaccinated after six months. For those subjects, no anamnestic response was observed which demonstrates that a single vaccination of VLA1553 is sufficient to induce sustaining, high titer, neutralizing antibodies. Vaccines were protected from vaccine induced viremia serving as "intrinsic human viral challenge".

Valneva is committed to advancing its chikungunya vaccine candidate as quickly as possible and expects to be in a position to announce an accelerated development plan to licensure in the third quarter of 2019.

On July 25, Valneva was awarded non-dilutive financial support of up to $23.4 million by CEPI for the manufacturing and late-stage clinical development of its single-dose, live-attenuated vaccine against chikungunya[15]. The funding underwrites a partnership effort to accelerate regulatory approval of VLA1553 for use in regions where outbreaks occur and support World Health Organization (WHO) prequalification to facilitate broader access in lower and middle-income countries.

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[16] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[17]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically. With no preventive vaccines or effective treatments available, chikungunya is considered a major public health threat.

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[18].

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[14] *Valneva press release: Valneva Reports Further Positive Results for Its Chikungunya Vaccine Candidate*
[15] *Valneva PR: CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[16] *PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[17] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*
[18] *Valneva PR: Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate*

ZIKA VACCINE CANDIDATE – VLA1601
Phase 1 concluded

Valneva has concluded Phase 1 for its vaccine candidate against the Zika virus, VLA1601[19]. The final results confirmed the interim Phase 1 data reported by Valneva and Emergent Biosolutions at the end of 2018.

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 as 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 is a mosquito-borne viral disease caused by the Zika virus (ZIKV), a flavivirus transmitted by *Aedes* mosquitoes[20]. Disease outbreaks have been reported in tropical Africa, Southeast Asia, the Pacific Islands, and, since 2015, in the Americas. According to the WHO, there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome[21]. Between 2015 and beginning of 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. There is currently no specific treatment available.

Valneva has developed a highly purified inactivated whole virus vaccine candidate, VLA1601, using its proven and licensed inactivated JE vaccine platform.

Other Business updates

Termination of the GSK Strategic Alliance Agreement[22]
At the end of June 2019, Valneva announced a mutual agreement with GSK to end the Strategic Alliance Agreement ("SAA"), originally agreed between Novartis and Intercell (predecessor companies of GSK and Valneva, respectively). The previously announced settlement arrangements result in €10.7 million of negative revenue impact to the Company (based on the

[19] *Valneva PR: Valneva Reports Strong Q1 2019 Operating Results and Advances Key R&D Programs towards Major Milestones*
[20] *https://www.cdc.gov/zika/transmission/index.html*
[21] *http://www.who.int/mediacentre/factsheets/zika/en/*
[22] *Valneva PR: Valneva Announces Mutual Agreement with GSK to End Strategic Alliance Agreement; Regains Control of R&D*

€9 million payment and €6 million recognition of marketing authorization-related milestones (excluding the financing component), offset by the release of €4.3 million of SAA-related contract liability). Product sales revenue is unaffected. As a result, Valneva has regained full control of its main R&D assets including its Lyme disease vaccine candidate, VLA15.

Drawdown of a further €10 million from the European Investment Bank facility[23]
In July 2019, Valneva drew down a further €10 million of the remaining European Investment Bank ("EIB") facility that was granted to the Company in July 2016. Valneva will therefore have drawn down a total of €20 million[24] of the €25 million facility. The Company plans to use the funds to advance its R&D programs, including its Lyme disease candidate. Under the terms of the agreement signed with the EIB, each credit tranche is repayable at the end of a five-year period commencing from the drawdown date.

Competition for DUKORAL® expected in the course of 2020
The Company expects to face competition for DUKORAL® in the course of 2020. Valneva assumes, however, that the overall product sales implications will be limited especially since DUKORAL® is a very successfully established brand and its indications are broader in Canada, the largest market for this product.

Submission of delisting application to the Vienna Stock Exchange[25]
At the beginning of July, Valneva submitted a request to the Vienna Stock Exchange (VSE) to delist its ordinary shares from VSE's Official Market (Amtlicher Handel). The application was submitted after Valneva's shareholders approved the delisting at the Company's annual general meeting on June 27, 2019. The delisting from the VSE shall be effective by the end of 2019. The decision to delist from the VSE was made by the Company in order to focus on the best capital markets for life science companies and increase liquidity by centralizing trading on Euronext Paris. The listing on Euronext Paris remains unchanged.

Half Year 2019 Financial Review
(Unaudited, consolidated under IFRS)

Revenues
Valneva's total revenues for the first half of 2019 include an effect relating to the GSK SAA termination in June 2019. A negative effect of net €10.7 million was included in Valneva's revenues from collaboration and licensing reflecting both the current and future payment obligations related to the termination of the SAA.

Valneva's total revenues (on an AER basis) in the first half of 2019 were €54.5 million (€65.2 million excluding the GSK SAA termination effect) compared to €59.0 million in the first half of 2018.

[23] *Valneva PR: Valneva Announces Drawdown of Further €10 million from its Existing European Investment Bank Loan*
[24] *Two tranches of €5 million each have been drawn down in April and December 2017 respectively.*
[25] *Valneva PR: Valneva Submits Delisting Application to the Vienna Stock Exchange*

Product sales revenues (on an AER basis) in the first half of 2019 increased to €61.6 million from €53.5 million in the first half of 2018, representing year over year growth of 15.1%.
Revenues from collaborations and licensing amounted to negative €7.1 million (positive €3.6 million excluding the SAA termination effect) in the first half of 2019 compared to €5.4 million in the comparator period of 2018.

Operating result and EBITDA
Costs of goods and services sold (COGS) were €23.1 million in the first half of 2019. Gross margin on product sales amounted to 66.1% compared to 60.0% in the first half of 2018. €13.4 million of COGS related to IXIARO®/JESPECT® sales, yielding a product gross margin of 70.2%. €6.4 million of COGS related to DUKORAL® sales, yielding a product gross margin of 57.6%. Of the remaining COGS in the first half of 2019, €1.0 million related to the Third Party Product distribution business and €2.2 million were related to cost of services. In the first half of 2018, overall COGS were €24.0 million, of which €21.4 million related to cost of goods and €2.6 million related to cost of services.

Research and development expenses in the first half of 2019 increased to €14.1 million from €12.9 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 half of 2019 amounted to €11.8 million, compared to €10.9 million in the first half of 2018. In the first half of 2019, general and administrative expenses remained on the same level as in the comparator period of 2018 and amounted to €8.8 million. Amortization and impairment charges in the first half of 2019 amounted to €1.4 million compared to €1.6 million in the first half of 2018. Valneva realized an operating loss of €1.7 million (operating profit of €9.0 million excluding the GSK SAA termination effect) in the first half of 2019 compared to an operating profit of €2.3 million in the comparator period of 2018. EBITDA in the first half of 2019 was €2.4 million (€13.1 million excluding the GSK SAA termination effect), compared to an EBITDA of €5.8 million in the first half of 2018.

Net result
In the first half of 2019, Valneva generated a net loss amounting to €2.4 million (net profit of €8.3 million excluding the GSK SAA termination effect) compared to a net loss of €0.2 million in the first half of 2018.

Finance costs and currency effects in the first half of 2019 resulted in a net finance expense of €0.5 million, compared to a net finance expense of €2.0 million in the first half of 2018. The improved net finance result compared to the first half of the prior year was partly the result of foreign currency gains incurred during the first half of 2019, as well as lower interest expenses following the re-payment of the Biopharma (Pharmakon) loan in early January 2019.
Results from investments in associates comprise a €0.7 million profit from Valneva's 48.9% shareholding in BliNK Biomedical SAS.

Cash flow and liquidity
Net cash generated by operating activities in the first half of 2019 amounted to €13.3 million compared to €13.7 million in the first half of 2018.

Cash outflows from investing activities in the first half of 2019 amounted to €3.8 million, compared to €1.1 million in the first half of 2018, and resulted primarily from the purchase of equipment. Cash outflows from financing activities amounted to €16.6 million in the first half 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 €10.6 million in the first half of 2018.

Liquid funds on June 30, 2019 stood at €69.9 million compared to €81.7 million on December 31, 2018.

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 clinical 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.