

## Valneva Delivers Strong IXIARO® Sales Growth and Reports Further Progress on Key R&D Programs in H1

### Double-digit sales growth driven by IXIARO®

- Product sales of €53.5 million in H1 2018, representing 11.4% year on year growth (19% at CER<sup>1</sup>), in line with Company guidance of double-digit product sales growth in FY 2018.
  - Strong IXIARO® sales revenue growth of over 19% driven by the US private market
  - Total revenues were €59.0 million in H1 2018 (vs. €53.9 million in H1 2017)<sup>2</sup>.
- EBITDA of €5.8 million in H1 2018, in line with Company 2018 guidance of €5.0 million to €10.0 million.
- Increased R&D investment of €12.9 million from €9.7 million in H1 2017, as planned.
- Positive operating cash flow of €13.7 million in H1 2018 resulting in cash position of €37.7 million at the end of June 2018.
  - Position includes ongoing debt repayments and no further debt drawdown in H1

### H1 Pipeline Highlights

- Phase 2 preparation activities ongoing for the Company's Lyme vaccine candidate expected to enter Phase 2 at the end of 2018<sup>3</sup>.
- Recruitment completed for the Phase 1 study of the Company's Chikungunya vaccine candidate. Results expected early 2019.
- Recruitment completed for the Phase 1 study of the Company's Zika vaccine candidate. Results expected at the end of 2018 or early 2019.

**David Lawrence, Valneva's Chief Financial Officer**, commented, "We're extremely pleased with our half-year performance as we continued to deliver double-digit sales growth and are on track to meet our full-year guidance. The strong growth in IXIARO® sales validates our strategy to take direct control of the US private market. We also continue to advance our clinical candidates and are very much looking forward to the Phase 2 initiation of our Lyme vaccine candidate."

<sup>1</sup> CER and AER growth: In order to illustrate underlying performance, Valneva has decided to include information on its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Euros had remained unchanged from those used in the comparative period. CER% represents growth at constant exchange rates. AER% represents growth at actual exchange rates.

<sup>2</sup> For greater clarity, reporting of grants has been re-classified and included in the company's Other Income / Expense line as of 2018. The comparator period of 2017 was adjusted accordingly.

<sup>3</sup> Subject to regulatory clearances

## Key Financial Information

(Unaudited)

€ in million	6 months ending June 30	
	2018	2017
Product Sales	53.5	48.1
Total Revenues	59.0	53.9 <sup>4</sup>
Net profit/(loss)	(0.2)	(4.4)
EBITDA <sup>5</sup>	5.8	7.6
Cash, short-term deposits and marketable securities, end of period	37.7	47.3

**Saint Herblain (France), August 2, 2018** – Valneva SE (“Valneva” or “the Company”), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, reported today its consolidated financial results for the first half ended June 30, 2018. 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](http://www.valneva.com).

A webcast for the financial community and media will be held today at 2:00 pm (CET). A replay will be available on the Company’s website. Please refer to this link: <https://edge.media-server.com/m6/p/4p7bcso7>

## Commercial Vaccines

### JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

#### Strong sales growth driven by the US private market

In the first half of 2018, revenues from IXIARO®/JESPECT® product sales reached €37.6 million, compared to €31.5 million in the first half of 2017. The increase was largely driven by growth in the US, including in the private market where Valneva took direct control of sales and marketing at the end of November 2017. There were also increases in the Nordic and Canadian private markets. In March 2018, Health Canada approved an accelerated IXIARO® vaccination schedule for adult travelers (18-65 years old).

Based on first half sales, Valneva reaffirms double-digit growth expectations for IXIARO®/JESPECT® sales in 2018.

<sup>4</sup> 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.

<sup>5</sup> EBITDA (Earnings before interest, taxes, depreciation and amortization) was calculated by excluding depreciation, amortization and impairment of tangible and intangible assets (H1 2018: €3.5m, H1 2017: €5.7m) from operating profit (H1 2018: €2.3m, H1 2017: €1.8m).

## **CHOLERA / ETEC-DIARRHEA VACCINE (DUKORAL®)**

In the first half of 2018, revenues from DUKORAL® sales reached €14.2 million, compared to €15.4 million in the first half of 2017. Strong sales performance in Canada in the first half of 2018 was eroded by a combination of adverse exchange rate movements (mainly between the Canadian dollar and the Euro) and supply constraints. Valneva is executing a plan to address further supply constraints and aims for increased DUKORAL® sales in the second half of 2018.

## **Clinical Vaccine Candidates**

### **LYME DISEASE VACCINE CANDIDATE – VLA15 Progression into Phase 2 at end 2018**

Valneva reported positive Phase 1 interim data in March<sup>6</sup> 2018. Following these interim data, the Company amended the Phase 1 protocol to include a booster evaluation at one year post initial vaccination, in approximately 60 trial subjects. This booster evaluation is expected to accelerate the availability of safety and immunogenicity data on general booster responses for VLA15. Results are expected in the first half of 2019.

In July 2018, Valneva successfully concluded the end of Phase 1 process with the US Food and Drug Administration (FDA)<sup>7</sup>, reaching alignment with the FDA on the strategy for Phase 2 development. Valneva is now finalizing details for Phase 2 and, subject to regulatory clearances, will enter Phase 2 clinical development at the end of 2018.

The primary endpoint of the Phase 2 will be the evaluation of immunogenicity, with the objective of determining the final dose and schedule. The Phase 2 will evaluate further dosages and schedules in addition to those evaluated in Phase 1.

It is expected that the Phase 2 will be conducted in approximately 800 subjects, aged 18-70 years, at more than 10 study sites in the U.S. and Europe, including endemic areas within the US and in the EU, as well as some Lyme seropositive subjects. Phase 2 duration is expected to be approximately two years.

Pending a positive outcome in Phase 2, the company's preliminary plans for Phase 3 development are that product licensure would be supported by a pivotal, double-blind, placebo controlled field efficacy study in Lyme Disease endemic areas in the U.S. and Europe, enrolling approximately 16,000 subjects.

Assuming that the data generated during a single tick season are sufficient to support licensing, a first filing for licensure with regulators could be achieved in the second half of 2023.

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 US

<sup>6</sup>[http://www.valneva.com/download.php?dir=News\\_2018&file=2018\\_03\\_19\\_VLA15\\_Phase\\_I\\_Results\\_PR\\_ENG.pdf](http://www.valneva.com/download.php?dir=News_2018&file=2018_03_19_VLA15_Phase_I_Results_PR_ENG.pdf)

<sup>7</sup> Press Release, July 2, 2018: "Valneva Announces Significant Progress of its Lyme Disease Vaccine Candidate"  
<http://www.valneva.com/en/investors-media/news/2018#290>

Centers for Disease Control and Prevention (CDC), approximately 300,000<sup>8</sup> Americans are infected with Lyme disease annually with at least a further 200,000 cases in Europe<sup>9</sup>.

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.

The global market for a vaccine for Lyme disease is currently estimated at approximately €700 - €800 million annually<sup>10</sup>.

### **CHIKUNGUNYA VACCINE CANDIDATE – VLA1553** **Phase 1 study fully enrolled**

Enrollment is now complete in a Phase 1 trial of VLA1553 initiated in March 2018<sup>11</sup> in the U.S., and Valneva is expecting to announce initial data in early 2019.

The Phase 1 clinical trial is a randomized, observer-blinded, dose-escalation, multi-center study. It is investigating three different dose levels of VLA1553 in approximately 120 healthy adults vaccinated with a single-shot immunization. The trial design also includes measurements of antibody persistence and will evaluate an additional vaccination using the highest dose of VLA1553 at 6 and 12 months. This re-vaccination will serve as an intrinsic human viral challenge, with the goal of demonstrating that subjects are protected from vaccine-induced viremia, thereby indicating potential 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. As of December 2017, there have been more than 1 million reported cases in the Americas<sup>12</sup> and the economic impact is considered significant (e.g. Columbia outbreak 2014: \$73.6 million)<sup>13</sup>. 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 for protection against various Chikungunya virus outbreak phylogroups and strains designed for long-lasting protection conferred by neutralizing antibodies in adults and children<sup>14</sup>. In pre-clinical development, a single-vaccine shot was highly immunogenic, eliciting a strong, long lasting

<sup>8</sup> As estimated by the CDC [https://wwwnc.cdc.gov/eid/article/21/9/15-0417\\_article](https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article)

<sup>9</sup> As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.

<sup>10</sup> Company estimate supported by independent market studies

<sup>11</sup> Press Release, March 13, 2018: "Valneva Initiates Phase 1 Clinical Study to Evaluate its Single-Shot Vaccine Candidate against Chikungunya" <http://www.valneva.com/en/investors-media/news/2018#281>

<sup>12</sup> PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)

<sup>13</sup> Cardona-Ospina et al., *Trans R Soc Trop Med Hyg* 2015

<sup>14</sup> Hallengård et al. 2013 *J. Virology* 88: 2858-2866

neutralizing antibody response. Vaccinated non-human primates (NHP) (cynomolgus macaques) showed no signs of viremia after challenge<sup>15</sup>.

The target populations for vaccines against Chikungunya are travelers, military personnel or individuals at risk who live in endemic regions. The global market is estimated to be worth up to €500 million annually<sup>10</sup>.

## **ZIKA VACCINE CANDIDATE – VLA1601**

### **Phase 1 study fully enrolled, Partnered with Emergent BioSolutions**

After initiating a Phase 1 study in the US in February 2018<sup>16</sup>, Valneva has completed enrollment of study participants, 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.

Initial data from the Phase 1 trial are expected to be available in late 2018 or early 2019.

Zika Virus infection is a mosquito-borne viral disease caused by the Zika Virus (ZIKV), a flavivirus transmitted by *Aedes* mosquitoes<sup>17</sup>. 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 (WHO), there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome<sup>18</sup>. 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<sup>19</sup>. 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 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<sup>®</sup>.

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<sup>15</sup> Roques et al. 2017JCI Insight 2 (6): e83527

<sup>16</sup> [http://www.valneva.com/download.php?dir=News\\_2018&file=2018\\_02\\_26\\_Phase\\_1\\_Initiation\\_VLA1601\\_EN.pdf](http://www.valneva.com/download.php?dir=News_2018&file=2018_02_26_Phase_1_Initiation_VLA1601_EN.pdf)

<sup>17</sup> <https://www.cdc.gov/zika/transmission/index.html>

<sup>18</sup> <http://www.who.int/mediacentre/factsheets/zika/en/>

<sup>19</sup> [http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=12390&Itemid=42090&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en)

## Half Year 2018 Financial Review

(Unaudited)

### Revenues

Valneva's aggregate revenues in the first half of 2018 were €59.0 million compared to €53.9 million in the first half of 2017.

Product sales in the first half of 2018 increased by 11.4% to €53.5 million from €48.1 million in the same period of the previous year.

Revenues from collaborations and licensing amounted to €5.4 million in the first half of 2018 compared to €5.8 million in the first half of 2017. Reporting of grants has been re-classified and included in the Company's Other Income / Expense line as of January 2018. The comparator period of 2017 was adjusted accordingly.

### Operating result and EBITDA

Cost of goods and services sold (COGS) were €24.0 million in the first half of 2018, representing an overall gross margin of 59.3% compared to 54.6% for the same period in 2017. €13.8 million of COGS were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 63.4%. €6.5 million of COGS were related to DUKORAL® sales, yielding a product gross margin of 54.4%. Of the remaining COGS for the first half of 2018, €1.1 million were related to the Third Party product distribution business and €2.6 million were related to cost of services. In the comparative period of 2017, COGS were €24.4 million, of which €21.2 million were related to cost of goods and €3.2 million to cost of services.

Research and development expenses in the first half of 2018 increased to €12.9 million from €9.7 million in the first half of the previous year. This was driven by planned increased investments into Valneva's clinical stage vaccine candidates. Marketing and distribution expenses in the first half of 2018 amounted to €10.9 million, compared to €8.2 million in the first half of 2017. This increase was mainly a result of investment in the US Travel market combined with seasonally higher spending in other markets. In the first half of 2018, general and administrative expenses amounted to €8.8 million compared to €7.4 million in the comparator period of 2017. Amortization and impairment charges in the first half of 2018 amounted to €1.6 million compared to €3.6 million in the first half of 2017. The reduction resulted from re-assessment of the lifetime of IXIARO®/JESPECT® related intangible assets, driven by patent extensions in both Europe and the US (lifetime extended from 15 to 23.75 years).

In the first half of 2018, Valneva realized an operating profit of €2.3 million compared to an operating profit of €1.8 million in the first half of 2017. EBITDA in the first half 2018 was €5.8 million, compared to a positive EBITDA of €7.6 million in the first half of 2017. First half 2018 EBITDA was calculated by excluding €3.5 million of depreciation and amortization from the €2.3 million operating profit as recorded in the condensed consolidated income statement under IFRS.

### Net result

In the first half of 2018, Valneva's net loss was €0.2 million compared to a net loss of €4.4 million in the first half of the prior year.



Finance costs and currency effects for the first half of 2018 resulted in a net finance expense of €2.0 million, compared to a net finance expense of €5.1 million in the first half of 2017. The reduced net finance expense year over year was partly the result of lower interest expenses from continued loan re-payments and foreign currency related losses incurred during the first half of 2017.

### **Cash flow and liquidity**

Net cash generated by operating activities in the first half of 2018 amounted to €13.7 million compared to €16.6 million in the first half of 2017.

Cash outflows from investing activities in the first half of 2018 amounted to €1.1 million and resulted primarily from the purchase of equipment. Cash outflows from investing activities amounted to €2.6 million in the first half of 2017.

Cash outflows from financing activities amounted to €10.6 million in the first half of 2018 and were mainly related to re-payment of borrowings and interest payments. Cash outflows from financing activities amounted to €5.5 million in the first half of 2017.

Liquid funds on June 30, 2018 stood at €37.7 million compared to €38.1 million on December 31, 2017 and consisted of €34.6 million in cash and cash equivalents and €3.1 million in restricted cash.

### **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 various vaccines in development including a unique vaccine against Lyme disease. 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](http://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.