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# Valneva Reports Strong 2017 Revenues Driven by Double Digit Product Sales Growth

**Strong sales performance in 2017 (unaudited)**

- Total revenues of €109.8 million in 2017 (2016 - €97.9 million) representing year-on-year growth of 12%
- Product sales of €92.6 million in 2017 (2016 - €80.4 million) representing year-on-year growth of 15%, including
  - IXIARO®/JESPECT® sales of €60.0 million
  - DUKORAL® sales of €28.5 million
  - Third party distribution of €4.0 million
- Cash position of €38.1 million at the end of 2017
- 2017 audited results and financial statements to be released on March 22nd, 2018

**Lyme Phase I read-out on track**

- Valneva expects to announce Phase I top-line data for its Lyme disease vaccine candidate in the first quarter of 2018

**Additional business update**

- Two Phase I commencements imminent
  - Zika vaccine candidate VLA1601
  - Chikungunya vaccine candidate VLA1553
- Full year financial guidance and business update to be provided on March 22nd

**David Lawrence, Valneva's Chief Financial Officer**, commented, *"This revenue performance results from the successful execution of our strategy including the ongoing expansion of the Company's commercial capabilities. Our cash position also underlines a healthy balance sheet which has supported ongoing R&D investment and loan repayment."*

## Key Financial Information (Unaudited)

| **in million €** | **12 months ended December 31** | |
|---|---|---|
| | **2017 Unaudited** | **2016** |
| Product sales | 92.6 | 80.4 |
| Other revenues | 17.1 | 17.5 |
| **Total revenues** | **109.8** | **97.9** |
| **Cash, cash equivalents, and restricted cash, end of period** | **38.1** | **42.2** |

**Lyon (France), February 15, 2018** – Valneva SE ("Valneva" or "the Company"), a fully integrated, commercial stage biotech company focused on developing and commercializing innovative, life-saving vaccines, reported today its unaudited revenues and cash balance for the full year ended December 31, 2017. Audited full year financial results are scheduled to be released on March 22, 2018.

## Commercial Vaccines

### JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)
### Continued sales growth supported by market penetration

In 2017, IXIARO®/JESPECT® sales reached €60.0 million compared to €53.0 million in 2016, representing 13.3% year-on-year growth. The increase was mainly driven by growth in the UK, German and Canadian private markets where continued marketing and sales efforts increased product adoption by travelers. Sales to the US military also contributed to the growth and a new $39.6 million contract was signed with the US government in November 2017 to supply IXIARO® to the US Department of Defense, over a one-year period.
Valneva expects IXIARO®/JESPECT® revenues to continue to grow at a double-digit rate through continued market penetration and the development of its commercial network, including in the US private market where the Company took direct control of sales and marketing in late 2017.
Valneva has been recently granted a nine-year patent extension for the alum-adjuvant formulation of its Japanese encephalitis vaccine IXIARO® by the US Patent and Trademark Office (USPTO), extending the patent term in the US until 2032.

### CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL®)
### Double-digit sales growth in 2017

In 2017, DUKORAL® sales reached €28.5 million compared to €24.6 million in 2016, representing a 16.2% year-on-year growth. In addition to Canada, where more than 50% of DUKORAL® global revenues are generated, the vaccine benefited from strong sales in the UK market.
Valneva expects DUKORAL® revenues to continue to grow healthily in 2018 through continued market penetration.

## Clinical vaccine Candidates

### LYME DISEASE VACCINE CANDIDATE – VLA 15
### Phase I top-line data expected during first quarter of 2018

Valneva has focused its R&D expertise and resources on the development of a much-needed vaccine against Lyme disease, one of the fastest growing vector-borne infections for which there is no other clinical vaccine candidate in development worldwide.
After completing subject enrollment in the fourth quarter of 2017, the Company is currently conducting serological testing and aims to release top-line Phase I data in the first quarter of

2018. Valneva's Lyme vaccine candidate was granted FDA Fast Track designation in July 2017 with a view to potentially accelerate the availability of the vaccine on the market.
Lyme borreliosis (LB) is a systemic infection caused by *Borrelia* bacteria transmitted by infected ticks. According to the Centers for Disease Control and Prevention (CDC), approximately 400,000[1] Americans are diagnosed with Lyme disease each year with at least a further 200,000 cases in Europe[2].
Valneva's Phase I study was conducted at three sites – two in the U.S. and one in Europe (Belgium) – and enrolled approximately 180 subjects aged between 18 and 40 years. The primary objective of the observer-blind, partially randomized, dose escalation study was to evaluate the vaccine candidate's safety and tolerability profile at different dose levels and formulations. Immunogenicity, measured by observing IgG antibodies against the six most prevalent serotypes of Lyme borreliosis in the US and Europe present in the vaccine, was also monitored for different dose groups and formulations at different time-points.
The global market for a vaccine against Lyme disease is currently estimated at approximately €700 - €800 million annually[3].

**CHIKUNGUNYA VACCINE CANDIDATE – VLA 1553**
**Phase I initiation to commence in the first quarter of 2018 according to plan**

Valneva has developed a monovalent, live attenuated chikungunya vaccine candidate which is differentiated from other vaccines in development by the potential for single-shot protection.
Preclinical data including studies in non-human primates showed both a good safety profile and good immunogenicity after a single immunization. The Phase I study protocol was finalized at the end of 2017 and the Company plans to initiate Phase I in the US in the first quarter of 2018.
The chikungunya virus (CHIKV) is a *Togaviridae* virus that re-emerged in 2014. There were about 180,000 reported cases in the Americas in 2016[4] and it is now considered a major public health threat. The incidence and geographic spread of CHIKV is expected to grow as the distribution of its primary mosquito vectors continues to broaden.
With no effective treatment available for CHIKV infection, there is an important need for a vaccine and the global market is estimated at approximately €500 million annually[5].

**ZIKA VACCINE CANDIDATE – VLA 1601**
**Phase I initiation imminent, Partnered with Emergent BioSolutions**

In July 2017, Valneva and Emergent BioSolutions joined forces to accelerate the development of a vaccine against the Zika virus. After finalizing the Phase I study protocol at the end of 2017, the two companies are expected to initiate the Phase I in the US imminently and anticipate first Phase I data in late 2018 or early 2019.

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[1] *As estimated by the CDC based on US reported cases in 2015*
[2] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.*
[3] *Company estimate supported by independent market studies*
[4] *PAHA/WHO data: Number of reported cases of Chikungunya Fever in the Americas - EW 33 (August 19, 2016)*
[5] *Company estimate supported by independent market studies*

Upon availability of Phase I data, Emergent has an option to take the program over in exchange for an initial €5 million milestone payment, potential additional milestones of up to €44 million and future royalties on annual net sales.
The companies are expected to enter into a technology transfer agreement at a future date to enable transfer of Valneva's technology to Emergent's Bayview manufacturing facility in Baltimore, Maryland. Valneva retains a right of first negotiation for potential product commercialization in Europe.
The Zika virus is a flavivirus transmitted by *Aedes* mosquitos that causes no symptoms or a mild flu-like syndrome in infected persons. However, if women are infected during pregnancy, the virus is transmitted to the fetus and has been associated with the development of severe congenital abnormalities including microcephaly. Zika infection has also been linked with the risk of developing the autoimmune disorder Guillain-Barré syndrome. In 2015, a major Zika epidemic started in Brazil and spread to other parts of the Americas. Between 2015 and end of July 2017, 1 million cases of Zika infection and many cases of the congenital syndrome associated with Zika virus had been reported by countries and territories in the Americas, according to the World Health Organization[6].

**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 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.

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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

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

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.