

**VALNEVA SE**

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## Valneva Reports Strong Q4 and FY 2016 Business Performance; Expects Further Growth in Sales and EBITDA, R&D Progress in 2017

### The Company today announced its unaudited FY 2016 revenues and cash-balance, estimated EBITDA and 2017 outlook

- + Revenues and grants increased by 17.5% year-on-year and amounted to €97.9 million in 2016 (vs €83.3 million in 2015); Q4 2016 revenues and grants were €27.2 million (vs €22.7 million in Q4 2015) representing a 19.9% growth;
- + FY revenue growth driven mainly by a 73.1% increase in IXIARO<sup>®</sup>/JESPECT<sup>®</sup> revenues following the successful establishment and development of the Company's marketing & distribution network;
- + Valneva reported a positive estimated EBITDA of €2.8 million in 2016 (vs. an EBITDA loss of €8.5 million in 2015);
- + Cash position of €42.2 million at the end of 2016 further strengthened by equity financing proceeds of €7.5 million in Q4;
- + Final 2016 results and audited full financial statements to be released on March 23<sup>rd</sup>, 2017.

### 2017 Outlook

- + Valneva expects 2017 overall IFRS revenues to reach €105 to €115 million, reflecting up to 17% total revenue growth compared to 2016;
- + The Company anticipates product sales this year to grow by 10-15% over the €80.4 million reported in 2016, driven mainly by IXIARO<sup>®</sup>/JESPECT<sup>®</sup> and DUKORAL<sup>®</sup>;
- + After reaching operational profitability in 2016 with a positive EBITDA of €2.8 million for the full year, the Group expects to further grow its operational performance to an EBITDA of €5 to €10 million in 2017 while still investing approximately 20% of annual revenues in R&D.

### 2017 R&D catalysts

- + Valneva seeks to partner its Phase III-ready *Clostridium difficile* vaccine candidate in 2017 following the publication of positive final Phase II results in 2016;
- + In 2017 the Company expects to execute the Phase I trial of its Lyme vaccine candidate and to accelerate the program's progression towards Phase II;
- + Valneva also plans to advance at least one additional vaccine candidate into Phase I in the second half of 2017. The preclinical portfolio includes vaccine candidates against Chikungunya and Zika.

### Valneva's CFO resigns to pursue other interests

- + After 15 years with Valneva (Intercell), Chief Financial Officer, Reinhard Kandra, has decided to resign his position as Management Board member and CFO to pursue other interests. Mr. Kandra will leave at the end of March after the publication of the fully audited 2016 Financial Statements.
- + Valneva has initiated a process with Korn-Ferry to recruit a new CFO. In the interim, Manfred Tiefenbacher, VP Finance will manage operational Finance matters.

### Key financial information

in million €	3 months ended Dec 31,		12 months ended Dec 31,	
	2016 unaudited	2015	2016 Unaudited	2015
Product sales	23.8	17.4	80.4	61.5
Revenues from collaborations and licensing	2.2	3.6	13.6	16.8
Grant income	1.1	1.7	3.8	5.0
<b>Total revenues &amp; grants</b>	<b>27.2</b>	<b>22.7</b>	<b>97.9</b>	<b>83.3</b>
<b>EBITDA (2016 estimated)</b>	<b>(0.7)</b>	<b>(4.2)</b>	<b>2.8</b>	<b>(8.5)</b>
<b>Cash, short-term deposits and marketable securities, end of period</b>	<b>42.2</b>	<b>42.6</b>	<b>42.2</b>	<b>42.6</b>

**Lyon (France), February 23, 2017** – Valneva SE (“Valneva” or “the Company”), a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines, published today its unaudited revenues and cash balance, and estimated EBITDA for the fourth quarter and the full year ended December 31, 2016. Audited full year financial results are scheduled to be released on March 23, 2017.

### Business highlights

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

##### Significant sales growth following establishment of new commercial network

In 2016, IXIARO®/JESPECT® revenues increased to €53.2 million compared to €30.7 million in 2015, representing a 73.1% year-on-year growth which was supported by robust fourth quarter revenues of €13.1 million. The increase in revenue was largely the result of Valneva taking over marketing and distribution responsibilities for the product in several geographic territories. Valneva expects IXIARO®/JESPECT® revenues to continue to grow double-digit in 2017 through continued marketing and sales efforts and increase in product adoption by travelers.

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

### **Strong sales performance**

DUKORAL<sup>®</sup> revenues grew to €24.6 million in 2016 compared to €21.2 million reported in 2015. In the fourth quarter of 2016, DUKORAL<sup>®</sup> revenues were €9.6 million compared to €8.5 million in the fourth quarter of 2015 primarily due to increased sales in Canada, a country which accounts for more than 50% of global revenue. Valneva will continue to invest in growing the DUKORAL<sup>®</sup> vaccine by way of promotional efforts and geographic expansion and expects DUKORAL<sup>®</sup> sales to grow by approximately 10% in 2017.

## **Technologies and services**

### **EB66<sup>®</sup> CELL LINE**

In 2016, Valneva signed 10 new agreements (9 research agreements and 1 commercial agreement) for the development of human and veterinary vaccines on its EB66<sup>®</sup> platform. GE Healthcare and Valneva also announced the launch of a new cell culture medium, CDM4Avian, to optimize virus productivity in the EB66<sup>®</sup> cell-line. Valneva also expects that the European Medical Agency's decision in 2016 to issue new guidelines allowing the production of live attenuated vaccines in immortal cell-lines such as EB66<sup>®</sup> will open new markets for the technology. Valneva will continue to licence its vaccine platform in 2017 and has already signed two new research agreements since the beginning of the year.

## **Vaccine Candidates**

### **CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE- VLA 84**

#### **Partnering agreement sought in 2017**

*Clostridium difficile* (*C. difficile*) is the most common infectious cause for nosocomial diarrhea in Europe and the US. There are an estimated 450,000 cases of *C. difficile* in the US annually<sup>1</sup> and no vaccine against the disease is commercially available.

Valneva seeks to partner its *Clostridium difficile* vaccine candidate and has ongoing discussions with interested parties. Published Phase II data<sup>2</sup> from the most advanced vaccine program targeting primary prevention of *Clostridium Difficile Infections* (CDI) indicates that Valneva's VLA84 provides a comparable immunological profile to that other product.

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<sup>1</sup> Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34

<sup>2</sup> G. de Bruyn et al. Vaccine 34 (2016) 2170-2178

## **LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15**

### **Phase I clinical trial initiated – First patient vaccinated at the end of January**

Currently, there is no licensed vaccine available to protect humans against Lyme disease, a multi systemic tick-transmitted infection affecting 300,000 Americans each year. Following clearance from the Food & Drug Administration (FDA) and the Belgian authorities at the end of December 2016, Valneva has initiated a Phase I clinical trial in the US and Europe, and vaccinated the first patient at the end of January. In 2017, the company expects to execute the Phase I trial of its Lyme vaccine candidate and to accelerate the program's progression towards Phase II.

Valneva also plans to progress at least one additional vaccine candidate from its promising preclinical portfolio into Phase I in the second half of 2017. The pipeline includes candidates against Chikungunya and Zika.

## **Financial Review**

### **Fourth quarter revenues and grants (unaudited)**

Valneva's aggregate fourth quarter 2016 revenues and grants increased by 19.9% to €27.2 million compared to €22.7 million in the fourth quarter of 2015.

Product sales in the fourth quarter of 2016 increased to €23.8 million from €17.4 million in the same period of the previous year. The increase in product sales was driven by Valneva's two proprietary vaccines. IXIARO<sup>®</sup>/JESPECT<sup>®</sup> sales contributed €13.1 million to revenues in the fourth quarter of 2016 significantly increasing from €5.9 million in the fourth quarter of 2015. DUKORAL<sup>®</sup> contributed €9.7 million to the fourth quarter 2016 product sales, growing by 11.6% from €8.7 million in the fourth quarter of 2015. Sales of third party products marketed by Valneva decreased to €1.0 million in the past quarter compared to €2.8 million in the fourth quarter of 2015.

Revenues from collaborations and licensing in the fourth quarter of 2016 decreased to €2.2 million compared to €3.6 million in the fourth quarter of 2015. Grant income in the fourth quarter of 2016 decreased to €1.1 million from €1.7 million in the fourth quarter of 2015.

### **Full year 2016 revenues and grants (unaudited)**

Valneva's aggregate revenues and grants in the full year 2016 increased to €97.9 million from €83.3 million in 2015. This increase was mainly a result of strong growth of IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales.

Total product sales increased to €80.4 million in the full year 2016 from €61.5 million in the year 2015. IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales contributed €53.0 million to revenues in 2016

compared to €30.6 million in 2015 representing 73.1% growth. The strong increase was driven by the capturing of additional revenue margins under the new sales and distribution network and also benefited from strong demand from the US military and from private markets in Germany and the UK. DUKORAL<sup>®</sup> sales contributed €24.6 million to 2016 product sales representing growth of €3.5 million, or 16.8% compared the year 2015. Third Party product sales for the year 2016 decreased to €2.9 million from €9.9 million in the year 2015, due to the fact that several GSK vaccines were no longer marketed by Valneva.

Revenues from collaborations and licensing decreased from €16.8 million in 2015 to €13.6 million in the year 2016. Grant income decreased from €5.0 million in 2015 to €3.8 million in 2016.

#### Cash position at year-end (unaudited)

Liquid funds on December 31, 2016 stood at €42.2 million, compared to €42.6 million on December 31, 2015 and consisted of €35.3 million in cash and cash equivalents and €6.9 million in restricted cash.

#### Full year EBITDA (estimated)

Valneva's full year 2016 estimated EBITDA showed a strong improvement and amounted to an EBITDA profit of €2.8 million, compared to an EBITDA loss of €8.5 million in the year 2015. EBITDA is calculated by excluding depreciation, amortization and impairment charges from the operating loss as recorded under IFRS. EBITDA also excludes gains from bargain purchase in the calculation for the comparator period of the previous year.

#### Final 2016 results

Final full year 2016 results and audited financial statements will be released on March 23<sup>rd</sup>, 2017. As previously reported, Valneva's operating loss for the year 2016 will be impacted by €34.1 million of non-cash impairment charges which were recognized in the second quarter following negative Phase II/III study results for the *Pseudomonas* vaccine candidate and discontinuation of the program.

### 2017 Financial Outlook

in million €	2016 Actual unaudited	2017 Forecast	Growth
<b>Total revenues &amp; grants</b>	97.9	<b>105 - 115</b>	up to 17%
<b>Product sales</b>	80.4	<b>88 - 92</b>	10 - 15%
IXIARO <sup>®</sup> /JESPECT <sup>®</sup> sales	53.2	58 - 62	10 - 15%
DUKORAL <sup>®</sup> sales	24.6	27	10%
<b>EBITDA (estimated)</b>	2.8	<b>5 - 10</b>	80 – 250%

### **About Valneva SE**

Valneva is a fully integrated, commercial stage biotech company focused on developing innovative lifesaving vaccines.

The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

Valneva's portfolio includes two commercial vaccines for travelers: IXIARO<sup>®</sup>/JESPECT<sup>®</sup> indicated for the prevention of Japanese encephalitis and DUKORAL<sup>®</sup> indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has proprietary vaccines in development including candidates against *Clostridium difficile* and Lyme Borreliosis. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (EB66<sup>®</sup> vaccine production cell line, IC31<sup>®</sup> adjuvant).

Valneva is listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Great Britain, Sweden, Canada and the US with over 400 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 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 in this press release will in fact be realized. Valneva is providing the information in these materials as of the date of this press release, and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.