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Valneva Posts 96% Revenue Growth in 2015; Forecasts 2016 Revenues of €90 to €100 Million

The Company today announced its unaudited FY 2015 revenues, unaudited year-end cash balance and 2016 outlook

- Revenues and grants increased by 96% year-on-year and amounted to €83.3 million in 2015 (vs €42.4 million in 2014); Q4 2015 revenues and grants were €22.7 million (vs €13.1 million in Q4 2014);
- Revenue growth driven mainly by the inclusion of acquired DUKORAL® vaccine and activities in Sweden as well as continued strong product sales of IXIARO®/JESPECT®;
- Cash position at the end of 2015 was €42.6 million.

2016 Outlook

- Revenues, including grants, expected to reach €90 to €100 million. This includes product sales in the expected range of €70 to €80 million, reflecting up to 30% growth compared to 2015 product sales;
- Revenue growth to be driven by expected IXIARO®/JESPECT® product sales of approximately €50 million (from €30.6 million in 2015);
- Expected gross margin on product sales of approximately 50%;
- EBITDA loss expected to be reduced to less than €5 million.

Significant pipeline catalysts in 2016

- Valneva expects to release the results of its Pseudomonas aeruginosa Phase II/III trial in the second quarter of 2016;
- The Company reported positive Phase II top-line data for its Clostridium difficile vaccine and aims for a Phase III partnership agreement in 2016;
- Valneva's new Lyme borreliosis vaccine candidate is expected to enter Phase I clinical trials in the second half of 2016.

Key financial information

in million €	3 months ended Dec 31,		12 months ended Dec 31,	
	2015 unaudited	**2014**	**2015 unaudited**	**2014**
Product sales	17.4	8.8	61.5	28.1
Revenues from collaborations and licensing	3.6	2.7	16.8	8.8
Grant income	1.7	1.6	5.0	5.5
Total revenues & grants	**22.7**	**13.1**	**83.3**	**42.4**
Cash, short-term deposits and marketable securities, end of period	**42.6**	**29.5**	**42.6**	**29.5**

Lyon (France), February 24, 2016 – Valneva SE ("Valneva" or "the Company"), a leading pure play vaccine company, published today its unaudited revenues and cash position for the fourth quarter and the full year ended December 31, 2015. Audited full year financial results are scheduled to be released on March 21, 2016.

Business highlights

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

Strong in-market sales despite transition – significant growth ahead

In 2015, IXIARO®/JESPECT® product sales increased to €30.6 million compared to €28.1 million in 2014, representing an 8.8% year-on-year growth which was supported by robust fourth quarter sales of €5.9 million. IXIARO®/JESPECT® recent sales performance exceeded the Company's prior expectations which had been lowered following the decision to terminate the Marketing and Distribution agreement with the Company's global distributor and to establish a new marketing and distribution network for this vaccine. The expected impact on sales as a result of the transition did not materialize owing to very collaborative and professional transition work with the Company's previous global distribution partner and to substantial in-market sales growth in 2015. Valneva expects the IXIARO®/JESPECT® product sales to grow to approximately €50 million in 2016 as a result of the new commercialization strategy and a continued increase in product adoption by travelers.

With the goal of complementing its own commercial sales infrastructure, Valneva has entered into a number of country-specific marketing and distribution agreements to ensure broad geographic availability of its products through leading local distribution partners including VaxServe, Inc., a Sanofi Pasteur company (US private market) and GlaxoSmithKline (GSK) (Germany / Austria).

More than 60% of the planned IXIARO® and DUKORAL® sales in 2016 are expected to be generated by Valneva's own commercial teams.

CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL®)

Strong Q4 2015 sales performance – label change in Canada triggers reduction of acquisition price

Valneva's 2015 DUKORAL® product sales, which were included from the acquisition date on February 10, 2015, reached €21.0 million, of which €8.7 million came from the seasonally strong fourth quarter. The product which is highly complementary to Valneva's first marketed product was added through the acquisition of Crucell Sweden AB in February 2015. DUKORAL® pro forma 2015 product revenues, for the entire 12 month period, were €26.3 million, representing a 2.7% growth over 2014 pro forma sales of €25.6 million under the previous owner. By achieving sales growth despite the integration and transition impact, DUKORAL® confirmed Valneva's expectations in its potential and strategic value for the Company.

In December 2015, Valneva announced that Health Canada had requested changes to the DUKORAL® product monograph. The updated product monograph and subsequent labeling refer to the "Prevention of diarrhea caused by cholera and/or LT-ETEC". LT-ETEC is the heat-labile toxin producing *Enterotoxigenic Escherichia coli. Enterotoxigenic Escherichia coli* (ETEC) is a type of *Escherichia coli* and the leading bacterial cause of diarrhea in the developing world, as well as the most common cause of travelers' diarrhea. The updated product indication may negatively impact DUKORAL® sales in Canada going forward. Canada is the single most important market for the product, accounting for more than 50% of 2015 global DUKORAL® sales.

In order to reflect the business changes resulting from the adjustments to the DUKORAL® label in Canada, the seller Crucell Holland BV and Valneva agreed on certain amendments to the purchase agreement including an adjustment to the purchase price. Crucell Holland BV waived a €10 million milestone payment that Valneva would otherwise have been obligated to pay and repaid €15 million from the acquisition price. Together, the €10 million milestone waiver and the €15 million cash repayment resulted in a €25 million reduction of the purchase consideration, bringing it from originally €45 million down to €20 million. Valneva used the €15 million repayment amount to fully repay a loan which had been granted by Athyrium Capital Management LLC ("Athyrium") for purposes of this acquisition. Crucell Holland BV also paid for prepayment fees owed to Athyrium (€3 million). Following this repayment, Athyrium resigned its position as observer to the Company's supervisory board.

Valneva will continue to invest in growing the DUKORAL® vaccine by way of promotional efforts and geographic expansion and to leverage its strategic value for the Group.

THIRD PARTY PRODUCT DISTRIBUTION

Through the acquisition of Crucell Sweden AB in February 2015, Valneva also acquired a vaccine distribution business in Sweden. Valneva´s commercial team in the Nordics marketed and distributed DUKORAL® and a range of third party products in 2015 which generated sales of €9.9 million, including €2.8 million in the fourth quarter of 2015. Since a number of vaccines, representing more than 60% of the third party business, will no longer be marketed and distributed by Valneva following the transfer of the Novartis vaccines business to GSK, third party product sales are expected to fall significantly behind the previous year's level. Valneva expects that new third party distribution agreements will be entered into in the course of the year.

Vaccine Candidates

PSEUDOMONAS AERUGINOSA VACCINE CANDIDATE– VLA 43
Results from Phase II/III trial expected in the second quarter of 2016
Currently, there are no approved prophylactic vaccines for *Pseudomonas aeruginosa*, and Valneva's VLA43 is the only vaccine in development. Valneva has completed enrolment of its phase II/III efficacy trial with a total of 800 ventilated intensive care unit patients recruited across approximately 40 different study sites. Valneva will release data, including day 180 follow-up time-points, in the second quarter of 2016. The development of Valneva's vaccine candidate against *Pseudomonas aeruginosa* is part of the strategic alliance agreement signed between Valneva and Novartis in 2007, which transitioned to GSK in 2015. The current trial is co-financed by GSK.

CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE– VLA 84
Final study results expected in Q2 leading to potential partnership agreement
In December 2015, Valneva reported positive topline data from its Phase II trial evaluating VLA84 as a prophylactic vaccine for *Clostridium difficile* (C. difficile) infections. Valneva expects to report final study results in the second quarter of 2016. Following that step, GSK will have an opportunity to exercise their opt-in rights for the VLA84 development program. Valneva is in discussions with other potential partners in case GSK chooses not to pursue the program.

LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15
Phase I clinical trial expected to be initiated in the second half of 2016
Currently, there is no licensed vaccine available to protect humans against Lyme disease, a multi systemic tick-transmitted infection that is increasingly common in the US and Europe. Valneva expects to initiate a phase I clinical study in the second half of 2016.

Technologies and services

EB66® CELL LINE
At the beginning of February, Valneva announced the signing of a new R&D collaboration agreement with GSK for the development of EB66®-based influenza vaccines. Under the new agreement, Valneva secured additional research fees in addition to the potential milestone payments and royalties that were included in the 2007 agreement signed with GSK. GSK is developing its EB66®-based influenza vaccines in the US in partnership with the Texas A&M University System.

In 2015, Valneva signed 10 new agreements on its EB66® platform (5 research agreements and 5 commercial agreements), including an exclusive agreement with Jianshun Biosciences Ltd (JSB) granting this Chinese company rights to commercialize the EB66® cell line in People's Republic of China. Under the JSB agreement, Valneva received a €2.5 million upfront payment and is entitled to further annual license fees and royalties.

Financial Review

Note: As a result of the acquisition of Crucell Sweden AB and all DUKORAL® related assets ("Crucell Sweden"), Crucell Sweden's business has been included in the Group's consolidated financial statements from the acquisition date on February 10, 2015. Therefore, the 2015 and 2014 IFRS results are not fully comparable as the Crucell Sweden operations were only included for the 2015 period starting from February 10, 2015.

Fourth quarter revenues and grants (unaudited)

Valneva's total fourth quarter 2015 revenues and grants increased by 72.7% to €22.7 million compared to €13.1 million in the fourth quarter of 2014. This increase was driven by a €13.2 million contribution in revenues from the acquired ex-Crucell operations. Acquired revenues offset a decrease in IXIARO® fourth quarter product sales which was due to temporary effects from the transition to Valneva's new commercialization structure and is expected to be fully offset in 2016.

Fourth quarter 2015 product sales were €17.4 million, compared to €8.8 million in the same period of 2014. IXIARO®/JESPECT® product sales amounted to €5.9 million while DUKORAL® product sales were €8.7 million and product sales of third party products contributed €2.8 million to fourth quarter 2015 revenues.

Revenues from collaborations, licensing and services increased to €3.6 million in the fourth quarter of 2015, from €2.7 million in the fourth quarter of 2014. Grant income was €1.7 million in the fourth quarter of 2015 compared to €1.6 million in the fourth quarter of 2014.

Full year 2015 revenues and grants (unaudited)

Valneva's aggregate revenues and grants increased to €83.3 million in the full year 2015 from €42.4 million in the year 2014. This increase was mainly a result of the acquisition of the Crucell Sweden's business whose overall revenue contribution amounted to €36.4 million in 2015 of which €31.0 were product sales, and €5.5 million related to revenues from collaborations and licensing. IXIARO®/JESPECT® product sales contributed €30.6 million to revenues in 2015, representing an 8.8% increase compared to 2014 product sales of €28.1 million. This increase was recorded despite the transition towards a newly established global marketing and distribution network following Valneva's termination of the marketing and distribution partnership with GSK in June 2015. DUKORAL® product sales contributed €21.0 million and third party product distribution contributed €9.9 million to the full year 2015 product sales.

Revenues from collaborations and licensing increased to €16.8 million in 2015 from €8.8 million in 2014. Acquisition effects from the Crucell Sweden business amounted to €5.5 million and primarily related to R&D services provided to Johnson & Johnson. Excluding acquired revenues, revenues from collaborations and licenses grew to €11.3 million in 2015 from €8.8 million in 2014. They mainly benefited from additional licensing agreements and milestone payments received for the EB66®

platform as well as co-development revenues for the Pseudomonas project from partner GSK.

Grant income amounted to €5.0 million in 2015 representing a reduction of €0.5 million compared to 2014.

Net loss and operating expense details will be released in the audited full year financial results publication scheduled for March 21, 2016.

Estimated Cash position at year-end

Liquid funds at December 31, 2015 stood at €42.6 million compared to €29.5 million at the end of December 2014 and consisted of €38.2 million in cash and cash equivalents, €3.7 million short term bank deposits and €0.7 million in restricted cash.

About Valneva SE

Valneva is a fully integrated vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to protect people from infectious diseases through preventative medicine.
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: one for the prevention of Japanese Encephalitis (IXIARO®/JESPECT®) and the second (DUKORAL®) indicated for the prevention of Cholera and, in some countries, prevention of Diarrhea caused by LT- ETEC (Enterotoxigenic Escherichia coli). The Company has proprietary vaccines in development including candidates against Pseudomonas aeruginosa, 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® vaccine production cell line, IC31® adjuvant).
Valneva is incorporated in Lyon, France, listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Scotland, Canada and Sweden with approximately 400 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 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.