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Valneva Announces Best Quarterly Results since Vivalis/Intercell Merger, Meets Business Objectives & Reconfirms Full Year Outlook

The Company posts balanced EBITDA and significantly reduced net loss

- *Balanced EBITDA of EUR 0.0m in Q3 2014 (vs EUR -5.5m in Q3 2013). While the Group still expects negative EBITDA in the near future due to R&D investments, it confirms its objective to be EBITDA profitable in the mid-term.*
- *Net loss decreased to EUR 2.6m in Q3 2014 (vs EUR 10.0m in Q3 2013) benefiting from the positive impact of merger synergies and a strong improvement in the profitability of IXIARO®.*
- *Revenues and grants were down to EUR 12.8m in Q3 2014 (vs EUR 14.7m in Q3 2013) mainly due to IXIARO®/JESPECT®'s fluctuating supply patterns and a decrease in collaboration and licensing revenues.*
- *Cash position of EUR 36.9m at quarter-end, only slightly below cash position at end of previous quarter (EUR 37.3m).*

OUTLOOK:

- Valneva reconfirms its 2014 overall IFRS revenue expectations of EUR 40 – 45 million and anticipates continued growth of IXIARO®/JESPECT® in-market sales.

- The Company also reaffirms its prior guidance of a significant improvement of its operational results (excluding any non-cash amortization and impairment charges) in 2014 compared to the pro-forma financial performance of the combined two businesses (Vivalis and Intercell) in 2013. This improvement will be mainly due to EUR 5 – 6 million merger synergies and a strong improvement in the profitability of IXIARO®.

- Valneva will continue to financially support the Group's strategy of focused spending in research and development in order to create long-term value through innovation while at the same time striving towards mid-term financial break-even. Valneva confirms that its key research and development projects are progressing according to plan.

Lyon (France), November 6, 2014 – European biotechnology company Valneva SE ("Valneva" or "the Group") today reported its consolidated financial results for the third quarter ended September 30, 2014. The condensed consolidated interim financial report is available on the Company's website www.valneva.com.

A webcast for financial analysts, fund managers, investors and journalists will be held today at 2:00pm (CET)
link: **http://www.media-server.com/m/p/rqqvqg9m**
A replay will be available after the webcast on the Company's website.

KEY FINANCIAL INFORMATION:

EUR in thousands	3 months ended September 30,		9 months ended September 30,		
	2014	2013	2014	2013	2013 Pro-forma
Revenues & Grants	12,844	14,680	29,315	24,351	32,045
Net profit/(loss)	(2,568)	(9,968)	(14,752)	(18,082)	(31,942)
EBITDA	(15)	(5,523)	(3,610)	(10,436)	(18,198)
Net operating cash flow	8	(14,928)	(7,098)	(22,033)	n/a
Cash, short-term deposits and marketable securities, end of period	36,920	18,179	36,920	18,179	18,179

PRODUCT:

+ **IXIARO®/JESPECT®: Continuous strong in-market sales growth and uptake in travelers**

In the first nine months of the year, IXIARO®/JESPECT® product sales revenues were EUR 19.3 million compared to EUR 20.7 million pro-forma product sales in the same period last year. This decrease was mainly due to the change in the U.S. military sales responsibility from late 2013 onwards which resulted in Valneva now recognizing only two thirds of the total sales revenue to the U.S. military instead of 100% previously.

The Company reiterates its product sales revenue guidance for full year 2014, which it expects to be in the same range as full year 2013 (EUR 27.2 million pro-forma), representing a solid double-digit year-on-year growth rate taking into account the change in revenue recognition resulting from the transition of the U.S. military sales responsibility to Novartis.

Valneva is working closely with the Company's main distributor Novartis to increase public awareness on the disease, which is progressively having a positive impact on in-market sales as observed in the third quarter 2014.

Total IXIARO®/JESPECT® product sales revenue were EUR 9.5 million in the third quarter 2014 compared to EUR 11.4 million in the third quarter 2013 due to fluctuating supply patterns to the U.S. military and to the prior-year-effect of the largest U.S. military order the Company ever received, which boosted 2013 third-quarter sales.

In the third quarter 2014, Valneva continued to record the first revenues from royalties on Biological E.'s sales of Japanese encephalitis vaccines (JEV) in India under the trade name JEEV. Valneva expects the royalties on Biological E.'s sales to increase progressively, especially as the vaccine has been prequalified by the World Health Organization (WHO) - a key step for distribution of the vaccine in developing countries.

Similarly, Valneva's collaboration with vaccine manufacturer Adimmune Corporation to whom it granted the rights to register and commercialize its JE vaccine under a local trade name in April 2014 is progressing well towards mid-term market approval in Taiwan. Under the agreement, intermediate-stage bulk product will be supplied by Valneva while Adimmune will be responsible for final release and commercialization of the product.

With further in-market sales growth, the newly signed agreement with Adimmune, increasing revenues from royalties on Biological E.'s JEV sales in India, and the changes to the Company's main marketing & distribution agreement earlier this year, Valneva expects further significant improvement in the profitability of its commercial product franchise.

TECHNOLOGY AND LICENSING BUSINESS:

+ **EB66® Cell Line: construction of EB66®-based Influenza facility in Texas progressing well; additional EB66® license agreements expected in Q4**

In September 2014, Valneva joined GlaxoSmithkline (GSK) in celebrating the site dedication of the Texas A&M pandemic influenza vaccine facility in Texas and welcomed the confirmation that it was on track for completion of construction by the end of 2015, to be followed by its start-up phase in 2016. This new facility is expected to provide the capabilities to produce, within four months of a declared influenza pandemic, the bulk antigen needed for up to 50 million doses of GSK's next generation pandemic influenza vaccine, based on Valneva's proprietary EB66® cell line.

Valneva granted an exclusive commercial license to GSK in 2007 to develop and market worldwide pandemic and seasonal human influenza vaccines using Valneva's EB66® technology. GSK's EB66®-based H5N1 pandemic influenza vaccine candidate has successfully completed a Phase I clinical trial. GSK also signed an agreement with the Chemo-Sero Therapeutic Research Institute (Kaketsuken) in 2009 to co-develop, manufacture, and supply

EB66®-based influenza vaccines in Japan. At the beginning of 2014, the Japanese health authorities granted the first ever marketing approval for a human vaccine produced in the EB66® cell line for a pandemic H5N1 influenza vaccine.
Valneva also announced at the beginning of August a new clinical development license agreement with US firm GeoVax Labs, Inc. to develop MVA-based vaccines against HIV/AIDS. The agreement will allow GeoVax to enter clinical trials with a vaccine candidate derived from EB66® cells and also permits the transfer of the cell line to a third party GMP manufacturer.

Valneva expects to announce additional EB66® cell line license agreements in the fourth quarter of the year.

+ **IC31® Adjuvant / IC31® Tuberculosis Vaccine: First phase II data expected in Q4/2014**

Valneva has granted multiple licenses (Novartis, Statens Serum Institut – SSI) to evaluate IC31® in new vaccine formulations in infectious disease and additional collaborations have been initiated in oncology.

In the field of tuberculosis, three clinical vaccine candidates, all formulated with Valneva´s IC31® adjuvant, are currently being tested in phase I and II clinical trials as part of the Company's agreement with SSI and their partners, including Aeras and Sanofi Pasteur. First Phase II data from one of the trials is expected to be published in the fourth quarter of 2014.

In March 2014, Aeras announced the initiation of another phase II randomized clinical trial for its tuberculosis (TB) vaccine candidate Aeras-404 using Valneva's IC31® proprietary adjuvant.

+ **VIVA|Screen® antibody platform:**

As already announced in its first-half results publication, Valneva is currently reviewing its strategy for the VIVA|Screen® business, looking for new ways to maximize the value of its antibody platform.

The move follows a change in the strategy of its main licensee Sanofi Pasteur which decided not to exercise certain options and to delay one of its programs on the VIVA|Screen® platform. Valneva successfully completed antibody discovery work for Sanofi Pasteur in 2013 and delivered respective antibody candidates for three different targets. At the end of February 2014, Valneva announced the initiation of a fourth antibody discovery program for Sanofi-Pasteur.

In July 2014, Valneva announced the signing of a research collaboration and license agreement with a leading global animal health care company to discover antibodies from animal B-lymphocytes using VIVA|Screen® technology. Financial details were not disclosed.

PRODUCT CANDIDATES IN DEVELOPMENT:

- **Pseudomonas aeruginosa: recruitment of patients for phase II/III continuation progressing well**

The enrolment of further patients in the phase II/III pivotal efficacy trial for which the group announced the continuation following an interim analysis at the end of March 2014 is progressing according to plan and the enrolment should be completed by mid-2015.

In addition to the 394 patients already enrolled in the study, the Company has started the recruitment of another 400 ventilated intensive care patients in 40 different sites. Valneva is also considering the option to extend the study further if necessary. Preliminary results are expected at the end of 2015 / early 2016.

Pseudomonas aeruginosa is one of the leading causes of nosocomial infections, which are infections acquired or occurring during the course of hospitalization. The presence of Psuedomonas Aeruginosa in ventilated patients is associated with increased mortality. Valneva estimates that the up to one million intensive care unit patients on mechanical ventilation in the U.S. and Europe annually could represent a potential target population for a respective vaccine.

- **Clostridium difficile Vaccine Candidate: phase II initiation expected in Q4/2014 or in Q1/2015**

After reporting positive phase I results for its Clostridium difficile (C.difficile) vaccine candidate at the end of 2013, Valneva has defined further its development approach which got confirmed by a positive FDA pre-IND meeting. The company has now submitted the Investigational New Drug (IND) application and is preparing the initiation of the phase II clinical trial in elderly subjects which the Company expects to commence in the fourth quarter of 2014 or in the first quarter of 2015.

Phase I showed a favorable safety and tolerability profile in both study populations, elderly subjects and adults, with local tolerability being even better in elderly subjects. The vaccine candidate was also highly immunogenic in elderly subjects and was able to induce immune responses to C. difficile toxins A and B, similar to the ones observed in adults.

C. difficile is the most common pathogen of acute healthcare- associated diarrhea in Europe and the U.S. In 2013, 470,000 cases of Clostridium difficile have been estimated globally with rising incidence rates and a respective economic burden primarily due to prolongation of hospitalization. Valneva estimates that elderly people (above 50 years of age) with elective

hospital admissions as well as long-term care facility residents could represent the first target group for a respective prophylactic vaccine.

+ **Borrelia (Lyme disease): pre-clinical development completed**

Valneva has developed a multivalent, protein subunit based vaccine candidate. This candidate has completed pre-clinical development and has entered the IND - Investigational New Drug - process. Valneva expects to announce a decision on the next development steps in 2015.

To date, there is currently no vaccine available to protect humans against Lyme disease. According to the Centers for Disease Control and Prevention (CDC), 300,000 Americans are diagnosed each year with Lyme disease and the disease spread keeps increasing. In Europe, 180,000 to 200,000 cases are diagnosed each year.

FINANCIAL REVIEW:

Third quarter 2014 financial review

+ **Revenues and Grants**

Valneva's third-quarter 2014 revenues and grants decreased by EUR 1.8 million to EUR 12.8 million compared to EUR 14.7 million in the same period of the previous year. This decrease was due to a decrease in product sales and revenues from collaborations, licensing and services and was only partly offset by the increase in grant income.

+ **Operating result and EBITDA**

Cost of goods and services sold in the third quarter 2014 amounted to EUR 6.2 million of which EUR 5.8 million related to IXIARIO®/JESPECT® sales and EUR 0.4 million related to cost of services. On similar sales levels, cost of goods related to IXIARIO®/JESPECT® in the third quarter of the current year was higher than in the first half due to variabilities in inventory accounting which are expected to largely revert over the full fiscal year. In the third quarter 2013, cost of goods was EUR 6.6 million.

Research and development expenses in the third quarter 2014 reached EUR 4.6 million compared to EUR 7.8 million in the third quarter 2013. The decrease was mainly due to the disposal of the CMO business in the fourth quarter 2013 and a decrease in clinical study costs.

Valneva's operating loss decreased by EUR 5.8 million to EUR 3.0 million in the third quarter 2014 compared to EUR 8.8 million in the third quarter 2013.

In the third quarter 2014, Valneva's EBITDA result was balanced at EUR 0.0 million, whereas in the third quarter 2013 EBITDA was minus EUR 5.5 million. Third quarter 2014 EBITDA was calculated by excluding EUR 3.0 million in depreciation, amortization and impairment charges from the operating loss recorded in the condensed consolidated interim income statement under IFRS. Third quarter 2013 EBITDA was calculated by excluding EUR 3.3m in depreciation, amortization and impairment charges from the operating loss recorded in the condensed consolidated interim income statement under IFRS.

+ **Net result**

Valneva's net loss in the third quarter 2014 was EUR 2.6 million compared to EUR 10.0 million for the same period of the previous year. The decrease reflects the progress made through the cost savings and synergies resulting from the merger.

Finance income, net of finance expenses in the third quarter 2014 was positive at EUR 0.6 million compared to net finance expenses of EUR 1.1 million in the third quarter 2013. The positive finance income in the third quarter of the current year was mainly due to unrealized foreign currency gains.

Nine months 2014 financial review

Note: As a result of the merger with Intercell AG ("Intercell"), Intercell's business has been included in the Group's consolidated financial statements from the merger closing date May 28, 2013. Therefore, the first nine months 2014 and 2013 IFRS results are not fully comparable as the ex-Intercell operations were only included for the period starting from June 2013. Pro-forma figures including the Intercell business for the first nine months 2013 period and excluding one-time effects due to the merger were prepared for illustrative purposes only. For detailed explanation of pro-forma assumptions and reconciliation to IFRS results, please refer to note 10 of the condensed consolidated interim financial report.

+ Revenues and grants

On a pro-forma basis (i.e. including the ex-Intercell business from January 2013 to May 2013), revenues and grants decreased by EUR 2.7 million, or 8.5%, to EUR 29.3 million in the nine months ended September 30, 2014 from EUR 32.0 million in the nine months ended September 30, 2013. The year-on-year decrease in revenues on a pro-forma basis was due to lower product sales and lower revenues from collaborations, licensing and services, which were only partly offset by an increase in grant income. On an unadjusted basis, aggregate revenues and grants in the first nine months of 2014 were EUR 29.3 million compared to EUR 24.4 million in the same period of the previous year, which included ex-Intercell revenues only from June 2013 to September 2013.

+ Operating result and EBITDA

On a pro-forma basis, operating loss decreased by EUR 13.1 million, or 48.3%, to EUR 14.0 million in the nine months ended September 30, 2014 from EUR 27.0 million in the nine months ended September 30, 2013. This decrease was mainly due to cost synergies and prioritization of R&D activities in connection with the merger, including the disposal of the CMO business in the fourth quarter 2013. On an unadjusted basis, operating loss decreased by EUR 2.3 million, or 14.2%, to EUR 14.0 million in the nine months ended September 30, 2014 from EUR 16.3 million in the nine months ended September 30, 2013.

Valneva's EBITDA improved to minus EUR 3.6 million in the first nine months of 2014 from minus EUR 10.4 million in the first nine months of 2013. On a pro-forma basis, EBITDA improved to minus EUR 3.6 million in the first nine months of 2014 from minus EUR 18.2 million in the same period of the previous year. EBITDA was calculated by excluding depreciation, amortization and impairment from the operating loss recorded in the condensed consolidated interim income statement under IFRS.

+ Net result

Valneva's net loss in the first nine months of 2014 was EUR 14.8 million compared to EUR 18.1 million for the same period of the previous year. On a pro-forma basis, the net loss decreased by 53.8% to EUR 14.8 million in the first nine months of 2014 from

EUR 31.9 million in the first nine months of 2013. The decrease reflects the progress made in both, the merger consolidation and the cost saving projects.

+ **Cash flow and liquidity (unadjusted)**

Net cash used in operating activities decreased by EUR 14.9 million from EUR 22.0 million in the nine months ended September 30, 2013 to EUR 7.1 million in the nine months ended September 30, 2014. This decrease resulted primarily from the improved operating loss and from a lower increase in working capital.

Cash in/out-flows from investing activities changed by EUR 28.0 million, or 141.3%, to a net cash used in investing activities of EUR 8.2 million in the first nine months ended September 30, 2014 from a net cash generated from investing activities of EUR 19.8 million in the nine months ended September 30, 2013. The change resulted primarily from purchases of financial assets. The purchases of intangible assets and property, plant and equipment (net of proceeds from thereof) amounted to EUR 2.9 million in the nine months ended September 30, 2014 and to EUR 2.2 million in the nine months ended September 30, 2013.

Cash in-flows from financing activities decreased by EUR 10.0 million, or 63.3 %, to EUR 5.8 million in the nine months ended September 30, 2014 from EUR 15.8 million in the nine months ended September 30, 2013. In the nine months ended September 30, 2014, net cash generated from financing activities resulted primarily from a capital increase through the newly established equity line. In the nine months ended September 30, 2013, net cash generated from financing activities resulted primarily from the net proceeds of a capital increase completed in July 2013.

Liquid funds stood at EUR 36.9 million at September 30, 2014, compared to EUR 18.2 million at September 30, 2013 and consisted of EUR 27.1 million in cash, EUR 0.6 million in restricted cash, EUR 2.6 million in short-term deposits, and EUR 6.7 million in securities.

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About Valneva SE
Valneva is a European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger between Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery, and vaccine development and commercialization, either through in-house programs or in collaboration with industrial partners using innovative technologies developed by the company. Valneva generates diversified revenue from both its marketed product, a vaccine for the prevention of Japanese encephalitis (IXIARO®), commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66®cell line, VIVA|Screen® and IC31®) that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquartered in Lyon, France, the company employs approximately 270 people in France, Austria, Scotland, the United States, and Japan. The internationally experienced management team has a proven track-record across research, development, manufacturing and commercialization.
www.valneva.com

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 achievement 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.