VALNEVA SE
Gerland Plaza Techsud
70, Rue Saint-Jean-de-Dieu
69007 Lyon, *France*

Valneva Reports Q1 2014 Results, Confirms Full Year Outlook, and Provides Business update

The Company successfully meets its business & financial objectives

- *Revenues and grants were EUR 7.1m in Q1 2014 (Q1 2013: EUR 6.0m pro forma), benefiting from an increase in product sales*
- *Net loss was EUR 7.1m in Q1 2014 (Q1 2013: EUR 9.6m pro forma), reflecting the progress in costs savings and consolidation resulting from the merger*
- *Strong newsflow announced in Q1:*
  - *Continuation of the phase II/III clinical trial for Pseudomonas vaccine candidate*
  - *First ever marketing approval of a human vaccine produced in Valneva's EB66® cell line*
  - *Approval and launch in South America of a second veterinary vaccine produced in the EB66® cell line*

OUTLOOK:

- Valneva confirms it expects 2014 overall IFRS revenue to grow to EUR 40 – 45 million and anticipates continued growth of in-market sales of IXIARO®/JESPECT® leading to a significant increase in the profitability of its JEV vaccine.
- The Company also confirms it expects 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 savings in sales expenses following the recent amendment of the Company's main distribution contract for IXIARO®.
- Valneva will continue to report losses in 2014 in order to support the Company's strategy of focused spending in research and development and to create long-term value through innovation. The company confirms that it expects to achieve break-even in the mid-term.

Lyon (France), May 13, 2014 – European biotechnology company Valneva SE ("Valneva" or "the Company") reports today its consolidated financial results for the first quarter ended March 31, 2014. The condensed consolidated interim financial report is available on the Company's website.

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/fhdbeebd**
A replay will be available after the webcast on the Company's website.

KEY FINANCIAL INFORMATION:

(unaudited)

EUR in thousands	3 months ended		
	March 31, 2014	March 31, 2013	Pro-Forma March 31, 2013
Revenues & Grants	7,095	1,877	6,043
Net profit/(loss)	(7,112)	(2,549)	(9,604)
EBITDA	(3,293)	(1,575)	(5,255)
Net operating cash flow	(10,037)	(3,606)	n/a
Cash, short-term deposits and marketable securities, end of period	28,706	5,800	46,218

OPERATIONAL BUSINESS REVIEW:

+ **Merger synergies positively impact Q1 2014**

The alignment and consolidation of key business activities, processes, and structures across the two previous organizations (Intercell and Vivalis), which the Company completed at the end of 2013, had a positive impact on general and administrative expenses and led to focused and reduced R&D spending compared to Q1 2013 pro forma results.

Valneva will continue to benefit from the merger related cost savings for the rest of the year and expects a significant improvement of its operating activities (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.

PRODUCT:

+ **IXIARO®/JESPECT®: Towards continued growth and increased profitability**

Q1 sales in line with Company's expectations showing solid double-digit year-on year in-market sales growth.

Revenues from IXIARO®/JESPECT® product sales increased to EUR 3.8 million in the first quarter 2014 compared to EUR 2.1 million (on a pro forma basis) in the first quarter 2013.

Due to seasonality patterns, the first quarter typically represents the lowest net sales revenue period for Valneva but the first quarter 2013 was affected by a reduction in the Company's main distribution partner inventory levels, resulting in a 83% growth in the first quarter 2014.

Valneva reiterates its net sales revenue guidance for 2014, which the Company expects to be in the same range as 2013, 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 – as previously announced.

In-market sales growth is expected to be driven by further improved recommendations and awareness.

At the beginning of April 2014, Valneva also announced that it had granted vaccine manufacturer Adimmune Corporation certain exclusive rights to its Japanese encephalitis (JE) vaccine in Taiwan. Adimmune will be entitled to register and commercialize Valneva´s JE vaccine under a local trade name and to develop, manufacture and commercialize the vaccine from bulk product delivered by Valneva. Adimmune, for decades, has supplied its mouse brain-derived JE vaccine in Taiwan, selling approximately 600,000 doses per year, but the Taiwanese Advisory Committee on Immunization Practices (ACIP) has recently recommended the introduction of a modern, cell culture-derived vaccine.

With further in-market sales growth, the newly signed agreement with Adimmune and the recent changes to the Company's main marketing & distribution agreement, Valneva expects a significant improvement in the profitability of its product.

RESEARCH & DEVELOPMENT:

+ **Pseudomonas aeruginosa: continuation of phase II/III clinical trial**

At the end of March 2014, Valneva announced the continuation of the current phase II/III clinical trial of its Pseudomonas aeruginosa vaccine candidate IC43. Valneva and its co-development partner (Novartis) decided to continue the trial following different assessments including analyses conducted by a Data

Monitoring Committee (DMC) and consultation with two European regulatory agencies and experts.
Valneva expects to resume recruitment for the phase II/III trial in the second quarter of 2014. In addition to the 394 patients already enrolled in the study, the Company is planning to recruit 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.
Valneva estimates that 700,000 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.
The Company currently anticipates an all-cause mortality rate of 20% to 40% (at day 28) in this patient group and estimates that a reduction in this mortality rate by at least 5 percentage points could lead to a licensable vaccine.

+ **Clostridium difficile Vaccine Candidate - phase II initiation expected in Q4/2014**

After reporting positive phase I results for its C. difficile vaccine candidate at the end of 2013, Valneva is preparing the initiation of Phase II studies, which the Company expects to initiate by the end of 2014.
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. Next development steps will be decided in agreement with Valneva's strategic alliance partner, Novartis.

+ **Borrelia (Lyme disease):**

Valneva has developed a multivalent, protein subunit based Vaccine candidate. This candidate is nearing completion of pre-clinical development and is expected to be ready for clinical entry towards the end of 2014. Valneva has not taken a decision on the start of clinical development as the Company has decided to allocate its R&D budget primarily to the development of its later stage assets.
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.

PLATFORMS UPDATE:

+ **EB66® Cell Line:**

At the end of March 2014, Valneva announced the first ever marketing approval for a human vaccine produced in the EB66® cell line. The approval was granted by the Japanese health authorities to the Chemo-Sero Therapeutic Research Institute (Kaketsuken), a co-development partner of GlaxoSmithKline (GSK), for a pandemic H5N1 influenza vaccine. The vaccine has been developed in accordance with the Japanese government's plan to rapidly respond to an influenza pandemic both before and during an outbreak. Kaketsuken has recently completed the construction of a state-of-the-art manufacturing facility in Kumamoto with a pandemic production capacity of approx. 80 million doses. As part of a national stockpiling directive through the Japanese Ministry of Health, Labour and Welfare, Kaketsuken may produce and supply pandemic vaccine for stockpiling on which Valneva would get royalties equivalent to seasonal flu vaccine royalties.

GSK, which has an exclusive commercial license for worldwide marketing rights to pandemic and seasonal human influenza vaccines produced in Valneva's EB66® cell line, is developing its own EB66® cell based influenza vaccines in the US in partnership with the Texas A&M University System. After receiving approval from the U.S. Department of Health and Human Services (HHS) in 2013 to establish a USD 91 million manufacturing facility for influenza vaccines in Texas, the HHS recently announced that the site could be on-line and supply under Emergency Use Authorization (EUA) in case of a pandemic from 2017 onwards.

Mid-March 2014, Valneva announced the approval and launch of a second veterinary vaccine produced in the EB66® cell line in South America. The vaccine for the prevention of inclusion body hepatitis virus (IBH) was developed by Lima (Peru) based biopharmaceutical company FARVET SAC (FARVET), and will also be available for sale in Peru and several other South American countries. Financial terms of the agreement were not disclosed but do include milestone payments and royalties on net sales of the product. Under the current

commercial license, FARVET has the rights to develop two additional vaccines using Valneva's EB66® cell line.

At the beginning of March, Valneva also announced the signing of a new research license agreement and transferred an existing commercial agreement to Emergent BioSolutions Inc. (NYSE:EBS), to develop new vaccines using Valneva's EB66® cell line. The commercial license, which was initially granted to the Oxford-Emergent Tuberculosis Consortium (OETC) for the development of tuberculosis vaccines, will be transferred to Emergent. Financial terms of the agreements were not disclosed but do include upfront and annual maintenance payments. If successful, product candidates from these agreements may lead to additional cash payments for achieved milestones along with future royalties on net sales.

+ **VIVA|Screen® antibody platform:**

At the end of February 2014, Valneva announced the initiation of a fourth antibody discovery program for Sanofi Pasteur, the vaccine division of Sanofi, on its proprietary screening platform VIVA|Screen®. Valneva, successfully completed antibody discovery work for Sanofi Pasteur in 2013 and delivered respective antibody candidates for three different targets. The initiation of the new antibody program is part of an agreement signed with Sanofi Pasteur in June 2010, granting Sanofi Pasteur worldwide exclusive development and commercialization rights for the discovered antibodies. Sanofi Pasteur also finances collaborative research activities with Valneva.
Valneva may receive development milestone payments of up to EUR 35 million per indication, as well as royalty payments associated with product sales if Sanofi Pasteur choose to progress towards clinical development and licensure.
The first option period expires at the end of 2014 and could trigger a milestone payment.

+ **IC31® Adjuvant / IC31® Tuberculosis Vaccine**:

In the field of tuberculosis, Valneva is collaborating with the Statens Serum Institut (SSI) in Denmark. 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. In March 2014, Aeras announced the initiation of a Phase II randomized clinical trial for its tuberculosis (TB) vaccine candidate

Aeras-404 using Valneva's IC31® proprietary adjuvant. Data from two of the trials is expected to be published by the fourth quarter of 2014.
Under a strategic alliance agreement signed in 2007, Novartis received a license for the use of IC31® adjuvant in selected new vaccines. Following investigation of IC31® in influenza vaccines, Novartis is currently clinically investigating the adjuvants in an undisclosed vaccine candidate.

OTHER IMPORTANT INFORMATION

+ **Valneva´s partners Novartis and GlaxoSmithKline (GSK) to join forces and exchange assets**

Novartis and GlaxoSmithKline (GSK) announced a major contemplated transaction, including the divestment of Novartis' vaccine business (excluding flu) to GSK, expected to close in the first half of 2015.
Overall, Valneva expects to benefit from its two existing strategic partners joining forces. The Company sees Valneva's key assets partnered with Novartis as potentially highly complementary to GSK.
Valneva's late stage Pseudomonas and C. difficile vaccines are not programs GSK already has in its R&D portfolio and may add significant value to the GSK R&D portfolio.
The Company does not expect any impact regarding its Flu/EB66® cell-culture partnership with GSK since the Novartis flu business (including their cell-culture based flu vaccine) is not part of the contemplated transaction at this point in time.

+ **Valneva and Credit Agricole CIB have agreed on an equity line.**

In order to increase its financial flexibility, Valneva has set up an equity line with Crédit Agricole CIB. The equity line enables Valneva to issue up to 5,474,633 new ordinary shares representing up to 10 percent of its ordinary share capital. The equity line has been implemented by way of issuance of 5,474,633 equity warrants subscribed by Crédit Agricole CIB which are exercisable exclusively upon Valneva's request in several tranches within the next 24 months. The new shares issued will be subsequently sold on the market by Crédit Agricole CIB. For each tranche, the subscription price of the shares issued upon exercise of the equity warrants will represent a 5% discount to the volume weighted average price for the three trading days preceding the pricing date.
As an illustration, based on the current share price, the amount of equity that could be raised through this equity line could reach approximately EUR 32

million. Based on the latest share prices and the financial statements as at December 31, 2013, the per-share equity attributable to owners of the Company would increase by around 11% on a non-diluted basis and by around 11.8% on a diluted basis (as a result of the dilutive impact of potential share issues). This equity financing scheme, which enlarges the existing financing capabilities of the Company, will be managed by Valneva based on its financing needs. In particular, it will enable Valneva to further develop its current pipeline of clinical and preclinical projects and to reinforce the company's financial flexibility.

FIRST QUARTER 2014 FINANCIAL REVIEW:

(unaudited)

Note: As a result of the merger, Intercell's business has been included in the Group's consolidated financial statements from the merger closing date May 28, 2013. Therefore, first quarter 2014 and first quarter 2013 IFRS results are not fully comparable because the ex-Intercell operations are not part of the results for the comparator period of 2013. Pro-forma figures including Intercell Business for the first quarter 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 see the condensed consolidated interim financial report on the Company's website www.valneva.com

+ **Revenues and grants**

Valneva's aggregate first-quarter 2014 revenues and grants increased by EUR 5.2 million to EUR 7.1 million compared to EUR 1.9 million in the same period of the previous year. This increase was mainly due to the contribution of ex-Intercell revenues to the business as it was not included in the Valneva figures for the first quarter 2013. IXIARO® product sales contributed EUR 3.8 million to Valneva's first-quarter 2014 revenues.

On a pro-forma basis, including the Ex-Intercell business for the first three months of 2013, revenues increased by 17.4%, from EUR 6.0 million in the first quarter 2013 to EUR 7.1 million in the first quarter 2014. This increase was mainly due to a significant increase in product sales from EUR 2.1 million in the first quarter 2013 to EUR 3.8 million in the first quarter 2014, which resulted mainly from timing of product deliveries to the main distributor and to the prior year effect of inventory reductions by the distributor. Revenues from collaborations, licensing and services decreased slightly to EUR 2.5 million in the first quarter 2014 from EUR 2.7 million on a

pro-forma basis in the first quarter 2013. Grant income decreased from EUR 1.3 million on a pro forma basis in the first quarter 2013 to EUR 0.8 million in the first quarter 2014, primary due to a decrease in R&D tax credit.

+ **Operating Result and EBITDA**

Cost of goods and services sold in the first quarter 2014 amounted to EUR 2.4 million of which EUR 1.8 million related to sales of IXIARO® (yielding a product gross margin of 53.3%) and EUR 0.6 million related to cost of services. In the first quarter 2013, no cost of goods was recorded as the Ex-Intercell business started to be included only from June 2013 onward. On a pro-forma basis cost of goods increased from EUR 1.3 million in the first quarter 2013 to EUR 2.4 million in the first quarter 2014.

Research and development expenses in the first quarter 2014 reached EUR 5.8 million compared to EUR 2.8 million in the first quarter 2013. On a pro-forma basis R&D expenses decreased from EUR 8.3 million in the first quarter 2013 to EUR 5.8 million in the first quarter 2014, mainly due to cost synergies and prioritization of R&D activities in connection with the merger.

Selling, General and Administrative expenses amounted to EUR 3.2 million in the first quarter 2014, compared to EUR 1.0 million in the first quarter 2013. On a pro-forma basis the SG&A expenses decreased from EUR 3.8 million in the first quarter 2013 to EUR 3.2 million in the first quarter 2014 primarily due to savings and to cost synergies from the merger.

Non-cash amortization expenses for intangible assets increased to EUR 2.2 million in the first quarter 2014 from EUR 0.4 million in the first quarter 2013. EUR 1.6 million of the total amortization expenses in the first quarter 2014 were related to intangible assets, which were acquired through the merger and recorded at their fair value as of the merger's effective date.

Valneva's operating loss increased by EUR 4.0 million to EUR 6.4 million in the first quarter 2014 compared to EUR 2.4 million in the first quarter 2013. On a pro-forma basis the operating loss decreased by EUR 1.4 million from EUR 7.9 million in the first quarter 2013 to EUR 6.4 million in the first quarter 2014.

Valneva's EBITDA changed to minus EUR 3.3 million in the first quarter 2014 from minus EUR 1.6 million in the first quarter 2013. On a pro-forma basis, EBITDA improved from minus EUR 5.3 million in the first quarter 2013 to minus EUR 3.3 million in the first quarter 2014.

In the first quarter 2014, Valneva started to report a split of operating results for its three business segments "Products", "Technologies and Services" and "Product R&D". The Products segment includes marketed vaccines, currently the Group's JEV vaccine, which - without taking into account the non-cash amortization charges on intangible assets – showed an operating profit of EUR 1.1 million in the first quarter 2014. The Technologies and Services segment includes EB66®, VivaIScreen®, IC31® and other revenue-generating service and licensing activities. In the first quarter 2014, this segment showed a net loss of EUR 0.8 million without taking into account non-cash amortization charges on intangible assets. The Product R&D segment includes proprietary research and development programs aiming to generate new products with significant market potential such as the vaccine candidates against Pseumonas aeruginosa and C. difficile. This segment, which is currently the company's main area of investment, showed an operating loss of EUR 1.9 million in the first quarter 2014.

+ **Net Result**

Valneva's net loss in the first quarter 2014 was EUR 7.1 million compared to EUR 2.5 million for the same period of the previous year. On a pro-forma basis the net loss decreased from EUR 9.6 million in the first quarter 2013 to EUR 7.1 million in the first quarter 2014. The decrease reflects the progress made in both the consolidation and cost saving projects.

+ **Cash flow and Liquidity**

Net cash used in operating activities in the first quarter 2014 amounted to EUR 10.0 million and resulted primarily from the operating loss in connection with the Group's R&D activities and from an increase in working capital due to a significant reduction of trade payables and an increase in inventory at quarter-end.

Cash out-flows from investing activities reached EUR 0.9 million in the first quarter 2014 and resulted mainly from purchases of intangible assets (capitalized development costs).

Cash out-flows from financing activities amounted to EUR 0.8 million, resulting primarily from repayment of borrowings of EUR 0.7 million.

Liquid funds at March 31, 2014, stood at EUR 28.7 million compared to EUR 5.8 million at March 31, 2013 as reported and EUR 46.2 million on a pro-forma basis. Liquid funds at March 31, 2014 consisted of EUR 24.8 million cash, EUR 0.5 million restricted cash and EUR 3.4 million short-term deposits.

Contact:
Laetitia Bachelot Fontaine
Investor Relations Manager & External Communication Manager
Communications@valneva.com
T +33 2 28 07 37 10
M + 33 6 45 16 70 99

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®) developed by Valneva that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquartered in Lyon, France, the company employs approximately 300 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.