Valneva Reports Strong Q1 Revenue Growth and Positive EBITDA; Reaffirms Financial Guidance and Pipeline Outlook for 2016

Solid Q1 financial performance – EBITDA turns positive, confirming trend towards operational break-even

- Total revenues and grants were €24.7 million in Q1 2016 (vs. €19.5 million in Q1 2015) benefitting from strong IXIARO®/JESPECT® growth and full inclusion of acquired DUKORAL® sales;
- Q1 2016 sales performance driven by IXIARO® sales to the US military; travel market sales still negatively affected by transition towards new sales & marketing structure which has now been successfully completed;
- DUKORAL® Q1 2016 sales down on a pro-forma basis as a result of the narrower updated product indication in Canada but in-line to meet full year Company expectations with good potential for further growth;
- Q1 2016 EBITDA slightly above break-even at €0.0 million (vs. minus €1.0 million in Q1 2015);
- Operating loss improved to €2.7 million (vs. €3.7 million in Q1 2015), net loss was €5.0 million (compared to adjusted net profit of €9.8 million in Q1 2015 which included a positive €13.2 million one-time acquisition effect);
- Cash position at €33.4 million at end of March 2016.

Important R&D news-flow ahead

- Valneva expects to release Phase II/III results for its *Pseudomonas aeruginosa* vaccine candidate in the second quarter of 2016;
- The close-out of Valneva´s Phase II study for the *Clostridium difficile* vaccine candidate, for which successful Phase II topline data were reported at the end of 2015, is anticipated around mid-year 2016. GlaxoSmithKline (GSK) has informed Valneva that, for strategic reasons, it has waived its option rights ahead of the final data analysis and the start of the option exercise period. The company reaffirms its expectation to enter into a partnering agreement for this program by the end of this year;
- Outcome of the proof of concept for the development of a Zika vaccine using the IXIARO® platform is expected within the coming months.

2016 Outlook

Valneva confirms its FY 2016 financial outlook:

- 2016 IFRS revenues expected to reach €90 to €100 million, with product sales between €70 and €80 million - reflecting up to 30% growth over 2015 product sales;
- Improved revenues due to Valneva´s new global marketing & distribution network are expected to lead to a gross margin on product sales of approximately 50% in 2016.
- Valneva will continue to strive towards financial self-sustainability and expects to reduce its EBITDA loss to less than €5 million in 2016 while continuing to invest around €25 million in R&D.

Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva, commented, *"Our strong first quarter financial performance is consistent with our goal to establish Valneva as a fully integrated company that specializes in vaccines from discovery to commercialization in segments where innovative vaccines are needed. Importantly, our new global marketing & distribution network is now fully operational, allowing us to maximize the value of our own commercial products and potential customer products. We are looking forward to the important R&D news-flow ahead which has the potential to transform the Company."*

Key Financial Information

€ in thousand	3 months ended March 31	
	2016	**2015**
Revenues & grants	24,687	19,501
Net profit /(loss)	(5,037)	9,792
EBITDA	14	(961)
Net operating cashflow	(6,602)	(9,857)
Cash, short-term deposits and marketable securities, end of period	33,408	38,979

Lyon (France), May 11, 2016 – Valneva SE ("Valneva" or "the Company"), a leading independent pure play vaccine company, reported today its consolidated financial results for the first quarter ended March 31, 2016. The condensed consolidated interim financial report is available on the Company's website at www.valneva.com.

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

Q1 2016 Business Highlights

At the beginning of 2016, Valneva announced the successful establishment of its new global marketing & distribution network, providing a strong platform for significant further value growth from the Company's first two commercial vaccines IXIARO®/JESPECT® and DUKORAL®.

Valneva´s first-quarter sales revenues were still impacted in some countries by the transition towards the new marketing & distribution structure. As of today, the Company´s own dedicated sales & marketing organization, with offices in the US, Canada, UK and Sweden, is now fully operational and on track to deliver on the expected margin improvement and product sales growth.

Commercialized vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)
Significant growth of Q1 2016 revenues compared to Q1 2015

In the first quarter of 2016, IXIARO®/JESPECT® product sales increased to €14.6 million compared to €9.7 million in the first quarter of 2015 – mainly driven by strong sales to the US military following the signing of a $42 million contract with the US Government's Department of Defense. Under the terms of the agreement, Valneva will supply IXIARO® doses to the US military for a total value of $42 million over a two-year period to protect the nearly 360,000 US military and civilian personnel, and their families, working and living in endemic countries.

Based on the observed demand pattern in the travel markets and anticipated further supplies to the US military, Valneva re-confirms that IXIARO®/JESPECT® product sales are expected to grow to approximately €50.0 million in 2016.

At the beginning of 2016, Valneva announced that vaccine manufacturer Adimmune, to which it granted the rights to commercialize its Japanese encephalitis (JE) vaccine in Taiwan in 2014, was granted marketing approval for the vaccine by the Taiwanese Food & Drug Administration (TFDA). Adimmune now intends to establish a local fill-and-finish operation for the vaccine which is expected to be supplied to the Taiwanese national immunization program within the next two years under the trade name JEVAL®.

CHOLERA / ETEC- DIARRHEA VACCINE (DUKORAL®)
Good potential for further growth

DUKORAL® product sales in the first quarter of 2016 reached €5.4 million. In the first quarter of 2015, Valneva consolidated €4.5 million product sales revenues in a shortened sales quarter starting from the acquisition date on February 10, 2015. Pro-Forma first-quarter 2015 sales (including sales by the seller before the acquisition closing) were €9.8 million but are not considered to be representative due to acquisition-related timing of sales.

However, first-quarter 2016 sales were negatively impacted by the update of the DUKORAL® product monograph in Canada at the end of 2015 and the fact that Valneva largely ceased promotional efforts to include the updates in the indication and labeling. Canada is DUKORAL®'s largest market, accounting for more than 50% of the 2015 global DUKORAL® sales. Following Health Canada´s review of the product monograph, DUKORAL® is now indicated for immunization against cholera and the prevention of diarrhea caused by LT-ETEC[1], the most frequent cause of travelers' diarrhea.

Following the label change, Valneva announced it was expecting DUKORAL® sales to reach approximately €23 million in 2016 (vs €26.3 million on a pro-forma basis in 2015). The Company confirms first-quarter 2016 sales are in line to meet its full-year expectation.

Valneva will continue to invest in growing the DUKORAL® vaccine by way of promotional efforts and geographic expansion.

[1] A heat-labile toxin producing Enterotoxigenic *Escherichia coli*

Technologies and services

EB66® CELL LINE
Additional licensing agreements expected in 2016

In February 2016, Valneva announced the signing of a new R&D collaboration agreement with GlaxoSmithKline (GSK) for the development of influenza vaccines based on Valneva's EB66® vaccine production cell-line. Under the new agreement, Valneva secured additional research fees in addition to the potential milestone payments and royalties that were included in the 2007 EB66® license agreement signed with GSK[2]. The scope of this R&D collaboration has recently been reduced and is now focused on the development and validation of EB66® analytical assays. GSK is developing its EB66®-based influenza vaccines in the US in partnership with the Texas A&M University System.

With more than 35 research and commercial agreements with the world's largest pharmaceutical companies (GSK, Sanofi-Pasteur, Zoetis etc.), Valneva's EB66® cell-line, derived from duck embryonic stem cells, today represents a compelling alternative to the use of chicken eggs for large scale manufacturing of human and veterinary vaccines. Valneva expects to announce additional EB66® agreements in 2016.

Clinical vaccine candidates

PSEUDOMONAS AERUGINOSA VACCINE CANDIDATE– VLA 43
Data from Phase II/III trial expected in the second quarter of 2016

Pseudomonas aeruginosa is a bacterium with a high incidence of drug resistance that is responsible for approximately 51,000[3] healthcare-associated infections annually, which carries an economic burden exceeding $614 million. Currently, there are no approved prophylactic vaccines, and Valneva's *Pseudomonas* vaccine candidate, VLA43, is the only one in clinical development right now. The Company estimates that the total market potential for the product could be significant.

Valneva expects to release Phase II/III results for its *Pseudomonas aeruginosa* vaccine candidate in the second quarter of 2016.

The data will determine potential routes to first licensure or next clinical development steps. Based on the program´s Phase II data and the interim analysis for the current Phase II/III confirmatory efficacy trial, various outcomes would be considered successful. If the Phase II/III primary endpoint (reduction of all-cause mortality on Day 28) is met, the trial can be used as a pivotal efficacy trial in support of licensure. If the primary endpoint is not met (a possible outcome if there is not enough statistical power) but a trend towards a clinically meaningful vaccine effect (observed in all prior analyses) is confirmed, the trial will provide a solid basis for a Phase III pivotal efficacy trial, the details of which will be determined upon data discussion and consultation with the authorities.

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.

[2] In 2007, Valneva (formerly Vivalis) granted an exclusive license to GSK for the development of pandemic and seasonal influenza vaccines

[3] Antibiotics resistance threat in the United States, 2013; http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf

CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE– VLA 84
Phase II study closure and licensing agreement expected in the second half of 2016 following GSK opt-out

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[4]. Currently, no vaccine against *C. difficile* exists and antibiotic treatment of the established disease has significant limitations with recurrence in ~20% of cases. Valneva estimates that the total market potential for prophylactic C. difficile products may exceed USD 1 billion annually.

At the end of 2015, Valneva reported positive topline Phase II data for VLA84, its prophylactic vaccine targeting primary prevention of *Clostridium difficile* infections (CDI). VLA84 generated strong immune responses against *C. difficile* toxins A and B and showed a good safety and tolerability profile. Valneva will present the Phase II topline results at the American Society for Microbiology symposium (ASM Microbe 2016) which will take place from June, 16 to 20 this year.

The close-out of the Phase II study is anticipated around mid-year. The study design was agreed with regulators in Europe and the US with the aim of potentially supporting a subsequent progression into Phase III. Therefore, Valneva considers this program to be Phase III ready.

GSK had opt-in rights to the program under the above-mentioned Strategic Alliance Agreement. GSK has informed Valneva that, for strategic reasons, it has waived its option rights ahead of the final data analysis and the start of the option exercise period.

The company reaffirms its expectation to enter into a partnering agreement for this program by the end of year.

LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15
Phase I clinical trial expected to commence in 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 has developed a multivalent vaccine candidate which addresses OspA, one of the most dominant proteins expressed by the bacteria when present in a tick. Pre-clinical data showed that this vaccine candidate can provide protection against the majority of Borrelia species pathogenic for humans[5].

Valneva expects to commence a Phase I trial towards the end of 2016. The single-blind, partially randomized, dose escalation Phase I study trial will be conducted in the US and Europe. Besides its primary objective of evaluating safety and tolerability, immunogenicity, measured by observing IgG antibodies specific against six OspA serotypes, will also be monitored for different dose groups and formulations at different time-points.

[4] Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34.
[5] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0113294

Pre-clinical vaccine candidates

Beyond its clinical product candidates, Valneva is working on a range of pre-clinical programs as well as early stage research programs.

Valneva has prioritized pre-clinical candidates which are technologically and scientifically complementary to the Company´s strong viral vaccines development competence. The Company's most advanced pre-clinical project focuses on Chikungunya which Valneva expects to enter Phase I clinical development in 2017.

Valneva also announced at the beginning of January that it is evaluating the development of a Zika vaccine. The Zika Virus (ZIKV) is related to the Japanese encephalitis virus against which Valneva has already successfully developed an inactivated vaccine (IXIARO®/JESPECT®). Both viruses are arthropod-borne flaviviruses transmitted through mosquito bites. Valneva is currently conducting proof of concept experiments to determine the potential use of the IXIARO® platform for a vaccine against Zika and expects results in the coming months. The Company was recently invited to participate to the global consultation on research related to Zika virus infection convened by the World Health Organization (WHO) in Geneva. Health authorities, including WHO, have expressed a preference for an inactivated vaccine approach, meaning that the Company´s platform approach could be perfectly suited.

Financial Review

FIRST QUARTER 2016 FINANCIAL REVIEW (unaudited)

Note: First quarter 2016 and first quarter 2015 IFRS results are not fully comparable because of the acquisition of the Crucell Sweden AB business in February, 2015. As a result of the acquisition, which included all assets, licenses and privileges related to DUKORAL® as well as a vaccine distribution business in the Nordics, the comparator quarter of 2015 includes specific acquisition-related transaction effects but does not include the results of the acquired business from the start of the year 2015 until the acquisition closing date on February 9, 2015.

Revenues and grants

Valneva's aggregate first quarter 2016 revenues and grants increased to €24.7 million from €19.5 million in the first quarter of 2015. This increase was mainly a result of strong growth of IXIARO®/JESPECT® product sales.

Product sales increased to €20.4 million in the first quarter of 2016 from €15.1 million in the first quarter of 2015. IXIARO®/JESPECT® product sales contributed €14.6 million to revenues in the first quarter of 2016, representing a 50% increase over the first quarter 2015 product sales of €9.7 million. The strong increase was primarily driven by shipments to the US military related to the recently awarded 2 year supply contract announced in March 2016. DUKORAL® sales contributed €5.4 million to the first quarter 2016 product sales representing a growth of €0.9 million compared to the first quarter of 2015. Third Party product sales decreased to €0.4 million in the first quarter of 2016 from €0.9 million in the first quarter of 2015.

Revenues from collaborations and licensing decreased slightly from €3.5 million in the first quarter of 2015 to €3.3 million in the first quarter of 2016.

Grant income remained unchanged compared to the first quarter of 2015 and amounted to €0.9 million.

Operating result and EBITDA

Cost of goods and services sold (COGS) were €12.9 million in the first quarter of 2016 of which €6.4 million related to IXIARO® sales, yielding a product gross margin of 55.9%. €4.2 million of COGS related to DUKORAL® sales, yielding a gross margin of 21.7%. Of the remaining COGS for the first quarter of 2016, €0.6 million related to the Third Party product distribution business and €1.6 million related to cost of services. In the comparator period of 2015, COGS were €12.1 million, of which €6.7 million related to IXIARO®, €4.6 million to DUKORAL® and Third Party product, and €0.8 million to cost of services.

Research and development (R&D) expenses in the first quarter of 2016 reached €5.8 million compared to €5.5 million in the first quarter of the previous year. This increase was mainly due to increased costs related to the pre-clinical projects and was only partially offset by reduced spending on Valneva's Clostridium difficile vaccine candidate and the phase II/III study of the *Pseudomonas* vaccine candidate ahead of data release expected in the late second quarter of 2016.

Distribution and marketing expenses in the first quarter of 2016 amounted to €3.3 million, compared to €1.2 million in the first quarter of 2015. Distribution and marketing costs increased as a result of the built-up of the Company's own sales and marketing organization following the termination of its global distribution partnership with GSK in June 2015.

General and administrative (G&A) expenses in the first quarter of 2016 amounted to €3.8 million, compared to €2.8 million in the first quarter of 2015. The increase resulted from G&A expenses of the acquired Crucell Sweden AB business, which was included from February 10, 2015 onward.

Amortization and impairment expenses for intangible assets slightly decreased to €1.7 million in the first quarter of 2016 from €1.8 million in the first quarter of 2015.

Valneva's operating loss improved by €1.0 million, or by 27.3% to €2.7 million in the first quarter of 2016 compared to a loss of €3.7 million reported for the first quarter of 2015.

Valneva's first quarter 2016 EBITDA was slightly positive at €0.0 million (rounded down), compared to an EBITDA loss of €1.0 million in the first quarter of 2015. EBITDA was calculated by excluding depreciation, amortization and impairment charges amounting to €2.7 million from the operating loss of €2.7 million as recorded in the condensed consolidated income statement under IFRS.

Segment overview

The Commercialized Vaccines segment showed an operating profit of €3.1 million in the first quarter of 2016, compared to an operating profit of €0.7 million in the first quarter of 2015. Excluding amortization expenses for acquired intangible assets, the profit of that segment was €4.8 million in the first quarter of 2016 and €2.3 million in the first quarter of 2015.

The Technologies and Services segment showed an operating profit of €0.6 million in the first quarter of 2016 compared to €0.7 million operating profit in the first quarter of 2015. Excluding amortization and impairment, the profit of the Technologies and Services segment

amounted to €0.6 million in the first quarter of 2016 compared to €0.8 million in the first quarter of 2015.

The Vaccine Candidates segment currently represents the Company's main area of investment and showed an operating loss of €2.6 million in the first quarter of 2016 compared to €2.4 million in the first quarter of 2015.

Net result

Valneva's net loss in the first quarter of 2016 was €5.0 million compared to a net profit of €9.8 million in the first quarter of the prior year. The first quarter of 2015 included a €13.2 million gain on bargain purchase ("negative goodwill") related to the acquisition of the Crucell Sweden AB business. Without taking into account the positive one-time effect, the net loss of €5.0 million in the first quarter of 2016 would compare to a net loss of €3.4 million in the first quarter of 2015. This increase by €1.6 million - despite the improvements in operating loss and EBITDA - was driven by net finance expenses of €2.3 million in the first quarter of 2016 compared to a net finance income of €0.7 million in the first quarter of 2015, primarily resulting from positive foreign currency effects in early 2015. Interest expenses increased to €1.6 million in the first quarter of 2016 from €1.3 million in the first quarter of 2015 due to a higher level of average outstanding debt.

Cash flow and liquidity

Net cash used in operating activities in the first quarter of 2016 amounted to €6.6 million, compared to €9.9 million in the first quarter of 2015, and resulted primarily from an increase in working capital driven by a temporary high level of accounts receivable at quarter-end which was collected at the beginning of the second quarter.

Cash inflows from investing activities in the first quarter of 2016 amounted to €17.8 million and resulted primarily from a payment received from Johnson & Johnson in connection with the adjustment of the purchase consideration for the Crucell Sweden AB business and the DUKORAL® vaccine.

Cash out-flows from financing activities in the first quarter of 2016 amounted to €19.8 million and primarily included the re-payment of borrowings to Athyrium LLC.

Liquid funds stood at €33.4 million on March 31, 2016, compared to €42.6 million on December 31, 2015 and consisted of €31.8 million in cash and cash equivalents, €1.0 million in short-term bank deposits and €0.6 million in restricted cash.

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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 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 headquartered in Lyon, France, listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Scotland and Sweden with approximately 400 employees. More information is available at 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 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.