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Valneva Reports Strong 2018 Results, Expects Further Growth and Major Pipeline Progression in 2019

Major R&D milestones achieved in 2018, double-digit product sales revenue growth delivered; Lyme and chikungunya programs expected to advance further in 2019

Strong financial results in 2018[1]

- Product sales revenue of €103.5 million in 2018, representing 16% growth at constant exchange rate (CER[2])
  - Exceeded guidance of >€100 million
  - IXIARO® sales revenue growth 19% (CER) in 2018
  - DUKORAL® sales 12% higher (CER) in 2018 despite H1 supply constraints
- Total revenues were €113.0 million in 2018
- EBITDA[3] of €13.1 million in 2018
  - Exceeded guidance of €5.0 million to €10.0 million
- Net profit of €3.3 million; first ever profitable annual result for Valneva
- R&D investment of €25.3 million in 2018, in line with guidance of €25 million to €30 million
- €50 million financing led by blue-chip U.S. healthcare investors combined with positive operating cash flow of €16.3 million resulted in strong cash position of €81.7 million at the end of 2018
  - Biopharma (Pharmakon) loan fully repaid in January 2019 thereby reducing cost of capital in 2019
  - Further €15 million European Investment Bank loan facility available

Double-digit product sales growth expected to continue in 2019

- Valneva expects product sales revenues in 2019 of between €115 million and €125 million, representing 15% to 20% (CER) year on year growth
  - New $59 million IXIARO® supply contract with the US Department of Defense (DoD) recently announced; DoD option to increase to $70 million
    - Doses to be supplied in 2019 and 2020
  - IXIARO® product sales growth expected to be 15% (CER) or more, according to supply logistics with DoD
  - Further DUKORAL® product sales growth of up to 5% (CER) is expected
  - Other revenues (service revenue, license fees) are expected to approach 2018 levels
  - Overall revenue expected to be between €125 million and €135 million in 2019

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[1] Financial statements are not audited. The audit procedures by the Statutory Auditors are underway. The Company plans to publish its audited annual financial report on or about March 21, 2018.
[2] CER and AER growth: In order to illustrate underlying performance, Valneva has decided to include information on its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates used to determine the results of overseas companies in Euros had remained unchanged from those used in the comparative period. CER% represents growth at constant exchange rates. AER% represents growth at actual exchange rates.
[3] FY 2018 EBITDA was calculated by excluding €6.8 million of depreciation and amortization from the €6.3 million operating profit as recorded in the consolidated income statement under IFRS

- Gross margin is expected to be above 60% and net operating margin, prior to R&D investments[4], is expected to be between 25% to 35%
- Valneva expects to invest €35 million to €40 million in R&D projects, notably Lyme and chikungunya, in 2019
- Valneva expects to generate EBITDA of €5 million to €10 million in 2019

Key R&D Progress reported in 2018

- Valneva reported nine key R&D milestones in 2018, the highest number in the Company's history, including:
  - Positive Phase 1 data for its Lyme disease vaccine candidate. Valneva also aligned its development strategy with both the FDA and EMA, and advanced the program into Phase 2
  - Initiation of Phase 1 clinical trial for the Company's promising vaccine candidates against chikungunya and Zika
    - Positive initial data reported for both candidates

Further significant R&D progress expected in 2019

- Major confirmatory and supportive data points for the Lyme vaccine candidate (VLA15):
  - First booster data including final Phase 1 data[5] (Q1)
  - Determination of final doses and initiation of second Phase 2 trial (Q2)
  - Further alignment with regulators on Phase 3 strategy
- Development acceleration of chikungunya vaccine candidate (VLA1553)
  - Phase 1 data (ungrouped) including first intrinsic human challenge (Q2/3)
  - Alignment with regulators on potential route to licensure (Q2/3)
  - Initiation of next clinical trial (by end 2019)

David Lawrence, Valneva's Chief Financial Officer, commented, "2018 has been a significant year for Valneva. We broke the €100 million threshold for product sales, made significant progress in R&D and successfully executed a strategic capital raise as part of our capital formation strategy. 2019 is already off to an excellent start with the new DoD IXIARO® supply contract and positive Phase 1 interim results for our chikungunya vaccine candidate. We are excited about continuing to execute our strategy and unlocking shareholder value."

Key Financial Information

(2018 unaudited, consolidated per IFRS)

€ in million	**12 months ending December 31**	
	2018	**2017**
Product Sales	103.5	92.6
Total Revenues	113.0	105.3
Net profit/(loss)	3.3	(11.5)
EBITDA	13.1	10.8
Cash	81.7	38.1

[4] Net operating margin prior to R&D investment is calculated by excluding R&D expenses from the operating profit as recorded in the consolidated income statement under IFRS divided by total revenues

[5] Valneva press release: Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate

Saint Herblain (France), February 21, 2019 – Valneva SE ("Valneva" or "the Company"), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, reported today its full year unaudited[6] consolidated financial results for the year ending December 31, 2018. A brief unaudited report, including the profit and loss statement and the balance sheet, is available on the Company's website, www.valneva.com.
A webcast for the financial community and media will be held today at 3:00 pm. (CET). A replay will be available on the Company's website. Please refer to this link: ***https://edge.media-server.com/m6/p/dk7vyzzx***

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In 2018, revenues from IXIARO®/JESPECT® product sales reached €69.6 million, representing year-on-year growth of 19% (CER). The increase was largely driven by demand in the U.S., including in the private market where Valneva has taken direct control of sales and marketing. There was also a strong increase in IXIARO® sales in Canada in 2018 compared to 2017.

Last month, Valneva announced the signing of a new $59 million contract with the U.S. government DoD. Under the terms of the agreement, Valneva will supply IXIARO® doses to the Defense Logistics Agency of the DoD, in 2019 and 2020, with $59 million in guaranteed revenues and potentially worth up to $70 million.

Following this contract award, subject to detailed supply planning to the U.S. DoD, Valneva projects that revenues from IXIARO®/JESPECT® sales will grow at a minimum of 15% in 2019. Further penetration of the U.S. private market will continue to be a key growth driver in 2019, in addition to the DoD supply. Noting that detailed logistical planning for supply to the DoD is ongoing, the Company will provide mid-term guidance during 2019 regarding the IXIARO® sales outlook for 2019 and 2020.

CHOLERA / ETEC[7]-DIARRHEA VACCINE (DUKORAL®)

In 2018, despite supply constraints in the first half of the year, revenues from DUKORAL® sales increased to €30.4 million, largely driven by strong sales performance in Canada. This was somewhat offset by a combination of adverse exchange rate movements (mainly between the Canadian dollar and the Euro).

Valneva expects DUKORAL® revenues to grow by up to 5% in 2019, through continued market penetration in key markets such as Canada and the UK.

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[7] Indications differ by country -Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Phase 2 development underway; Positive initial booster data and final Phase 1 data reported

Valneva's vaccine candidate VLA15 is currently in Phase 2 clinical development[8]. The overall objective of Phase 2 is to determine the final dose and schedule for use in Phase 3 pivotal field efficacy studies.

Given the range of immune response and the variability across the different serotypes observed in Phase 1, the ongoing Phase 2 study (VLA15-201) includes two higher doses (135 µg and 180µg, both adjuvanted with alum). An additional study evaluating an alternative vaccination schedule (VLA15-202) is scheduled to commence mid-2019. The Company expects initial Phase 2 data (on the primary endpoint) mid-2020.

Valneva also recently reported positive initial booster data and final Phase 1 data[9]. The final Phase 1 data confirmed the safety and tolerability profile observed at all time-points, as reported in the interim analysis. VLA15 demonstrated a favorable safety profile and had no associated safety concerns. In addition, the final Phase 1 immunogenicity results indicated that the alum-adjuvanted formulations elicit higher immune responses at all time-points, confirming the interim data findings. As expected, based on the interim Phase 1 data, antibody titres declined post-Day 84 across all groups, trending towards baseline at approximately one-year post initial vaccination. The single booster re-vaccination in the period 12 to 15 months after the initial dose in the primary immunization resulted in a significant immune response, yielding OspA antibody titres at levels 2.7-fold (ST3) to 5.8-fold (ST1) over the initial titres observed at Day 84 (geometric mean fold rise (GMFR)).

Lyme disease is the most common vector-borne illness in the northern hemisphere for which there is no other clinical vaccine candidate in development worldwide. According to the US Centers for Disease Control and Prevention (CDC), approximately 300,000[10] Americans are infected with Lyme disease annually with at least a further 200,000 cases in Europe[11].

VLA15 is a multivalent, protein subunit vaccine that targets the outer surface protein A (OspA) of *Borrelia* and is intended to protect against the majority of human pathogenic *Borrelia* species. VLA15 is designed to confer protection by raising antibodies that prevent *Borrelia* from migrating from ticks to humans after a bite.

VLA15 has been awarded Fast Track Designation by the U.S. Food and Drug Administration (FDA)[12].

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[8] Valneva press release: https://www.valneva.com/en/investors-media/news/2018#303
[9] Valneva press release: Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate
[10] As estimated by the CDC https://wwwnc.cdc.gov/eid/article/21/9/15-0417_article
[11] As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.
[12] Valneva press release: Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Positive initial Phase 1 results reported

Valneva recently reported positive Phase 1 interim results for its chikungunya vaccine candidate[13].

The interim results showed an excellent immunogenicity profile after a single vaccination with a 100% seroconversion rate[14] achieved at Day 28 in a pooled analysis[15] of all vaccinated groups. Results also showed that 96.5% of subjects achieved at least a 16-fold increase in antibody titres and a high geometric mean titre, fully supporting VLA1553's differentiated target product profile.

The pooled safety profile of all groups was considered acceptable, supporting further development. No serious adverse events nor adverse events of special interest were reported up to Day 28 and the local tolerability was considered excellent.

Valneva is committed to advance its chikungunya vaccine candidate as quickly as possible into pivotal trials, after dialogue and alignment with the authorities. The Company expects unblinded safety and immunogenicity data at dose group level by mid-2019 including additional information on whether subjects are protected from chikungunya viremia. This may allow Valneva to determine a future development pathway to licensure.

Chikungunya is a mosquito-borne viral disease caused by the chikungunya virus (CHIKV), a Togaviridae virus, transmitted by *Aedes* mosquitoes. As of 2017, there have been more than one million reported cases in the Americas[16] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[17]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically. There are no preventive vaccines or effective treatments available and as such, chikungunya can be considered a major public health threat.

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate aiming for protection against various chikungunya virus outbreak phylogroups and strains designed for long-lasting protection conferred by neutralizing antibodies in adults and children[18]. The target populations for vaccines against chikungunya are travelers, military personnel or individuals at risk who live in endemic regions.

VLA1553 has been awarded Fast Track Designation by the FDA[19].

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[13] Valneva press release: https://www.valneva.com/en/investors-media/news/2019#305
[14] SCR was defined as the proportion of subjects achieving a CHIKV specific neutralizing antibody titre of NT50≥20
[15] Since the Phase 1 study continues blinded with re-vaccinations to potentially obtain a first indication of efficacy, the interim results were not analyzed by dose group but through a pooled analysis of all dose groups.
[16] PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)
[17] Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015
[18] Hallengärd et al. 2013 J. Virology 88: 2858-2866
[19] Valneva press release: Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate

ZIKA VACCINE CANDIDATE – VLA1601
Positive interim Phase 1 results reported

At the end of 2018, Valneva and its partner, Emergent BioSolutions, reported positive Phase 1 results for their vaccine candidate against the Zika virus[20] in a randomized, observer-blinded, placebo-controlled, single center study.

VLA1601 met the study's primary endpoint showing a favorable safety profile in all doses and schedules tested. The vaccine candidate was also immunogenic in all treatment groups and induced both dose- and schedule-dependent neutralizing antibodies against the Zika virus with the kinetics expected for an inactivated, alum-adjuvanted whole-virus vaccine. Seroconversion Rates (SCR) reached up to 85.7% on Day 35 (interim analysis of data up to Day 56).

The final analysis at day 208 after first vaccination, which is expected in the first half of 2019, will include additional immunogenicity data such as Geometric Mean Titres (GMTs), rate of subjects with seroconversion and fold-increase of Zika virus-specific neutralizing antibody titres as compared to baseline, measured by plaque reduction neutralization tests (PRNT).

Zika virus infection is a mosquito-borne viral disease caused by the Zika virus (ZIKV), a flavivirus transmitted by *Aedes* mosquitoes[21]. Disease outbreaks have been reported in tropical Africa, South-East Asia, the Pacific Islands, and, since 2015, in the Americas. According to the World Health Organization (WHO), there is scientific consensus that the ZIKV is a cause of microcephaly and Guillain-Barré syndrome[22]. Between 2015 and early January 2018, over 500,000 cases of suspected Zika infection and many cases of the congenital syndrome associated with the ZIKV were reported by countries and territories in the Americas, according to the WHO[23]. There is currently no specific treatment available.

VLA1601 is a highly purified inactivated whole virus vaccine candidate developed using Valneva's proven and licensed inactivated Japanese encephalitis (JE) vaccine platform.

[20] *Valneva press release: https://www.valneva.com/en/investors-media/news/2018#300*
[21] *https://www.cdc.gov/zika/transmission/index.html*
[22] *http://www.who.int/mediacentre/factsheets/zika/en/*
[23] *http://www.paho.org/hq/index.php?option=com_content&view=article&id=12390&Itemid=42090&lang=en*

Full Year 2018 Financial Review
(Unaudited, consolidated under IFRS)

Revenues
Valneva's total revenues (on an AER basis) in 2018 were €113.0 million compared to €105.3 million in 2017.
Product sales revenues (on an AER basis) in 2018 increased to €103.5 million from €92.6 million in 2017, representing year over year growth of 11.7%.
Revenues from collaborations and licensing amounted to €9.6 million in 2018 compared to €12.7 million in 2017. Reporting of grants, including R&D tax credits, has been re-classified and included in "Other income and expenses, net" as of January 2018. The comparator period of 2017 has been adjusted accordingly.

Operating result and EBITDA
Costs of goods and services sold (COGS) were €44.4 million in 2018, representing an overall gross margin of 60.7% compared to 56.3% in 2017. €23.6 million of COGS related to IXIARO®/JESPECT® sales, yielding a product gross margin of 66.2%. €13.7 million of COGS related to DUKORAL® sales, yielding a product gross margin of 54.8%. DUKORAL® COGS were also positively impacted by favorable Swedish Krona (SEK) exchange rates. Of the remaining COGS in 2018, €2.4 million related to the Third Party Product distribution business and €4.8 million were related to cost of services. In 2017, overall COGS were €46.0 million, of which €39.7 million related to cost of goods and €6.3 million related to cost of services.
Research and development expenses in 2018 increased to €25.3 million from €23.4 million in the previous year. This was driven by planned increased investments into Valneva's clinical stage vaccine candidates. Marketing and distribution expenses in 2018 amounted to €20.9 million, compared to €17.9 million in 2017. This increase was mainly a result of investment in the U.S. private commercial operations combined with further investment in certain other markets. In 2018, general and administrative expenses amounted to €16.9 million compared to €15.5 million in 2017; this increase was primarily driven by non-cash charges for the Company's share option program. Amortization and impairment charges in 2018 amounted to €3.2 million compared to €10.7 million in 2017. The reduction resulted from re-assessment of the lifetime of IXIARO®/JESPECT®-related intangible assets, driven by patent extensions in both Europe and the U.S. (lifetime extended from 15 to 23.75 years). Furthermore, 2017 included a one-time non-cash impairment charge amounting to €3.6 million related to Valneva's Phase 3-ready *Clostridium difficile* vaccine candidate.
As a result of sales growth, improved margins and reduced amortization and impairment charges, Valneva realized an operating profit of €6.3 million in 2018 compared to an operating loss of €4.0 million in 2017. EBITDA in 2018 was €13.1 million, compared to an EBITDA of €10.8 million in 2017.

Net result
In 2018, Valneva generated a net profit amounting to €3.3 million compared to a net loss of €11.5 million in the prior year.
Finance costs and currency effects in 2018 resulted in a net finance expense of €4.0 million, compared to a net finance expense of €8.6 million in 2017. The reduced net finance expense

compared to the prior year was partly the result of lower interest expenses from continued loan re-payments and foreign currency related losses incurred during 2017.
Results from investments in associates comprise a €1.1 million profit from Valneva's 43.3% shareholding in BliNK Biomedical SAS.

Cash flow and liquidity
Net cash generated by operating activities in 2018 amounted to €16.3 million compared to €12.8 million in 2017.
Cash outflows from investing activities in 2018 amounted to €2.9 million (compared to €4.1 million in 2017) and resulted primarily from the purchase of equipment.
Cash inflows from financing activities amounted to €30.9 million in 2018 and consisted of €49.3 million net proceeds from private placement of new shares in October as well as re-payment of borrowings and interest payments. Cash outflows from financing activities amounted to €10.4 million in 2017.
Liquid funds on December 31, 2018 stood at €81.7 million compared to €38.1 million on December 31, 2017 and consisted of €77.1 million in cash and cash equivalents and €4.6 million in restricted cash.

About Valneva SE
Valneva is a fully integrated, commercial stage biotech company focused on developing innovative life-saving vaccines.
Valneva's portfolio includes two commercial vaccines for travelers: IXIARO®/JESPECT® indicated for the prevention of Japanese encephalitis and DUKORAL® indicated for the prevention of cholera and, in some countries, prevention of diarrhea caused by ETEC. The Company has various vaccines in development including a unique vaccine against Lyme disease. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with approximately 480 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 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.