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Valneva Raises Product Sales Guidance Following Strong Nine-Month Results and R&D Execution

Company product sales guidance raised for FY 2019, EBITDA confirmed

- Valneva now projects product sales revenues of €125 million to €130 million representing year on year growth exceeding 20%. Previously, Valneva expected product sales revenue of between €115 million to €125 million.
  - Expected overall 2019 revenues (product sales and revenues from collaboration, licensing and services) confirmed between €125 million and €130 million including the negative revenue impact of the termination of the GlaxoSmithKline (GSK) Strategic Alliance Agreement (SAA)[1].
  - Excluding this GSK SAA termination effect, expected overall revenues would be between €135 million - €140 million
- The Company also confirms expected EBITDA, in line with its previous guidance, of €5 million to €10 million in 2019.
  - Excluding the GSK SAA termination effects, EBITDA would be €15m - €20m

Two significant R&D milestones reported in the third quarter

- Completion of Phase 2 patient recruitment across both Phase 2 studies for the Lyme disease vaccine candidate VLA15.
- Up to $23.4 million awarded by the Coalition for Epidemic Preparedness Innovations (CEPI) for the late-stage development of the chikungunya vaccine candidate VLA1553.[2]

Strong financial results in the first nine months of 2019

- Product sales revenue of €86.4 million in the first nine months of 2019, representing 22% year on year growth (18% at CER[3])
  - Significant growth of 28% (24% at CER) in IXIARO® revenues to €64.2 million in the first nine months of 2019 driven largely by growth in the US
  - Growth in DUKORAL® revenues of 6% (5% at CER) to €19.8 million in the first nine months of 2019
- Total revenues of €81.4 million in the first nine months of 2019
  - €92.1 million excluding the negative revenue impact from the termination of the GSK SAA
- Gross margin on product sales revenue of 65.2% in the first nine months of 2019 (compared to 59.7% in the first nine months of 2018) – growth largely driven by sales mix and improved manufacturing performance
- Positive EBITDA of €3.0 million in the first nine months of 2019

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[1] *Valneva press release: Valneva Announces Mutual Agreement with GSK to End Strategic Alliance Agreement; Regains Control of R&D*
[2] *Valneva press release: CEPI awards up to US$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine*
[3] *CER% represents growth at constant exchange rates.*

- EBITDA of €13.7 million excluding the negative impact of the GSK SAA termination
- Net loss of €2.4 million in the first nine months of 2019
  - Net profit of €8.3 million excluding the negative effect of the GSK SAA termination
- Strong cash position of €67.4 million at the end of September 2019
  - Including €9 million GSK SAA termination settlement payment and borrowing of additional €10 million from the European Investment Bank (EIB) facility in the third quarter

David Lawrence, Valneva's Chief Financial Officer, commented, "The continued growth of IXIARO® and DUKORAL® sales, together with disciplined cost management, has enabled us to report strong results during the first nine months of the year. As a result, we feel confident about our full-year outlook and raise our product sales guidance. The recent completion of patient recruitment for our Lyme Phase 2 studies underscores the continuing execution on our key R&D value drivers."

Financial Information

(nine-month 2019 unaudited results, consolidated per IFRS)

€ in million	**9 months ending September 30**	
	2019	**2018**
Product sales	86.4	71.1
Total revenues	81.4	78.3
Net profit/(loss)	(2.4)	(3.3)
EBITDA[4]	3.0	6.1
Cash	67.4	33.0

Saint-Herblain (France), October 31, 2019 – Valneva SE ("Valneva" or "the Company"), a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs, reported today its nine-month financial results ending September 30, 2019. The condensed and consolidated interim financial results are available on the Company's website www.valneva.com.

Valneva will provide a live webcast of its nine-month 2019 financial results conference call beginning at 2 p.m. CET today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/tn3y9fnf

[4] *Nine-month year-to-date 2019 EBITDA was calculated by excluding €6.2 million of depreciation and amortization from the €3.2 million operating loss as recorded in the consolidated financial statements under IFRS*

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In the first nine months of 2019, revenues from IXIARO®/JESPECT® product sales reached €64.2 million compared to €50.0 million in the first nine months of 2018. The 28% increase (24% at CER) was largely driven by demand in North America, both in the public and private markets.

The Company's fastest growing market segment (excluding the U.S. Military) is U.S. private with 25% (18% at CER) year over year growth in the first nine months, validating our decision to invest in our own dedicated commercial infrastructure.

Under the current military supply contract, the U.S. Department of Defense (DoD) has ordered 375,000 doses for 2019, of which 250,000 were supplied in the first nine months representing a 48% volume growth versus the prior year period.

Based on nine-month sales, Valneva increases its full-year IXIARO®/JESPECT® sales guidance and now expects revenues from IXIARO®/JESPECT® sales to grow at a minimum of 20% (at CER) in 2019.

CHOLERA / ETEC[5]-DIARRHEA VACCINE (DUKORAL®)

In the first nine months of 2019, revenues from DUKORAL® sales increased to €19.8 million compared to €18.6 million. The 6% increase (5% at CER) over the prior year period was largely driven by a solid commercial performance and product supply in the first nine months of 2019.

Based on nine-month sales, Valneva reaffirms that it expects revenues from DUKORAL® sales to grow by up to 5% (at CER) in 2019, through continued market penetration in key markets.

Clinical Stage Vaccine Candidates

Valneva has decided to focus its attention and resources on its two most advanced programs against Lyme disease and chikungunya. Lyme disease and chikungunya both represent a significant unmet medical need for which there are no vaccines available despite their emergence as global threats.

LYME DISEASE VACCINE CANDIDATE – VLA15
Phase 2 patient recruitment completed – new partner search initiated

Valneva recently announced the completion of patient recruitment for the Phase 2 studies of its Lyme disease vaccine candidate, VLA15.

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[5] 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.

A total of 819 subjects have been recruited for Phase 2 development in two ongoing studies. The results of these studies, comprising immunogenicity and safety data, will support the dose and vaccination schedule to be used in Phase 3.

Study VLA15-201 includes 573 subjects across nine sites in Europe and the U.S., while study VLA15-202 includes 246 subjects across five sites in the U.S.

In both studies, dosage levels of 135µg and 180µg of VLA15 are administered either at Day 1, Month 1 and Month 2 (VLA15-201) or at Day 1, Month 2 and Month 6 (VLA15-202).

Phase 2 is expected to last approximately two years with initial data (primary endpoint) expected mid-2020.

As part of the preparation for Phase 3 trials, the Company has begun a search for a suitable development and commercialization partner for its Lyme vaccine and has now appointed an advisor to assist in this process.

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 U.S. Centers for Disease Control and Prevention (CDC), approximately 300,000 Americans[4] are infected with Lyme disease annually with at least an additional further 200,000 cases in Europe[6].

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.

The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[7].

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Up to $23.4 million awarded by CEPI

In July 2019, Valneva was awarded non-dilutive financial support of up to $23.4 million by CEPI for the manufacturing and late-stage clinical development of its single-dose, live-attenuated vaccine against chikungunya[8]. The funding underwrites a partnership effort to accelerate regulatory approval of VLA1553 for use in regions where outbreaks occur and support World Health Organization (WHO) prequalification to facilitate broader access in lower and middle-income countries.

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[6] As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.
[7] Valneva press release: Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15
[8] Valneva press release: CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

Valneva had previously announced further positive Phase 1 results for its chikungunya vaccine candidate[9].

VLA1553 was generally safe in all dose groups. The low and medium dose groups were well tolerated and showed a superior safety profile, including viremia, compared to the high dose. No adverse events of special interest (e.g. chikungunya infection related) were reported up to Month 7 and the product candidate's local tolerability profile was excellent.

The results showed an excellent immunogenicity profile in all vaccinated dose groups after a single vaccination, with a 100% seroconversion achieved at Day 14 after a single vaccination in all dose groups, which was fully sustained at 100% at Month 6.

A subset of study subjects were re-vaccinated after six months. For those subjects, no anamnestic response[10] was observed, which demonstrates that a single vaccination of VLA1553 is sufficient to induce sustaining, high titer, neutralizing antibodies. Vaccinees were protected from vaccine-induced viremia serving as "intrinsic human viral challenge."

Valneva is committed to advancing its chikungunya vaccine candidate as quickly as possible and aims to follow an accelerated approval pathway into Phase 3 in the U.S., subject to FDA approval. In order to support this accelerated approach, the Company is currently generating additional non-clinical data. All of the required experiments are fully on track to be completed in 2019 and to support an End of Phase 2 (EOP2) meeting with the FDA in early 2020.

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[11] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[12]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically. Chikungunya is considered a major public health threat with no preventive vaccines or effective treatments available.

Among the three chikungunya vaccine candidates currently in clinical development, the sponsor of the first chikungunya vaccine approved in the United States will be eligible to receive a Priority Review Voucher.

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya. It was granted Fast Track designation by the FDA in December 2018[13].

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[9] *Valneva press release: Valneva Reports Further Positive Results for Its Chikungunya Vaccine Candidate*
[10] *An anamnestic response is a renewed production of an antibody on the second encounter with the same antigen*
[11] *PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[12] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*
[13] *Valneva press release: Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate*

Other Business updates

Valneva Regains All Rights to its Zika Vaccine Candidate
In 2017, Valneva and Emergent Biosolutions signed an exclusive worldwide license agreement to develop Valneva's Zika vaccine candidate VLA 1601. Valneva has now regained all rights to this vaccine candidate, following Emergent Biosolutions' decision to focus its resources on other programs after its acquisition of PaxVax and to not exercise its option to continue with product development after Phase 1. Valneva had reported positive final Phase 1 results for its Zika vaccine in May 2019. The vaccine met its primary endpoint showing an excellent safety profile in all tested doses and schedules during the entire study.

Competition for DUKORAL® expected in the course of 2020
The Company expects to face competition for DUKORAL® in Europe from the second quarter of 2020. Valneva assumes, however, that the overall product sales implications will be limited especially since DUKORAL® is a very successfully established brand and its indications are broader in Canada, the largest market for this product.

Borrowing of an additional €10 million from the European Investment Bank facility[14]
In July 2019, Valneva borrowed an additional €10 million of the remaining European Investment Bank ("EIB") facility that was granted to the Company in July 2016. Valneva has therefore borrowed a total of €20 million[15] of the €25 million facility. The Company plans to use the funds to advance its R&D programs, including its Lyme disease candidate. Under the terms of the agreement signed with the EIB, each credit tranche is repayable at the end of a five-year period commencing from the borrowing date.

VSE delisting to take place on December 20, 2019
In September, Valneva announced that the Vienna Stock Exchange ("VSE") had accepted Valneva's application for delisting and resolved to revoke the admission of Valneva shares from the Official Market. Valneva's ordinary and preferred shares will no longer trade on the VSE after December 20, 2019. They will remain tradeable on Euronext Paris (Compartment B). All Valneva shares listed on the VSE will be automatically transferred to Euronext Paris free of charge. Transfer costs will be borne by Valneva. The decision to delist from the VSE was made by the Company in order to focus on the best capital markets for life science companies and increase liquidity by centralizing trading on Euronext Paris.

Nine-month 2019 Financial Review
(Unaudited, consolidated under IFRS)

Revenues
Valneva's total revenues in the first nine months of 2019 were €81.4 million (€92.1 million excluding the GSK SAA termination effect) compared to €78.3 million in the first nine months of 2018. A net negative effect of €10.7 million was included in Valneva's collaboration and

[14] *Valneva press release: Valneva Announces Drawdown of Further €10 million from its Existing European Investment Bank Loan*
[15] *Two tranches of €5 million each have been drawn down in April and December 2017 respectively.*

licensing revenues to reflect both the current and future payment obligations related to the termination of the SAA.

Product sales revenues in the first nine months of 2019 increased to €86.4 million from €71.1 million in the first nine months of 2018, representing year-over-year growth of 22%. Revenues from collaborations and licensing amounted to negative €5.0 million (positive €5.7 million excluding the GSK SAA termination effect) in the first nine months of 2019 compared to €7.2 million in the same period of 2018.

Operating result and EBITDA

Costs of goods and services sold (COGS) were €33.4 million in the first nine months of 2019. Gross margin on product sales amounted to 65.2% compared to 59.7% in the first nine months of 2018. COGS of €19.2 million related to IXIARO®/JESPECT® sales, yielding a product gross margin of 70.0%. €9.1 million of COGS related to DUKORAL® sales, yielding a product gross margin of 53.9%. Of the remaining COGS in the first nine months of 2019, €1.8 million related to the Third Party Product distribution business and €3.3 million were related to cost of services. In the first nine months of 2018, overall COGS were €32.3 million, of which €28.7 million related to cost of goods and €3.6 million related to cost of services.

Research and development expenses in the first nine months of 2019 increased to €23.2 million from €18.2 million in the same period of 2018. This was driven by planned increased investments into Valneva's clinical stage vaccine candidates. Marketing and distribution expenses in the first nine months of 2019 amounted to €17.1 million, compared to €15.0 million in the first nine months of 2018 as a result of continued investments in Valneva's key markets USA and Canada. In the first nine months of 2019, general and administrative expenses increased to €13.0 million from €12.6 million in the same period of 2018. Amortization and impairment charges of fixed assets/intangibles in the first nine months of 2019 amounted to €2.2 million compared to €2.4 million in the first nine months of 2018.

Valneva realized an operating loss of €3.2 million (operating profit of €7.5 million excluding the GSK SAA termination effect) in the first nine months of 2019 compared to an operating profit of €0.9 million in the same period of 2018. EBITDA in the first nine months of 2019 was €3.0 million (€13.7 million excluding the GSK SAA termination effect), compared to an EBITDA of €6.1 million in the first nine months of 2018.

Net result

In the first nine months of 2019, Valneva generated a net loss amounting to €2.4 million (net profit of €8.3 million excluding the GSK SAA termination effect) compared to a net loss of €3.3 million in the first nine months of 2018.

Finance costs and currency effects in the first nine months of 2019 resulted in a net finance expense of €0.4 million, compared to a net finance expense of €3.1 million in the first nine months of 2018. The improved net finance result compared to the first nine months of the prior year was the result of foreign currency gains incurred during the first nine months of 2019, as well as lower interest expenses following the re-payment of the Biopharma (Pharmakon) loan in

early January 2019. Results from investments in associates comprise a €1.7 million profit from Valneva's 48.9% shareholding in BliNK Biomedical SAS.

Cash flow and liquidity

Net cash generated by operating activities in the first nine months of 2019 amounted to €5.0 million compared to €11.7 million in the first nine months of 2018. Cash flow from operating activities included a cash payment of €9.0 million related to the SAA termination.

Cash outflows from investing activities in the first nine months of 2019 amounted to €8.0 million, compared to €1.5 million in the first nine months of 2018, and resulted primarily from the purchase of equipment.

Cash outflows from financing activities amounted to €6.8 million in the first nine months of 2019 and consisted of €9.7 million repayments of the Biopharma (Pharmakon) loan, €2.5 million of fees related to the private placement of new shares in October 2018, €2.8 million of payments of lease liabilities, €1.3 million of interest paid and also included proceeds from a €10.0 million disbursement from the EIB debt facility as well as €1.4 million from BPI loan related to the financing of the R&D tax credit in France. Cash outflows from financing activities amounted to €12.8 million in the first nine months of 2018.

Liquid funds on September 30, 2019 stood at €67.4 million compared to €81.7 million on December 31, 2018.

About Valneva SE

Valneva is a biotech company developing and commercializing vaccines for infectious diseases with major unmet needs. 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 490 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.