VALNEVA SE
Campus Bio-Ouest | 6, Rue Alain Bombard
44800 Saint-Herblain, *France*

Valneva Reports Record Product Sales and Major Pipeline Progress in 2019

Lyme and chikungunya passed key milestones in 2019. Significant value inflection expected in 2020 including Lyme Phase 2 data and partnering in addition to chikungunya entering Phase 3 clinical development

Strong financial results in 2019[1]

- Product sales revenue of €129.5 million (€125.0 million at CER) in 2019, representing 25% growth (22% at CER[2])
  - IXIARO® sales revenue growth of 35% (31% at CER) in 2019 mainly due to high US Military orders and continuing growth in US Private market
  - DUKORAL® sales revenue growth of 4% (3% at CER) in 2019
- Total revenues were €136.9 million excluding the negative revenue recognition impact of the termination of the GlaxoSmithKline (GSK) Strategic Alliance Agreement (SAA)[3].
  - Including the GSK SAA termination effect, total revenues were €126.2 million
- Gross Margin on Product Sales Revenues of 65.3% in 2019
- EBITDA[4] excluding the effect of GSK SAA termination would have been €18.5 million in 2019
  - Including the GSK SAA termination effect, EBITDA was €7.8 million
- R&D investment of €37.9 million in 2019
- Strong cash position of €64.4 million at the end of December 2019
    - Supplemented by recent $85 million debt financing arrangement with leading US funds

Private traveler market sales expected to grow by up to 10% in 2020

- Total revenue estimated to be between €135 million and €145 million in 2020
- Valneva expects product sales revenues of between €125 million and €135 million in 2020
  - Product sales from travelers vaccine business expected to continue to grow
    - IXIARO® product sales growth in the Private travelers markets expected to be 15% (at CER) or more, primarily from US
  - US Military business peaked in 2019 and grew by over 50% compared to 2018
    - 2020 Military business may be lower than 2019 but still significantly above 2018 uptake
  - New IXIARO® supply contract with U.S. Department of Defense (DoD) expected in the first half of 2020

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[1] *Financial figures reported in this press release are unaudited. The audit procedures by the Statutory Auditors are underway. The Company plans to publish its audited annual financial report on March 31, 2020.*
[2] *CER% represents growth at constant exchange rates*
[3] *Valneva PR: Valneva Announces Mutual Agreement with GSK to End Strategic Alliance Agreement; Regains Control of R&D*
[4] *2019 EBITDA was calculated by excluding €8.6 million of depreciation, amortization and impairment from the €0.8 million operating loss as recorded in the consolidated financial statements under IFRS*

- Other revenues (service revenue, license fees) are expected to be up to €10 million in 2020
- Gross margin is expected to be similar to 2019 levels at around 65% and net operating margin, prior to R&D investments[5], is expected to be between 30% and 35%
- Valneva expects to invest up to €85 million in R&D projects, notably Lyme and chikungunya, in 2020
    - The Company recently announced a new $85 million financing arrangement with leading US Healthcare funds Deerfield and OrbiMed to further advance its leading Lyme and chikungunya programs and repay existing debt
- Valneva expects negative EBITDA of up to €35 million in 2020 due to the investment into its Lyme and chikungunya programs as they advance into late stage development

Key R&D Progress reported in 2019

- Valneva completed patient recruitment for the Phase 2 studies of its Lyme disease vaccine candidate in September 2019 and initiated a partnering process for late stage co-development and commercialization
- Valneva reported excellent final Phase 1 results for its chikungunya vaccine candidate
    - Based on these excellent Phase 1 results, and acceptance of the Accelerated Approval Pathway, the Company has held its End of Phase 2 (EoP2) meeting with the FDA and now awaits confirmation to proceed into Phase 3.
    - Valneva was awarded up to $23.4 million by the Coalition for Epidemic Preparedness Innovations (CEPI) to support the development of its chikungunya vaccine for LMIC countries
- Valneva regained full control of its R&D assets through the termination of the GSK SAA

Major R&D milestones expected in 2020

- Lyme disease vaccine candidate VLA15:
    - First Phase 2 data expected mid-2020
    - Partnering deal
- Chikungunya vaccine candidate VLA1553:
    - Final Phase 3 plans following the EoP2 meeting with the FDA expected during the first quarter 2020
    - Phase 3 initiation mid-year (pending confirmation by the FDA)

David Lawrence, Valneva's Chief Financial Officer, commented, "2019 has been a fantastic year for Valneva marked by major achievements across our business. Unlocking shareholder value is fundamental to our strategy, so 2020 and 2021 will be significant years for Valneva as we progress our two leading clinical assets into late stage development. This shapes the future of our Company. We recently strengthened our capital base to fund our key pipeline assets and with an eye to a potential US IPO in the first half of 2021."

[5] *Net operating margin is based on the P&L for the Commercial Products segment including an allocation (56%) of G&A costs from Corporate Overheads and Amortisation of Intangibles related to IXIARO®*

Financial Information[6]

(2019 unaudited results, consolidated per IFRS)

€ in million	12 months ending December 31	
	2019	2018
Product sales	129.5	103.5
Total revenues	126.2	113.0
Net profit/(loss)	(1.7)	3.3
EBITDA[7]	7.8	13.1
Cash	64.4	81.7

Saint-Herblain (France), February 27, 2020 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on prevention against diseases with major unmet needs, reported today its full year unaudited consolidated financial results for the year ending December 31, 2019. 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/mmc/p/dpm3upxc

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In 2019, revenues from IXIARO®/JESPECT® product sales grew to €94.1 million compared to €69.6 million in 2018. The 35% increase (31% at CER) was largely driven by demand in North America, both in the public and private markets.

U.S. private has been the Company's fastest growing traveler market (excluding the U.S. Military) in 2019, followed by Germany and Canada. This has been driven by dedicated and targeted efforts by our commercial teams and partners.

A Request For Proposal (RFP) for the supply of Japanese encephalitis vaccine by the U.S DoD is anticipated during the first quarter of 2020. As sole supplier of the only FDA approved Japanese encephalitis vaccine, Valneva will respond to this RFP and expects to enter into a new contract with the DoD in the second quarter of this year.

This comes in addition to the option (within the existing contract signed in 2019[8]) that the DoD exercised in January 2020. This option brought the total contract value to $70 million.

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[6] 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 March 31, 2020.

[7] 2019 EBITDA was calculated by excluding €8.6 million of depreciation, amortization and impairment from the €0.8 million operating loss as recorded in the consolidated financial statements under IFRS; 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

Valneva expects further growth from its traveler vaccine business. Based on the peak 2019 sales to US Military and the anticipated new RFP from the DoD, the Company expects 2020 IXIARO® sales to US Military to be lower than in 2019 but still significantly above 2018.

CHOLERA / ETEC[9]-DIARRHEA VACCINE (DUKORAL®)

In 2019, revenues from DUKORAL® sales increased to €31.5 million compared to €30.4 million in 2018. The 4% increase (3% at CER) was largely driven by growth in Germany and Canada.

Valneva expects DUKORAL® 2020 revenues to be similar to 2019 levels noting the likely market entry of a competitor product in some territories during 2020.

Clinical Stage Vaccine Candidates

Valneva focuses its R&D efforts 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.

LYME DISEASE VACCINE CANDIDATE – VLA15
First Phase 2 results expected mid 2020; partnering discussions ongoing

Valneva´s Lyme vaccine candidate VLA15 is the only one in clinical development today and addresses the most common tick-transmitted infection in the Northern hemisphere. The program is currently in Phase 2 and the company completed Phase 2 patient enrolment in more than 800 people in two ongoing studies at the end of September 2019.

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).

Valneva expects to report first Phase 2 results mid-2020, starting with the shorter vaccination schedule (Day 1, Month 1 and Month 2). The results of these studies, comprising immunogenicity and safety data, will support the decision on final dose and vaccination schedule for Phase 3 development.

The Company has initiated a partnering process for late stage development and future commercialization. Discussions are ongoing and the Company expects to announce a partnering process outcome in 2020.

Lyme disease is a very severe disease. 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[10].

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[8] Valneva press release: Valneva Announces New $59 Million IXIARO® Supply Contract with US Government
[9] 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.

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[11].

Peak revenue potential for a Lyme disease vaccine in the US and EU is estimated at more than $1 billion[12].

SINGLE-SHOT CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Progression into late stage development expected post conclusions from End of Phase 2 meeting with the FDA

Valneva´s single shot chikungunya vaccine candidate VLA1553 is unique and addresses a highly prevalent mosquito transmitted infection in the tropical and subtropical regions.
The company plans to take this vaccine to market with the prospect of leveraging major manufacturing and commercial synergies. Whilst Valneva will focus its efforts on the traveler vaccine market, it plans to find a partner with the support of CEPI to meet LMIC[13] needs.

In November 2019, Valneva reported excellent Phase 1 results[14]. The vaccine candidate showed an excellent immunogenicity profile in all vaccinated dose groups after a single vaccination, with a 100% seroconversion[15] achieved at Day 14. Titers were sustained at 100% at Month 12. VLA1553 was generally safe and well-tolerated with a superior safety profile in low and medium dose groups compared to the high dose group, and showed an excellent local tolerability.

Valneva has received confirmation for the Accelerated Approval Pathway from the FDA. The EoP2 meeting took place on February 24, 2020. Confirmation of the detailed Phase 3 design and timing are being discussed with the agency and are expected to be finalized in the first quarter of 2020. This may lead to a Phase 3 initiation in mid-2020.

In July 2019, Valneva was awarded non-dilutive financial support of up to $23.4 million by CEPI for the late-stage clinical development of its single-dose, live-attenuated vaccine against chikungunya[16]. 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 (LMIC).

Chikungunya is considered a major public health threat with no preventive vaccines or effective treatments available. Chikungunya is a mosquito-borne viral disease caused by the chikungunya

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[10] As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.
[11] Valneva press release: Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15
[12] Lyme Disease. L.E.K. interviews, research and analysis
[13] LMIC: Low and middle-income countries
[14] Valneva press release: Valneva Reports Excellent Final Phase 1 Results for its Chikungunya Vaccine Candidate
[15] Seroconversion is defined as the proportion of subjects achieving a CHIKV-specific neutralizing antibody titer of NT50 ≥20.
[16] Valneva press release: CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine

virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. As of 2017, there have been more than one million reported cases in the Americas[17] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[18]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically.

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[19].

The global market potential for chikungunya vaccines is estimated at up to $500 million[20]. The traveler market is estimated at around $250 million.

The sponsor of the first chikungunya vaccine approved in the United States will be eligible to receive a Priority Review Voucher (PRV).

Full Year 2019 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues in 2019 were €126.2 million (€136.9 million excluding the GSK SAA termination revenue recognition effect) compared to €113.0 million in 2018. A net negative effect of €10.7 million was included in Valneva's collaboration and licensing revenues to reflect both the paid as well as the future payment obligations related to the termination of the SAA.

Product sales revenues in 2019 increased to €129.5 million from €103.5 million in 2018, representing year-over-year growth of 25% (22% on a CER basis). Revenues from collaborations and licensing amounted to negative €3.3 million (positive €7.4 million excluding the GSK SAA termination effect) in 2019 compared to €9.6 million in 2018.

Operating result and EBITDA

Costs of goods and services sold (COGS) were €50.0 million in 2019. Gross margin on product sales amounted to 65.3% compared to 61.7% in 2018. COGS of €28.3 million related to IXIARO®/JESPECT® sales, yielding a product gross margin of 70.0%. €14.0 million of COGS related to DUKORAL® sales, yielding a product gross margin of 55.6%. Of the remaining COGS in 2019, €2.8 million related to the Third Party Product distribution business and €4.9 million were related to cost of services. In 2018, overall COGS were €44.4 million, of which €39.7 million related to cost of goods and €4.8 million related to cost of services.

Research and development expenses in 2019 significantly increased to €37.9 million from €25.3 million in 2018. This was driven by planned increased investments into Valneva's clinical

[17] *PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[18] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*
[19] *Valneva press release: Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate*
[20] *Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market*

stage vaccine candidates. Marketing and distribution expenses in 2019 amounted to €24.1 million, compared to €20.9 million in 2018 as a result of continued investments in Valneva's key markets USA and Canada. In 2019, general and administrative expenses increased to €18.4 million from €16.9 million in 2018. Amortization and impairment charges of fixed assets/intangibles in 2019 amounted to €3.0 million compared to €3.2 million in 2018.

Other income, net of other expenses in 2019 increased to €6.4 million from €4.0 million in 2018. This increase was driven by increased R&D tax credit and the income from the CEPI funding, partly offset by expenses related to a potential settlement of the merger litigation.

Valneva realized an operating loss of €0.8 million (operating profit of €9.9 million excluding the GSK SAA termination effect) in 2019 compared to an operating profit of €6.3 million in 2018. EBITDA in 2019 was €7.8 million (€18.5 million excluding the GSK SAA termination effect), compared to an EBITDA of €13.1 million in 2018.

Net result

In 2019, Valneva generated a net loss amounting to €1.7 million (net profit of €9.0 million excluding the GSK SAA termination effect) compared to a net profit of €3.3 million in 2018.

Finance costs and currency effects in 2019 resulted in a net finance expense of €1.6 million, compared to a net finance expense of €4.0 million in 2018. The improved net finance result compared to prior year was the result of foreign currency gains incurred during 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 €1.6 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 €5.5 million compared to €16.3 million in 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 2019 amounted to €10.7 million, compared to €2.9 million in 2018, and resulted primarily from the purchase of equipment.

Cash outflows from financing activities amounted to €7.7 million in 2019 and consisted of €11.7 million repayments of borrowings, €2.5 million of fees related to the private placement of new shares in October 2018, €2.7 million of payments of lease liabilities, €2.6 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 a BPI loan related to the financing of the R&D tax credit in France. Cash inflows from financing activities amounted to €30.9 million in 2018 and included €49.3 million proceeds from the private placement of new shares.

Liquid funds on December 31, 2019 stood at €64.4 million compared to €81.7 million on December 31, 2018. The main change was driven by repayment of the legacy Biopharma (Pharmakon) loan in January 2019.

About Valneva SE

Valneva is a specialty vaccine company focused on prevention against 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 unique vaccines against Lyme disease and chikungunya. Valneva has operations in Austria, Sweden, the United Kingdom, France, Canada and the US with approximately 500 employees. More information is available at www.valneva.com.

Valneva Investor and Media Contacts

Laetitia Bachelot-Fontaine
Director of Investor Relations &
Corporate Communications
M +33 (0)6 4516 7099
investors@valneva.com

Teresa Pinzolits
Corporate Communications Specialist
T +43 (0)1 20620 1116
communications@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.