VALNEVA SE
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Valneva Reports Q1 2021 Financial Results and Business Update

- **Excellent progress on clinical programs in the first quarter of 2021 for:**
  - VLA15, currently the only clinical stage vaccine candidate against Lyme disease
    - Initiation of additional Phase 2 trial to accelerate pediatric development
  - VLA2001, currently the only inactivated, adjuvanted vaccine candidate for COVID-19 in clinical trials in Europe:
    - Initiation of pivotal Phase 3 clinical trial
    - Participation in the world's first COVID-19 vaccine booster trial in the UK
    - Publication of Phase 1/2 results
  - VLA1553, currently the only Phase 3 chikungunya vaccine program worldwide
    - Recruitment completion for pivotal Phase 3 trial
- **Successful Nasdaq listing (Q2 event); $107.6 million of gross proceeds raised in a US initial public offering and a concurrent private placement in Europe**
- **Cash and cash equivalents of €235.9 million at March 31, 2021**
  - Q1 2021 cash and cash equivalents do not include proceeds of $107.6 million from the Company's recent Global Offering
- **Total revenue of €23.2 million in the first quarter of 2021 compared to €35.2 million in the first quarter of 2020**
  - Product sales of €16.1 million in the first quarter of 2021 (€32.7 million in the first quarter of 2020), affected by the COVID-19 pandemic impact on the travel industry
  - €7.1 million of Other Revenues (revenues from collaborations, licensing and services) in the first quarter of 2021 (€2.5 million in the first quarter of 2020)
- **EBITDA[1] loss of €28.3 million in the first quarter of 2021 reflecting increased R&D investment in clinical stage programs, and lower sales (compared to EBITDA profit of €2.4 million in Q1 2020)**
  - R&D investment increased to €27.7 million in the first quarter of 2021 compared to €13.3 million in the first quarter of 2020

FY 2021 financial guidance updated
Updated guidance, excluding VLA2001 related activities (including revenue, costs of goods sold, R&D investments), for full-year 2021:

- Total revenues, excluding VLA2001, of €80 million to €105 million
  - Range modified noting that, despite initial signs of recovery in travel vaccine sales being seen, the 2021 outlook remains soft
- R&D expenses, excluding VLA2001, of €65 million to €75 million

Thomas Lingelbach, Valneva's Chief Executive Officer, commented, *"Valneva continues to achieve significant R&D milestones thanks to the huge efforts of our team and our partners. Our recent successful Nasdaq listing marks a significant strategic step for Valneva as we look forward.*

[1] *EBITDA is a non-IFRS financial measure. See "Non-IFRS Financial Measures" section included herein for more information regarding our use of EBITDA and a reconciliation to operating profit (loss), the most directly comparable financial measures calculated in accordance with IFRS.*

I would like to take this opportunity to thank our existing and new shareholders, partners and employees for their support and contribution to our journey. We are now in a strong position to continue to execute our key programs and continue to build shareholder value."

Financial Information

(unaudited results, consolidated under IFRS)

€ in million	**3 months ending March 31**	
	2021	**2020**
Total revenues	23.2	35.2
Product sales	16.1	32.7
Net profit/(loss)	(27.7)	(1.2)
EBITDA	(28.3)	2.4
Cash	235.9	80.8

Saint Herblain (France), May 20, 2021 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need, reported today its first quarter financial results ending March 31, 2021. The condensed consolidated interim financial results are available on the Company's website www.valneva.com.

Valneva will provide a live webcast of its first quarter financial results conference call beginning at 3 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/bhohhzn6

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

IXIARO® is the only Japanese encephalitis vaccine licensed and available in the United States, Canada and Europe.

Sales of IXIARO® were €13.3 million in the first quarter of 2021 compared to €22.9 million in the first quarter of 2020. First quarter 2021 sales were affected by the COVID-19 pandemic's impact on the travel industry.

CHOLERA / ETEC[2]-DIARRHEA VACCINE (DUKORAL®)

DUKORAL® is an oral vaccine for the prevention of diarrhea caused by Vibrio cholerae and/or heat-labile toxin producing ETEC, the leading cause of travelers' diarrhea. DUKORAL® is authorized for use in the European Union and Australia to protect against cholera and in Canada, Switzerland, New Zealand and Thailand to protect against cholera and ETEC[8].

DUKORAL® recorded sales of €0.1 million in the first quarter of 2021 compared to €9.7 million in the first quarter of 2020. First quarter 2021 sales were significantly affected by the COVID-19 pandemic impact on the travel industry.

[2] 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
Acceleration of pediatric development

Valneva is developing VLA15, a vaccine candidate targeting Borrelia, the bacterium that causes Lyme disease. VLA15 is a multivalent recombinant protein vaccine that targets six serotypes of Borrelia representing the most common strains found in the United States and Europe. VLA15 is the only vaccine undergoing clinical trials against Lyme disease.

Valneva announced a collaboration with Pfizer for late phase development and, if approved, commercialization of VLA15[3]. Valneva has reported positive initial results for two Phase 2 clinical trials of VLA15 in over 800 healthy adults.

As part of the collaboration with Pfizer, Valneva announced in December 2020[4] that it had accelerated VLA15's pediatric development with the initiation of an additional Phase 2 clinical trial, VLA15-221. The dosing of the first trial participant in March 2021[5] triggered a milestone payment from Pfizer of $10 million that was received in the second quarter of 2021. Initial pediatric data are expected by mid-2022.

SARS-CoV-2 VACCINE CANDIDATE – VLA2001
Pivotal Phase 3 clinical trial initiated

VLA2001 is a vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. VLA2001 is currently the only whole virus, inactivated, adjuvanted vaccine candidate in clinical trials against COVID-19 in Europe.

In April 2021, Valneva reported initial data from the Phase 1/2 clinical trial in which VLA2001 showed high immunogenicity and was generally well tolerated, with no safety concerns identified.

The Company initiated a pivotal Phase 3 clinical trial in April 2021 and aims to make initial regulatory licensure submissions in the autumn of 2021. In parallel, Valneva has developed viral seed banks, including South African and Kent, to be in a position to manufacture variant-based vaccines.

Valneva also announced yesterday that it is participating in a UK government-funded clinical trial looking at different COVID-19 'booster' vaccines. The Cov-Boost trial, led by University Hospital Southampton NHS Foundation Trust, will look at seven different COVID-19 vaccines, including Valneva's inactivated vaccine VLA2001, as potential boosters. It will be the first trial in the world to provide vital data on how effective a booster of each vaccine is in protecting individuals from the virus.

The vaccines will be given at least three months after a second dose as part of the ongoing vaccination programme. One booster will be provided to each volunteer and could be a different brand to the one they were originally vaccinated with. The trial will also include a control group.

[3] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[4] Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate
[5] *Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate*

Initial results from the trial, expected in September, will help inform decisions by the UK Joint Committee on Vaccination and Immunisation (JCVI) on any potential booster programme from autumn this year, ensuring the UK's most vulnerable people are given the strongest possible protection over the winter period.

Although vaccines against SARS-CoV-2 have already been approved, given the potential advantages often associated with inactivated whole virus vaccines, Valneva believes its vaccine will play a role in the overall portfolio of SARS-CoV-2 vaccines that will address the global need during the pandemic and in the future.

In September 2020, Valneva announced a collaboration with the UK Government, which has the option to purchase up to 190 million doses through 2025[6]. So far, the UK Government has ordered 100 million doses for supply in 2021 and 2022.

VLA2001 is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for Valneva's licensed Japanese encephalitis vaccine, IXIARO®. Valneva has commenced production in parallel to the ongoing clinical development in order to prepare for deliveries of VLA2001 following approval, if received.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Pivotal Phase 3 clinical trial initiated

VLA1553 is a vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to more than 100 countries with the potential to rapidly expand further. There are currently no preventive vaccines or effective treatments for the chikungunya virus available and, to Valneva's knowledge, VLA1553 is the only chikungunya vaccine candidate in Phase 3 clinical trials worldwide.

VLA1553 is a live-attenuated, single dose vaccine candidate for protection against chikungunya disease. VLA1553 has been designed by deleting a part of the chikungunya virus genome. As a live-attenuated vaccine, VLA1553 is particularly well suited to target long-lasting protection which differentiates it when compared to other chikungunya assets that are being evaluated in clinical trials.

The pivotal Phase 3 trial, VLA1553-301, was initiated in September 2020. The primary objective of the trial is to evaluate the immunogenicity and safety of VLA1553 at 28 days following a single immunization. A total of 4,131 adults aged 18 or above have been recruited across 44 sites in the United States[7]. Valneva has also initiated a clinical lot-to-lot consistency trial to show manufacturing consistency of the vaccine and an antibody persistence trial that will follow the immunogenicity subset for a period of up to five years.

[6] *Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program*
[7] *Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial*

The FDA has confirmed that Valneva can seek licensure through the FDA's accelerated approval pathway. Therefore, the Company plans to seek licensure of the vaccine based on a surrogate of protection that is expected to reasonably predict protection from chikungunya infection.

VLA1553 received Fast Track designation from the FDA and PRIME designation from the European Medicines Agency. The sponsor of the first chikungunya vaccine Biologics License Application to be approved in the United States may be eligible to receive a Priority Review Voucher.

To make VLA1553 accessible to Low and Middle Income Countries (LMIC), Valneva and the Butantan Institute in Brazil entered into a collaboration agreement in January 2021 for the development, manufacturing and marketing of VLA1553[8]. The collaboration falls within the framework of the $23.4 million funding agreement Valneva signed with the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019[9].

First Quarter 2021 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €23.2 million in the first quarter of 2021 compared to €35.2 million in the first quarter of 2020.

Product sales declined by 50.7% to €16.1 million in the first quarter of 2021 compared to €32.7 million in the first quarter of 2020. On a CER basis[10], product sales declined by 47.8% in the first quarter of 2021 compared to the first quarter of 2020 due to the COVID-19 pandemic impact on the travel industry. IXIARO®/JESPECT® sales declined by 41.8% (37.2% at CER) to €13.3 million and DUKORAL® sales by 98.9% (98.8% at CER) to €0.1 million in the first quarter of 2021 compared to €22.9 million and €9.7 million respectively in the first quarter of 2020. Third Party product sales grew to €2.7 million in the first quarter of 2021 from €0.1 million in the first quarter of 2020. The increase in Third Party product sales was driven by incremental sales related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur/RabAvert and Encepur in certain territories that commenced in 2021.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €7.1 million in the first quarter of 2021 compared to €2.5 million in the first quarter of 2020. This increase is primarily attributable to the €2.6 million of revenues related to the Lyme R&D collaboration agreement with Pfizer which was the main driver for the increase in collaboration and licensing revenues.

Operating result and EBITDA

Costs of goods and services sold (COGS) were €14.6 million in the first quarter of 2021. Gross margin on product sales was 41.7% compared to 67.3% in the first quarter of 2020. The decline

[8] *Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for Low and Middle Income Countries*
[9] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[10] *CER: Constant Exchange Rate; First quarter 2020 actuals restated to first quarter 2021 average exchange rates*

was mainly related to idle capacity costs combined with compressed product sales, both impacting gross margin as a percentage of sales. COGS of €5.9 million were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 55.9%. COGS of €1.7 million were related to DUKORAL® sales, causing a negative product gross margin. Of the remaining COGS in the first quarter of 2021, €1.9 million were related to the Third Party Product distribution business and €5.1 million were related to cost of services. In the first quarter of 2020, overall COGS were €12.8 million, of which €10.7 million related to cost of goods and €2.1 million related to cost of services.

Research and development investments continued to increase as planned in the first quarter of 2021, growing to €27.7 million compared to €13.3 million in the first quarter of 2020. This was mainly driven by investments in Valneva's COVID-19 vaccine VLA2001 as well as Phase 3 clinical study costs for Valneva's chikungunya vaccine program VLA1553. Excluding COVID-19, research and development investments amounted to €12.1 million in the first quarter of 2021 compared to €13.1 million in the first quarter of 2020. Marketing and distribution expenses in the first quarter of 2021 amounted to €4.9 million compared to €6.0 million in the first quarter of 2020. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity as a result of the COVID-19 pandemic. Marketing and distribution expenses in the first quarter of 2021 notably included €1.2 million of expenses related to the launch preparation costs of the chikungunya vaccine candidate (compared to none in the first quarter of 2020). In the first quarter of 2021, general and administrative expenses increased to €10.0 million from €5.2 million in the first quarter of 2020, mainly driven by increased costs to support corporate transactions and projects.

Other income, net of other expenses, increased to €3.0 million in the first quarter of 2021 from €2.2 million in the first quarter of 2020. This increase was mainly driven by increased R&D tax credits directly resulting from increased R&D spending.

Valneva recorded an operating loss of €31.1 million in the first quarter of 2021 compared to an operating profit of €0.1 million in the first quarter of 2020. EBITDA loss in the first quarter of 2021 was €28.3 million compared to an EBITDA profit of €2.4 million in the first quarter of 2020.

Net result

In the first quarter of 2021, Valneva generated a net loss amounting to €27.7 million compared to a net loss of €1.2 million in the first quarter of 2020.

Finance costs and currency effects in the first quarter of 2021 resulted in a net finance income of €3.1 million, compared to a net finance expense of €2.2 million in the first quarter of 2020. This was mainly a result of foreign exchange gains amounting to €7.7 million in the first quarter of 2021 primarily driven by revaluation gains of non-Euro denominated balance sheet positions compared to a net foreign exchange loss of €1.0 million in the first quarter of 2020. Interest charges increased to €4.6 million in the first quarter of 2021 compared to €1.3 million in the same period of 2020. This growth was driven by increased interest charges related to the financing agreement with US healthcare funds Deerfield & Orbimed entered into in 2020 as well as interest charges related to refund liabilities.

Cash flow and liquidity

Net cash generated by operating activities amounted to €47.6 million in the first quarter of 2021 compared to €3.0 million in the first quarter of 2020 mainly driven by milestone payments related to the COVID supply agreement concluded with the UK Government in September 2020.

Cash outflows from investing activities amounted to €16.9 million in the first quarter of 2021 compared to €0.6 million in the first quarter of 2020 mainly as a result of purchases of equipment related to the site expansion activities related to COVID manufacturing in both Scotland and Sweden.

Cash outflows from financing activities amounted to €1.6 million in the first quarter of 2021 and consisted of €3.4 million of interest payments as well as €2.2 million of cash proceeds related to issuance of new shares related to employee stock option programs. Cash inflows in the first quarter of 2020 amounted to €14.5 million and consisted of net proceeds from the financing arrangement with US healthcare funds Deerfield and OrbiMed, offset by €20.0 million of repayments of borrowings to the European Investment Bank (EIB).

Liquid funds increased to €235.9 million as of March 31, 2021 compared to €204.4 million as of December 31, 2020. The main changes related to payments made by the UK Government within the framework of the UK COVID-19 partnership.

About Valneva SE

Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

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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 expected total revenues and R&D expenses for full fiscal year 2021, 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 and estimates for future performance. 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 future performance. 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.

Non-IFRS Financial Measures

Management uses and presents IFRS results as well as the non-IFRS measure of EBITDA to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful as an aid to further understand Valneva's current performance, performance trends, and financial condition.

EBITDA is a common supplemental measure of performance used by investors and financial analysts. Management believes this measure provide additional analytical tools. EBITDA is defined as earnings (loss) from continuing operations before interest expense, income taxes, depreciation and amortization.

A reconciliation of EBITDA to operating profit (loss), the most directly comparable IFRS measure, is set forth below:

€ in million	**3 months ending March 31**	
	2021	**2020**
Operating (loss)/Profit	(31.1)	0.1
Add:		
Amortization	1.5	1.5
Depreciation	1.3	0.8
EBITDA	**(28.3)**	**2.4**