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Valneva Reports Q1 2022 Results and Provides Corporate Updates

Excellent progress on clinical programs

Lyme Disease Vaccine Candidate VLA15

- Further positive Phase 2 results reported, including first pediatric data
- Phase 3 expected to commence in the third quarter of 2022

Inactivated COVID-19 Vaccine Candidate VLA2001

- Conditional Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK)
- Emergency use authorization granted by the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain and first vaccinations confirmed
- Rolling review ongoing with the European Medicines Agency (EMA); Valneva has provided responses to the latest list of questions (LOQ)

Single-Shot Chikungunya Vaccine Candidate VLA1553

- Final positive pivotal Phase 3 results reported
- Pre-submission discussions initiated with the US Food and Drug Administration (FDA)

First COVID-19 vaccine sales and strong cash position

- **Total revenue of €21.8 million in the first quarter of 2022 compared to €23.2 million in the first quarter of 2021**
  - Includes product sales of €16.2 million (vs €16.1 million in the first quarter of 2021) with first COVID-19 vaccine sales of €3.8 million
  - €5.6 million of other revenues (vs €7.1 million in the first quarter of 2021)

- **Cash position of €311.3 million at March 31, 2022**
  - Up to an additional $40 million made available in April 2022 as part of a recent upsized financing arrangement with leading US Healthcare Funds Deerfield and OrbiMed (of which $20 million conditioned to EMA's approval of VLA2001)

FY 2022 financial guidance confirmed

The Company confirms it still expects its total 2022 revenues to be within the range announced in February (€430 million to €590 million). Considering the uncertainties on the timing of product deliveries, the distribution of total revenues by revenue category may differ from the figures announced in February.

Financial Information
(unaudited results, consolidated per IFRS)

€ in million	3 months ending March 31	
	2022	2021
Total revenues	21.8	23.2
Product sales	16.2	16.1
Net loss	(26.0)	(27.7)
Adjusted EBITDA[1]	(18.4)	(28.3)
Cash	311.3	235.9

Saint-Herblain (France), May 5, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, today reported its first quarter financial results ending March 31, 2022 and provided corporate updates. The condensed consolidated interim financial results are available on the Company's website (Financial Reports – Valneva).

Valneva will provide a live webcast of its first quarter financial results conference call beginning at 3 p.m. CEST or 9 a.m. EDT today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/pykk7aep

Peter Bühler, Valneva's Chief Financial Officer, commented, "*Valneva continued to achieve significant milestones in the first quarter of the year with the first approval and first sales of our COVID-19 vaccine, successful completion of the pivotal Phase 3 trial of our chikungunya vaccine candidate and further positive Phase 2 results for our Lyme disease vaccine candidate. More recently, receiving conditional approval from the UK MHRA is a great recognition for our inactivated COVID-19 vaccine and we are now focused on making it available to additional people in geographical Europe and other regions of the world. The first quarter was also marked by tangible signs of a travel industry recovery which has already started to positively impact our travel vaccine sales. I would like to take this opportunity to thank our shareholders, partners and employees for their ongoing support and contribution.*"

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Further positive Phase 2 results reported including first pediatric data

Valneva and Pfizer[2] are developing VLA15, a Lyme disease vaccine candidate that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. The vaccine candidate covers the six OspA serotypes expressed by *Borrelia burgdorferi sensu lato* species that are prevalent in North America and Europe.

In April 2022, Valneva and Pfizer reported first pediatric results for VLA15. In the Phase 2 study, VLA15 was found to be more immunogenic in pediatric participants (5-17 years old) than in adults with both two-dose or three-dose vaccination schedules. These positive data build on the strong

[1] *For additional information on Adjusted EBITDA, please refer to the "Non-IFRS Financial Measures" section at the end of the PR*
[2] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*

immunogenicity profile reported for adult participants (18-65 years old) in February 2022. Based on these latest Phase 2 immunogenicity and safety data, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule for both adult and pediatric participants in a Phase 3 clinical trial planned to-start in the third quarter of 2022.

SARS-CoV-2 INACTIVATED VACCINE CANDIDATE – VLA2001
UK MHRA Conditional Marketing Authorization granted

VLA2001 is currently the only whole virus, inactivated, adjuvanted COVID-19 vaccine candidate that has received an approval in geographical Europe. It is produced using Valneva's established Vero-cell platform, leveraging the manufacturing technology for the Company's commercial Japanese encephalitis vaccine, IXIARO®.

Valneva recently initiated a heterologous booster trial of VLA2001 to provide booster data following primary vaccination with an mRNA vaccine or natural COVID-19 infection[3]. These data, if positive, could support potential use of VLA2001 as heterologous booster, subject to applicable regulatory recommendations and approvals. Topline results are expected in the third quarter of 2022.

In April 2022, VLA2001 was granted Conditional Marketing Authorization by the UK Medicines and Healthcare products Regulatory Agency (MHRA) for primary immunization in adults 18 to 50 years of age[4]. This authorization followed emergency use authorization from the Bahraini NHRA in March 2022[5].

Valneva remains focused on achieving a Conditional Marketing Authorization for VLA2001 within the European Union. The Company is still in a rolling review process with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). Following its April meeting, the CHMP provided another List of Questions, to which Valneva has already responded. If the CHMP accepts these responses, the Company would expect a Conditional Marketing Authorization this quarter.

The Company signed a supply agreement with the European Commission (EC) in November 2021[6].

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Final Positive Phase 3 Results reported

Valneva is developing a single-dose vaccine candidate against the chikungunya virus, a mosquito-borne virus that has spread to over 100 countries.

In March 2022, Valneva announced successful completion of the Phase 3 pivotal trial of VLA1553[7]. The final six-month analysis confirmed the very high level of seroprotection reported in August 2021. Six months after receiving a single vaccination, 96.3% of participants showed protective chikungunya virus-neutralizing antibody titers. VLA1553's safety and tolerability profile was also

[3] *Valneva Initiates Heterologous Booster Trial of Inactivated, COVID-19 Vaccine Candidate*
[4] *Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine – Valneva*
[5] *Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001 – Valneva*
[6] *Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001*
[7] *Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate – Valneva*

consistent with topline Phase 3 data. Valneva has initiated pre-submission discussions with the US FDA and expects to submit its Biologics License Application (BLA) in the second half of 2022.

The Company also previously reported positive topline lot-to-lot manufacturing consistency trial results for VLA1553[8]. This is one of the standard requirements for vaccine licensure, and final lot-to-lot results are expected in the second quarter of 2022.

Valneva also initiated a Phase 3 trial in adolescents in January 2022. The trial, conducted in Brazil by Instituto Butantan, is designed to support label extension to this age group following a potential initial regulatory approval in adults in the US[9]. Funded by the Coalition for Epidemic Preparedness Innovations, the trial is also expected to support licensure of the vaccine in Brazil, which would be the first potential approval for use in an endemic region.

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

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

IXIARO®/JESPECT® product sales decreased by 68.6% (70.5% at constant exchange rates) to €4.2 million in the first quarter of 2022 compared to €13.3 million in the first quarter of 2021. Sales to the private travel markets showed significant recovery with IXIARO®/JESPECT® sales reaching €3.9 million in the first quarter of 2022 compared to €1.0 million in the first quarter of 2021 while sales to the US Government's Department of Defense (DoD) were lower in the first quarter of 2022 compared to the same period last year as per the planned delivery schedule.

CHOLERA / ETEC[10]-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.

DUKORAL® product sales increased significantly to €2.5 million in the first quarter of 2022 compared to €0.1 million in the first quarter of 2021 equally attributable to a recovery of the travel business across all markets.

[8] *Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate*
[9] *Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate – Valneva*
[10] *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.*

First Quarter 2022 Financial Review
(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues were €21.8 million in the first quarter of 2022 compared to €23.2 million in the first quarter of 2021, a decrease of 5.9%.

Product sales, including first COVID-19 vaccine sales, increased by 0.2% to €16.2 million in the first quarter of 2022 compared to €16.1 million in the first quarter of 2021. On a constant exchange rate (CER) basis, product sales decreased by 4.8% in the first quarter of 2022 as compared to the first quarter of 2021. Product sales excluding COVID-19 vaccine sales amounted to €12.4 million in the first quarter of 2022, a decrease of 23.3% (27.2% at CER) compared to the first quarter of 2021.

IXIARO®/JESPECT® product sales decreased by 68.6% (70.5% at CER) to €4.2 million in the first quarter of 2022 compared to €13.3 million in the first quarter of 2021. Sales to the private travel markets showed significant recovery while sales to the US Government's Department of Defense (DoD) were lower in the first quarter of 2022 compared to the same period last year as per the planned delivery schedule. DUKORAL® also benefited from the travel market recovery as sales increased significantly to €2.5 million in the first quarter of 2022 compared to €0.1 million in the first quarter of 2021. COVID-19 product vaccine sales amounted to €3.8 million resulting from first shipments of VLA2001 to Bahrain. Third Party product sales more than doubled to €5.6 million in the first quarter of 2022 from €2.7 million in the first quarter of 2021 driven by growth related to Valneva's distribution agreement with Bavarian Nordic for the sales of Rabipur®/RabAvert® and Encepur®.

Other revenues, including revenues from collaborations, licensing and services amounted to €5.6 million in the first quarter of 2022 compared to €7.1 million in the first quarter of 2021.

Operating Result and EBITDA

Costs of goods and services sold (COGS) were €13.9 million in the first quarter of 2022. Gross margin on product sales excluding COVID-19 sales was 68.5% compared to 41.7% in the first quarter of 2021. Both IXIARO® and DUKORAL®'s gross margins, of 99.3% and 92.0% respectively, were affected by inventory revaluation gains and releases of write-off provisions resulting from increased sales projections as well as the positive effect from the Company's share price development on the employee share-based compensation programs. Of the remaining COGS for the first quarter of 2022, €3.7 million were related to the Third-Party product distribution business, €8.0 million to the COVID-19 business and €1.9 million to cost of services. In the first quarter of 2021, overall COGS were €14.7 million, of which €9.6 million related to cost of goods and €5.1 million related to cost of services.

Research and development investments amounted to €20.7 million in the first quarter of 2022 compared to €27.7 million in the first quarter of 2021. This decrease was mainly driven by the progression of Valneva's chikungunya vaccine program, VLA1553, towards BLA submission and the lower clinical trial costs resulting from it as well as lower investments in Valneva's COVID-19 vaccine candidate VLA2001. Marketing and distribution expenses in the first quarter of 2022 amounted to €2.0 million compared to €4.9 million in the first quarter of 2021. Marketing and distribution expenses in the first quarter of 2022 notably included €0.9 million of expenses related to the launch preparation

costs of the chikungunya vaccine candidate, VLA1553, (compared to €1.2 million in the first quarter of 2021). In the first quarter of 2022, general and administrative expenses declined to €5.8 million from €10.0 million in the first quarter of 2021. COGS, research and development, marketing and distribution as well as general and administrative expenses benefited from a provision release of €11.7 million related to the positive effect of the Company's share price development on the employee share-based compensation programs. This income compares to a cost of €4.8 million in the first quarter of 2021.

Other income, net of other expenses, reduced to €2.1 million in the first quarter of 2022 from €3.0 million in the first quarter of 2021. This decrease was mainly driven by reduced R&D tax credits directly resulting from lower R&D spending.

Valneva recorded an operating loss of €18.4 million in the first quarter of 2022 compared to an operating loss of €31.1 million in the first quarter of 2021. Adjusted EBITDA loss in the first quarter of 2022 was €12.7 million compared to an EBITDA loss of €28.3 million in the first quarter of 2021.

Net Result

In the first quarter of 2022, Valneva generated a net loss of €26.0 million compared to a net loss of €27.7 million in the first quarter of 2021.

Finance expense and currency effects in the first quarter of 2022 resulted in a net finance expense of €7.1 million, compared to a net finance income of €3.1 million in the first quarter of 2021. This was mainly a result of a foreign exchange loss amounting to €2.4 million in the first quarter of 2022, primarily driven by revaluation results of non-Euro denominated balance sheet positions, compared to a net foreign exchange gain of €7.7 million in the first quarter of 2021. Interest charges slightly increased to €4.7 million in the first quarter of 2022 compared to €4.6 million in the first quarter of 2021.

Cash Flow and Liquidity

Net cash used in operating activities amounted to €26.9 million in the first quarter of 2022 compared to €47.6 million of cash generated in operating activities in the first quarter of 2021. Cash outflows in the first quarter of 2022 were mainly related to the operating loss generated in the period, while during the first quarter of 2021 cash inflows mainly resulted from pre-payments related to the vaccine supply agreement signed with the UK government.

Cash outflows from investing activities amounted to €9.4 million in the first quarter of 2022 compared to €16.9 million in the first quarter of 2021, both mainly as a result of COVID-19-related construction activities across production sites in Scotland and Sweden, as well as equipment purchases.

Net cash generated from financing activities amounted to €1.0 million in the first quarter of 2022, which was mainly a result of proceeds from the issuance of new shares in relation to employee stock option and free share programs. Cash outflows in the first quarter of 2021 amounted to €1.6 million and mainly consisted of payments related to interest and lease liabilities.

Liquid funds decreased to €311.3 million as of March 31, 2022, compared to €346.7 million as of December 31, 2021. The cash decrease mainly resulted from ongoing COVID-19-related investments into fixed assets and R&D expenses.

Non-IFRS Financial Measures

Management uses and presents IFRS results, as well as the non-IFRS measure of Adjusted 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 to further understand Valneva's current performance, performance trends, and financial condition.

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

A reconciliation of Adjusted EBITDA to operating loss, which is the most directly comparable IFRS measure, is set forth below:

€ in million	**3 months ending March 31**	
(unaudited results, consolidated per IFRS)	**2022**	**2021**
Operating Loss	(18.4)	(31.1)
Add:		
Amortization	1.6	1.5
Depreciation	3.6	1.3
Impairment of Tangible Assets	-	-
Adjusted EBITDA	**(13.3)**	**(28.3)**

About Valneva SE

Valneva is a specialty vaccine company focused on the development, production and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva 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 but not limited to statements regarding expected total revenues for full fiscal year 2022, possible regulatory approvals of product candidates, and initiation of clinical trials. 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 results. 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 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, regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, the ability to obtain or maintain patent or other proprietary intellectual property protection, the cancellation of existing contracts, including but not limited to the VLA2001 supply agreement with the UK government, and the impact of the COVID-19 pandemic, the occurrence of any of which could substantially harm Valneva's business, financial condition, prospects and results of operations. 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 this press release as of the date hereof and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.