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Valneva Reports H1 Results Marked by Major Corporate Achievements and Strong Cash Position

- **Unprecedented partnering deal signed with Pfizer for Lyme disease vaccine**
- **Binding preliminary agreement now in place with UK government to provide initial funding for manufacturing expansion of SARS-CoV-2 vaccine; agreement in principle to supply up to 100 million doses to UK government**
- **Positive initial results for Phase 2 study of Lyme disease vaccine VLA15**
- **Positive End-of-Phase 2 chikungunya meeting with the U.S. FDA**
- **Marketing and distribution partnership with Bavarian Nordic**
- **Product sales revenue adversely impacted by COVID-19 pandemic**
- **$85 million financing arrangement with leading US healthcare funds**

Strong cash position of €200 million at end of June 2020; H1 product sales revenue affected by COVID-19 pandemic

- Strong cash position of €200 million at the end of June 2020
  - Driven by $130 million upfront payment from Lyme vaccine collaboration with Pfizer[1]
  - Augmented by $85 million debt financing arrangement with leading U.S. funds in February 2020[2]. $60 million drawn down as at June 30, 2020
- Total revenues of €47.9 million in H1 2020 compared to €54.5 million in H1 2019
  - Product sales revenue of €40.9 million in H1 2020 adversely affected by the COVID-19 pandemic (€61.6 million in H1 2019)
- EBITDA[3] loss of €17.2 million in H1 2020 compared to an EBITDA profit of €2.4 million in H1 2019
  - Reflects increased R&D investment of €33 million in H1 2020 compared to €14.1 million in H1 2019

Valneva FY 2020 total revenue guidance confirmed with major EBITDA improvement compared to original guidance

- Subject to continuing uncertainty regarding the ongoing COVID-19 pandemic, Valneva forecasts total 2020 revenues of €120 million to €140 million, broadly in line with its original guidance
  - Guidance includes approximately €70 million to €80 million of product sales revenues
  - €40 million to €50 million revenue to be recognized resulting from the Lyme vaccine partnership with Pfizer
  - Approximately €10 million of Service and Technology revenues.
- Valneva expects R&D investments of up to €80 million including:
  - Lyme program related costs, noting the recent Lyme collaboration
  - Phase 3 initiation of the chikungunya vaccine candidate in Q4 2020
  - Initial investments in the Company´s SARS-CoV-2 vaccine candidate (VLA2001)

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[1] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[2] *Valneva Announces New $85 Million Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed*
[3] *H1 2020 EBITDA was calculated by excluding €4.7 million of depreciation and amortization from the €21.9 million operating loss as recorded in the consolidated income statement under IFRS*

- Valneva now estimates EBITDA of between zero and negative €10 million in 2020 (compared to its original guidance of up to €35 million negative EBITDA)

Significant milestones reported for R&D programs since the beginning of the year

- Signing of an unprecedented collaboration with Pfizer for Phase 2 Lyme disease vaccine VLA15[4]
  - $130 million upfront and $35 million development milestones
  - Up to a further $143 million in early commercialization milestone payments
  - Tiered royalties on sales starting at 19%
  - Valneva to fund 30% of all development costs through completion of development program
- Positive initial results for first Phase 2 study of Lyme disease vaccine candidate reported[5]. Initial results for second Phase 2 study expected within a few months.
- Positive End of Phase 2 meeting with the FDA for chikungunya vaccine candidate VLA1553[6]. Chikungunya Phase 3 study expected to commence in the fourth quarter of 2020
- Initiation of VLA2001 – a SARS-CoV-2 vaccine development program for COVID-19[7]
  - Binding preliminary agreement with UK government to provide initial funding of over £10 million to support expansion of Valneva's UK based manufacturing facilities; final supply agreement including further investments in manufacturing and clinical trials to be negotiated within the coming weeks
  - Agreement in principle with the UK government to provide up to 100 million doses of Valneva's SARS-CoV-2 vaccine candidate[8]
  - Valneva's SARS-CoV-2 vaccine to be manufactured at Valneva's FDA approved plant in Livingston, Scotland, with investment also at Solna, Sweden

David Lawrence, Valneva's Chief Financial Officer, commented, "The excellent progress across our business in all areas outweighs the adverse impact of the COVID-19 pandemic on the travel industry and our product sales revenues. The debt financing combined with the Pfizer partnership and the excellent progress with the UK Government collaboration puts the Company in a very strong position."

H1 2020 Financial Information

(unaudited, consolidated under IFRS)

€million	**6 months ending June 30**	
	2020	**2019**
Total revenues	47.9	54.5
Product sales	40.9	61.6
Net profit / (loss)	(25.6)	(2.4)
EBITDA	(17.2)	2.4
Cash	200.0	69.9

[4] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[5] *Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate*
[6] *Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study*
[7] *Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19*
[8] *Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program*

Saint Herblain (France), August 4, 2020 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company focused on prevention against diseases with major unmet needs, reported today its consolidated financial results for the first half of the year, ended June 30, 2020. The half year financial report, including the condensed consolidated interim financial report and the half year management report, is available on the Company's website www.valneva.com.

Valneva will provide a live webcast of its first-half 2020 results conference call beginning at 3 p.m. CEST today. This webcast will also be available on the Company's website. Please refer to this link: https://edge.media-server.com/mmc/p/usuqkrat

Commercial Vaccines

JAPANESE ENCEPHALITIS VACCINE (IXIARO®/JESPECT®)

In the first half of 2020, revenues from IXIARO®/JESPECT® product sales reached €28.4 million compared to €45.1 million in the first half of 2019. Sales were affected by the impact of the COVID-19 pandemic on the travel market primarily in the second quarter of the year.

During the first half of 2020, the US Government's Department of Defense (DoD) issued a Request For Proposal (RFP) for the supply of Japanese encephalitis vaccines to the U.S. military. As sole supplier of the only U.S. FDA approved Japanese encephalitis vaccine, Valneva has responded to this RFP and expects to enter into a new contract with the DoD imminently. Based on the RFP, Valneva expects the contract to span a total of three years (one base year and two further years via options) providing, for the first time, greater demand visibility which is especially important at a time when the travel market is hit by the COVID-19 outbreak.

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

In the first half of 2020, revenues from DUKORAL® sales reached €12.1 million compared to €15.2 million in the first half of 2019. DUKORAL® sales were also adversely impacted by the COVID-19 pandemic effect on travel in the second quarter of the year.

OVERALL SALES OUTLOOK

Taking into account the ongoing COVID-19 situation, Valneva expects that its sales could return to 2019 levels in 2022 with the expected sales recovery of its 2 commercial products and the marketing and distribution partnership with Bavarian Nordic announced in June 2020[10]. The successful development of a SARS-CoV-2 vaccine could accelerate that timeline.

MODIFICATION TO MINIMUM REVENUE COVENANT UNDER CREDIT AGREEMENT

Owing to (a) deferred recognition of revenues from the Pfizer deal under IFRS rules and (b) the forecasted product sales in the context of the COVID-19 pandemic, the Company was at risk of not meeting the minimum revenue covenant (€115 million on a 12-month rolling basis assessed monthly) under its Credit Agreement with its lenders, OrbiMed and Deerfield. Following discussions, an agreement was reached at the end of July whereby this minimum revenue

[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.*

[10] *Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership*

covenant will not apply until December 31, 2020, inclusive, in exchange for a minimum cash requirement of €75 million (instead of €35 million) during that period.

Clinical Stage Vaccine Candidates

LYME DISEASE VACCINE CANDIDATE – VLA15
Partnering deal with Pfizer; **Positive initial Phase 2 results reported**

Valneva has developed a multivalent vaccine candidate, VLA15, which is currently the only active vaccine program in clinical development against Lyme disease. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[11] and, in April 2020, the Company signed an exclusive, worldwide partnering deal with Pfizer Inc. for the late stage development and future commercialization of VLA15[12].

Valneva and Pfizer will work closely together throughout the development of VLA15. Valneva is eligible to receive a total of $308 million including a $130 million upfront payment received in May 2020. Under the terms of the agreement, Valneva will fund 30% of all development costs through completion of the development program and, in return, Pfizer will pay Valneva tiered royalties starting at 19%. Pfizer will lead late-stage development and have sole control over commercialization.

In July 2020, Valneva reported positive initial results for the first Phase 2 study (VLA15-201) of Lyme disease vaccine candidate VLA15[13]. The study met its endpoints. Compared to Phase 1, the higher doses used in this trial elicited higher antibody responses across all serotypes with Seroconversion Rates (SCR) in the highest dose ranging from 81.5% (ST1) to 95.8% (ST2). In the age group comparable to the age group investigated in Phase 1 (18-49 years), SCRs ranged from 85.6% to 97%. The immunological response in older adults, one of the main target groups for a Lyme vaccine, is particularly encouraging. Results did not indicate that prior exposure to Lyme (sero-positivity) has an impact on immunogenicity or safety. As part of further Phase 2 data to be released in a few months, an analysis of the functionality of the antibodies generated with VLA15 will be conducted. In close collaboration with regulatory authorities, Valneva has developed a Serum Bactericidal Antibody assay ("SBA") for that purpose.

VLA15 was generally safe across all dose and age groups tested. No related Serious Adverse Events (SAEs) were observed with VLA15 in this study in any treatment group. Reactogenicity decreased with subsequent vaccinations. Overall, the tolerability profile, including rates of fever, appeared to be comparable to other lipidated recombinant vaccines or lipid-containing formulations.

This first Phase 2 study, conducted in the EU and US, included 572 healthy adults aged 18 to 65 years. In the main study phase, 452 subjects received one of two dose levels (either 135µg or 180µg) of VLA15 (approximately 180 subjects each) in three injections (Days 1, 29 and 57) or placebo (approximately 90 subjects). Immunogenicity was measured by determining IgG

[11] *Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15*
[12] *Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15*
[13] *Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate*

antibodies against each of the six most prevalent Outer Surface Protein A serotypes of Lyme borreliosis in the US and Europe covered by the vaccine. The endpoint readout was immunogenicity at Day 85 (one month after finalization of primary immunization).

Valneva expects to report initial results for the second Phase 2 study, VLA15-202, within a few months. In the VLA15-202 study, identical doses to the VLA15-201 study were tested using a longer vaccination schedule (Days 1, 57 and 180).

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[14].

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.

Peak revenue potential for a Lyme disease vaccine in the U.S. and EU is estimated at more than $1 billion[15] annually.

CHIKUNGUNYA VACCINE CANDIDATE – VLA1553
Phase 3 initiation expected in the fourth quarter

Valneva has developed a unique vaccine candidate, VLA1553, which is the only single-shot target product profile vaccine in clinical development today. The program was granted Fast Track designation by the FDA in December 2018[16]. Valneva plans to take VLA1553 to market with the prospect of leveraging major manufacturing and commercial synergies primarily focusing on the traveler vaccine market.

To make VLA1553 also accessible to Low and Middle Income Countries (LMIC), Valneva and the Butantan Institute in Brazil signed a binding term sheet in May 2020 for the development, manufacturing and marketing of VLA1553[17]. The collaboration will be effective upon the signing of definitive agreements and will fall within the framework of the $23.4 million funding which Valneva received from the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2019[18].

During the first half of 2020, VLA1553's complete Phase 1 data were published in the peer-reviewed medical journal *The Lancet Infectious Diseases*[19]. *The Lancet* paper provides a detailed analysis of the unique Phase 1 results, which served as a basis for the Company´s End of Phase 2 meeting with the U.S. FDA[20] and will enable direct progression into Phase 3 as soon as the

[14] *As estimated from available national data. Case reporting is highly inconsistent in Europe and many LB infections still go undiagnosed.*
[15] *Lyme Disease. L.E.K. interviews, research and analysis*
[16] *Valneva PR: Valneva Awarded FDA Fast Track Designation for Chikungunya vaccine candidate*
[17] *Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle- Income Countries*
[18] *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
[19] *Valneva Announces Publication in The Lancet of Complete Phase 1 Data for its Single-Shot Chikungunya Vaccine Candidate*
[20] *Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study*

COVID-19 situation permits. Valneva is currently advancing all necessary activities, including with its Contract Research Organization (CRO), and intends to initiate the pivotal Phase 3 study in the fourth quarter as planned.

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 virus (CHIKV), a Togaviridae virus, transmitted by Aedes mosquitoes. As of 2017, there have been more than one million reported cases in the Americas[21] and the economic impact is considered significant (e.g. Colombia outbreak 2014: $73.6 million)[22]. The medical burden is expected to grow as the distribution of the CHIKV primary mosquito vectors continues to spread further geographically.

The global annual market potential for chikungunya vaccines is estimated at up to $500 million and the traveler market at around $250 million[23]. The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher (PRV).

SARS-CoV-2 VACCINE CANDIDATE – VLA2001
Agreement in principle with UK government to provide up to 100 million doses
Preliminary binding agreement to provide initial funding for manufacturing expansion

In April 2020, Valneva initiated a program aiming to rapidly develop a vaccine against SARS-COV-2, the pathogen that causes COVID-19[24].

In July 2020, Valneva reached an agreement in principle with the UK government to provide up to 100 million doses of its SARS-CoV-2 vaccine, to be manufactured at its facilities in Livingston, Scotland[25]. Valneva and the UK government have now entered into a binding preliminary agreement by which the Government will provide initial funding of over £10 million to support expansion of Valneva's UK-based manufacturing facilities. Valneva and the UK government will seek to finalize a full supply agreement in the next few weeks, including further investments in manufacturing and clinical trials. As part of its broader COVID-19 response, Valneva plans to further invest in its manufacturing facility in Livingston, Scotland and also in Solna, Sweden. Valneva is also in discussions with further potential customers for the vaccine.

Valneva is leveraging its technical and platform capabilities derived from IXIARO®, the Company's commercial vaccine product indicated for active immunization for the prevention of Japanese encephalitis, to develop an inactivated, whole virus vaccine candidate. The Company is collaborating with Dynavax to evaluate the adjuvant CpG 1018, which is a component of the U.S. FDA-approved HEPLISAV-B® vaccine.

Valneva has ramped up its Biosafety Level 3 laboratory capabilities at its sites in Nantes, Vienna and Livingston. Assuming that preclinical activities are successful and the requisite financing is in

[21] *PAHO/WHO data: Number of reported cases of Chikungunya Fever in the Americas – EW 51 (December 22, 2017)*
[22] *Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015*
[23] *Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market*
[24] *Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19*
[25] *Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program*

place, Valneva plans to commence clinical studies by the end of 2020 with the objective to achieve first regulatory approval in the second half of 2021, subject to the appropriate regulatory authority requirements.

SARS-CoV-2 is a new coronavirus identified in late 2019 and belongs to a family of enveloped RNA viruses that include MERS and SARS, both of which caused serious human infections of respiratory system. The virus, which causes a disease named COVID-19, has never before been found in humans. Since this outbreak was first reported in late-2019, the virus has infected over 18 million people and has caused over 690,000 reported deaths (as of August 3, 2020). It has been declared a pandemic by the World Health Organization (WHO). Currently, there is no vaccine available for COVID-19.

First Half 2020 Financial Review

(Unaudited, consolidated under IFRS)

Revenues

Valneva's total revenues in the first half of 2020 were €47.9 million compared to €54.5 million in the first half of 2019. Revenues in the first half of 2019 included negative revenue effects related to the termination of the Strategic Alliance Agreement (SAA) with GSK amounting to €10.7 million. Excluding the termination effect, total revenues would have amounted to €65.2 million in the first half of 2019.

Product sales revenues in the first half of 2020 declined to €40.9 million compared to €61.6 million in the same period of 2019. On a CER basis[26], product sales declined by 35% compared to the first half of 2019 with both commercial vaccines impacted by COVID-19 related consequences on the travel market. The sales decline was primarily driven by a 38% decrease at CER in IXIARO®/JESPECT® sales while DUKORAL® sales declined by 20.8% at CER compared to the first half of 2019.

Other Revenues, including revenues from collaborations, licensing and services, amounted to €7 million in the first half of 2020 and included for the first time revenues related to the Lyme R&D collaboration agreement with Pfizer. In the comparator period of 2019, negative Other Revenues amounting to €7.1 million were reported, including the effect of the termination of the SAA with GSK. Excluding the termination effect, other revenues would have amounted to €3.6 million in the first half of 2019.

Operating result and EBITDA

Costs of goods and services sold (COGS) were €21.1 million in the first half of 2020. Gross margin on product sales was 59.1% compared to 66.1% in the first half of 2019, with the decline mainly related to provisions taken for excess stock driven by reduced demand (due to the COVID-19 pandemic). COGS of €10.4 million were related to IXIARO®/JESPECT® sales, yielding a product gross margin of 63.3%. €6 million of COGS were related to DUKORAL® sales, yielding a product gross margin of 50.5%. Of the remaining COGS in the first half of 2020, €0.3 million were related

[26] *CER: Constant Exchange Rate; H1 2019 actuals restated to H1 2020 average exchange rates*

to the Third Party Product distribution business and €4.4 million were related to cost of services. In the first half of 2019, overall COGS were €23.1 million, of which €20.9 million related to cost of goods and €2.2 million related to cost of services.

Research and development investments in the first half of 2020 continued to increase as planned, more than doubling to €33 million compared to €14.1 million in the first quarter of 2019. This was driven by investments into Valneva's clinical stage vaccine candidates, notably Lyme and chikungunya. Marketing and distribution expenses in the first half of 2020 amounted to €10 million compared to €11.8 million in the first half of 2019. The decrease was the result of lower marketing and distribution spend across all Valneva's direct markets due to reduced sales activity further to the COVID-19 pandemic. In the first half of 2020, general and administrative expenses increased to €10.6 million from €8.8 million in the first half of 2019, mainly driven by increased costs to support corporate transactions and projects as well as costs related to Valneva's employee share option program. Amortization and impairment charges of fixed assets/intangibles in the first half of 2020 remained unchanged compared to the same period of 2019 and amounted to €1.4 million.

Other income, net of other expenses in the first half of 2020 increased to €6.5 million from €3 million in the first half of 2019. This increase was mainly driven by increased R&D tax credit directly resulting from increased R&D spend along with income from the CEPI funding for Valneva's chikungunya R&D program.

Valneva recorded an operating loss of €21.9 million in the first half of 2020 compared to €1.7 million in the first half of 2019. EBITDA loss in the first half of 2020 was €17.2 million compared to an EBITDA profit of €2.4 million in the first half of 2019.

Net result

In the first half of 2020, Valneva generated a net loss amounting to €25.6 million compared to a net loss of €2.4 million in the first half of 2019.

Finance costs and currency effects in the first half of 2020 resulted in a net finance expense of €5.6 million, compared to a net finance expense of €0.5 million in the first half of 2019. The increase of expenses was the result of increased interest charges related to the newly entered financing arrangement with the US Healthcare Funds Deerfield and OrbiMed as well as foreign currency losses.

Cash flow and liquidity

Net cash generated by operating activities in the first half of 2020 amounted to €113.2 million compared to €13.3 million in the first half of 2019 mainly driven by the $130 million upfront payment received from Pfizer related to the Lyme R&D collaboration agreement.

Cash outflows from investing activities in the first half of 2020 amounted to €1.8 million, compared to €3.8 million in the first half of 2019 mainly as a result of purchases of equipment.

Cash inflows from financing activities amounted to €24.5 million in the first half of 2020 and consisted mainly of €48.8 million net proceeds from the financing arrangement with the US Healthcare Funds Deerfield and OrbiMed, offset by €20 million repayments of borrowings to the

European Investment Bank (EIB). Cash outflows from financing activities amounted to €16.6 million in the first half of 2019, which included the repayment of the Biopharma (Pharmakon) loan of €11.3 million in early 2019.

Liquid funds on June 30, 2020 strongly increased and stood at €200.0 million compared to €64.4 million on December 31, 2019. The main change was driven by the $130.0 million upfront payment related to the Lyme collaboration agreement with Pfizer and proceeds from the new debt line net of loan repayment to the EIB in March 2020.

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 over 500 employees. For more information, visit www.valneva.com and follow the Company on LinkedIn.

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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 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.