# Valneva's Q1 2024 Financial Results and Business Update

May 7, 2024





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This presentation presents information about VLA1553, VLA15 and VLA1601, investigational vaccine candidates that have not been approved for use and have not been determined by any regulatory authority to be safe or effective.

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 supplemental measure of performance used by investors and financial analysts. Management believes this measure provides additional analytical tools.



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# First Quarter 2024 Key Results and Corporate Updates



#### **Q1 Pipeline Progress**

- Chikungunya: ACIP recommendation and first commercial revenues
- Lyme disease: Participants expected to complete primary vaccinations in Q2
- Zika virus: Advanced second-generation candidate to Phase 1

#### Q1 Financial Highlights (as of March 31, 2024)

- Proceeds from PRV sale led to:
  - Q1 net profit of €58.9m; €176.6m in cash
- Product sales of €32.1m in line with full-year guidance; total revenue €32.8m
- Significantly extended cash runway with recent update to debt financing agreement

#### **Reiterated strong mid-term financial outlook**

- Solidly funded with significantly lower expected cash burn going forward (final Lyme Phase 3 payment in Q2)
- Operational business considered sufficiently funded (excluding debt repayment) until Lyme commercial revenues enable sustained profitability\*

\*Subject to successful development, licensure and launch of the Company's Lyme disease vaccine candidate partnered with Pfizer.







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# **Our Strategy to become a Globally Recognized Vaccine Company**

Contribute to a world where no one dies or suffers from a vaccine preventable disease

# Drive Commercial Growth

- Unlock IXCHIQ<sup>®</sup> value by building awareness and market
- Capitalize on the bundle effect within travel business
- Expand global reach; reach more LMICs via partnerships
- Expect cash-flow positivity from 2025

# Capture R&D Upside

- Invest in new vaccines that address high unmet needs
- Leverage proven R&D engine and strategic partnerships
- Focus on vaccines that can make a difference (first, only, best-in-class)
- Generate meaningful catalysts – Next Phase 3 entry post Lyme

# Maximize integrated biotech model

- Build continual value from R&D and commercial execution
- Support timely Lyme approval(s)
- Achieve sustained profitability with potential VLA15 commercial revenues from partner Pfizer\*

\*Subject to successful development, licensure and launch of the Company's Lyme disease vaccine candidate partnered with Pfizer



# The World's First and Only Chikungunya Vaccine

# IXCHIQ<sup>®</sup> / VLA1553

\*IXCHIQ<sup>®</sup> is approved by the U.S. Food & Drug Administration (FDA) and is indicated for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV.

Continued approval of IXCHIQ<sup>®</sup> in the U.S. is contingent upon verification of clinical benefit in confirmatory studies.





# **IXCHIQ<sup>®</sup> Key Features and Differentiators**



- We expect to benefit by being first to market with a potentially best-in-class vaccine
- We believe we have a differentiated and competitive product characterized by a strong and durable immunological response from a single injection
- No difference in immunogenicity between younger and older adults (65+ years old)
- Generally well tolerated among the >3,600 adults and 754 adolescents evaluated for safety<sup>1</sup>

1 Please refer to the full Prescribing Information for contraindications, warnings, and other important information: https://www.fda.gov/media/173758/download



# **Next Steps:**

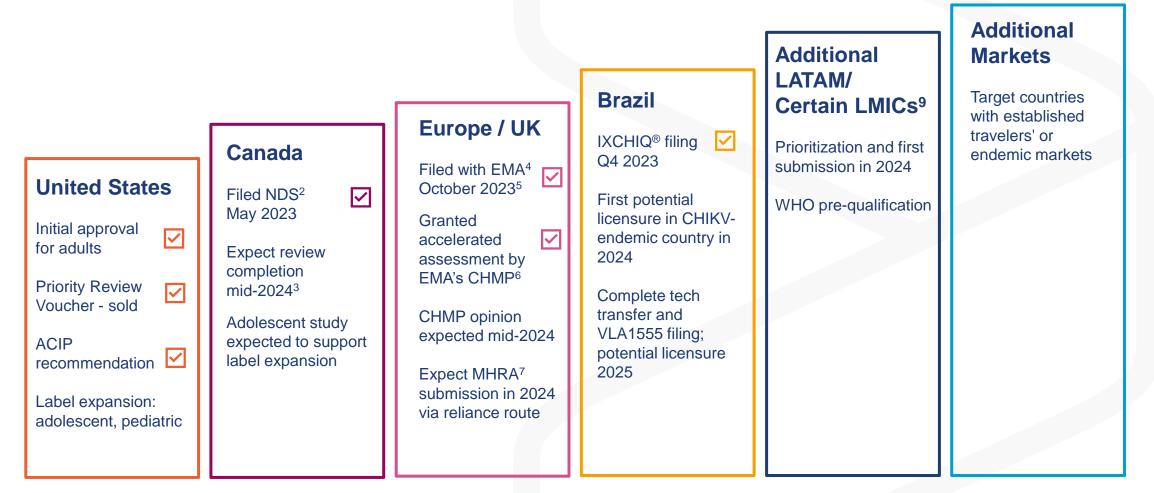
- Support customers who are already actively protecting travelers
- Activate consumers to seek travel health consults
- Ensure military officials understand risk, impact and threat levels
- Continuously monitor outbreaks and threat level, and adjust plans accordingly



# Driving Value by Executing Global Launch Plan

Multiple ex-U.S. regulatory processes currently ongoing<sup>1</sup>





1. IXCHIQ<sup>®</sup> is not currently approved in any other country or jurisdiction outside of the U.S.; 2. New drug submission; 3. Based on Health Canada's performance standards of approx. 300 days from acceptance; 4.. European Medicines Agency; 5. <u>Valneva Submits Chikungunya Vaccine Marketing Application to EMA and Announces CHMP Accelerated Assessment</u>; 6. Committee for Medicinal Products for Human Use; 7. Medicines and Healthcare Products Regulatory Agency; 8. Prefiling processes are ongoing and can take approximately 12 months from filing acceptance to potential approval; 9. Low-and-middle-income countries



# IXCHIQ<sup>®</sup> is FDA approved for adults under the accelerated pathway<sup>1</sup>

Robust clinical program to support continued approval, label expansion, product profile



### **Post-Marketing Effectiveness<sup>2</sup> (Phase 4)**

Observational effectiveness study: participants >12 years of age in Brazil (n ~5,000)

Pragmatic randomized controlled effectiveness and safety study<sup>3</sup>: adults in an endemic country (n ~ 20,000)

#### **Label Expansion**

Phase 3: Randomized, controlled study in adolescents aged 12 - <18 years; reported positive initial results Phase 2: Randomized, dose response study in healthy children aged 1 to 11 years

#### **Product Profile**

Phase 3: Open-label antibody persistence and long-term safety study in adults; reported positive 24-month results to date Phase 3: Open-label safety and immunogenicity study in moderately immunocompromised adults infected with HIV; starting soon

1. https://www.fda.gov/vaccines-blood-biologics/ixchiq; 2. https://www.fda.gov/media/173759/download; 3. https://www.fda.gov/media/172166/download



# World's leading Lyme Disease Vaccine Candidate

**VLA15** 





# World's leading Vaccine Candidate Against Lyme Disease

VLA15: the only Lyme disease program in advanced clinical development today



#### Vaccine Highlights



- Multivalent, recombinant proteins
- Targets six most prevalent *Borrelia* serotypes causing Lyme disease in U.S. and Europe
- Established mechanism of action
- U.S. FDA Fast Track Designation
- Phase 3 fully recruited

#### Market Opportunity



- Exclusive, worldwide partnership<sup>1</sup>
- >\$1billion estimated global market<sup>2</sup>
- Valneva eligible for milestones up to \$408 million (\$165 million received)
- Tiered sales royalties 14-22%

### **Upcoming Milestones**



- Complete Valneva contribution to Phase 3
  trial costs in H1 2024
- Phase 3 trial execution (Q2 2024):
  - Complete full vaccination for Cohort 1
  - Complete primary vaccination for Cohort 2
- Two-year antibody persistence and booster results in Q3 2024
- Efficacy results from Phase 3 trial (end 2025); Regulatory filings (U.S. + EU) in 2026<sup>2</sup>

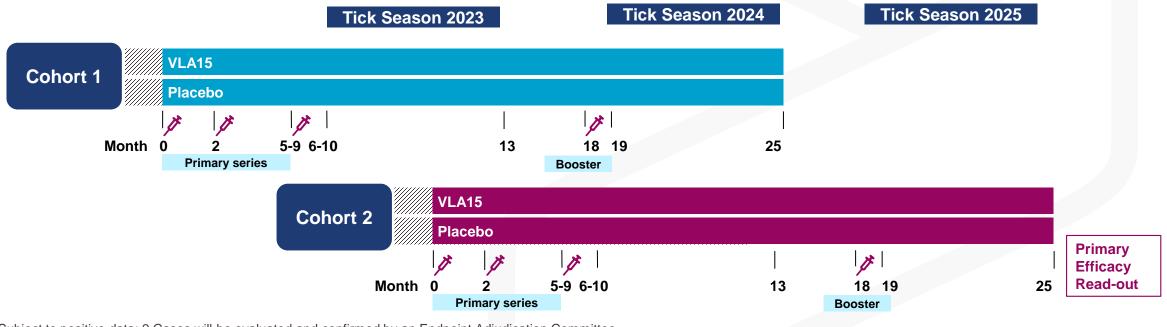
1 Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; 2 Lyme Disease research and analysis conducted by an independent market research firm; 3 Subject to positive data;



# **Phase 3 Efficacy Study Fully Enrolled**

# Pfizer aims to submit regulatory applications in U.S. and Europe in 2026<sup>1</sup>

- VALCER Vaccine Against Lyme for Outdoor Recreationists
- Population: 9,437 evaluable participants ≥5 years of age at high risk of Lyme disease (LD) (by residence and occupational/recreational activities) in U.S., Canada and Europe (randomization approx. 1:1 VLA15/Placebo and 2:1 N. America/EU)
- Primary endpoint: Rate of confirmed LD cases<sup>2</sup> after two consecutive tick seasons (i.e., after completion of full vaccination series 3+1)
- Secondary endpoints include rate of confirmed<sup>1</sup> LD cases after 1st Lyme season (i.e., after completion of primary vaccination series) amongst other secondary endpoints as defined in Phase 3 protocol



1 Subject to positive data; 2 Cases will be evaluated and confirmed by an Endpoint Adjudication Committee

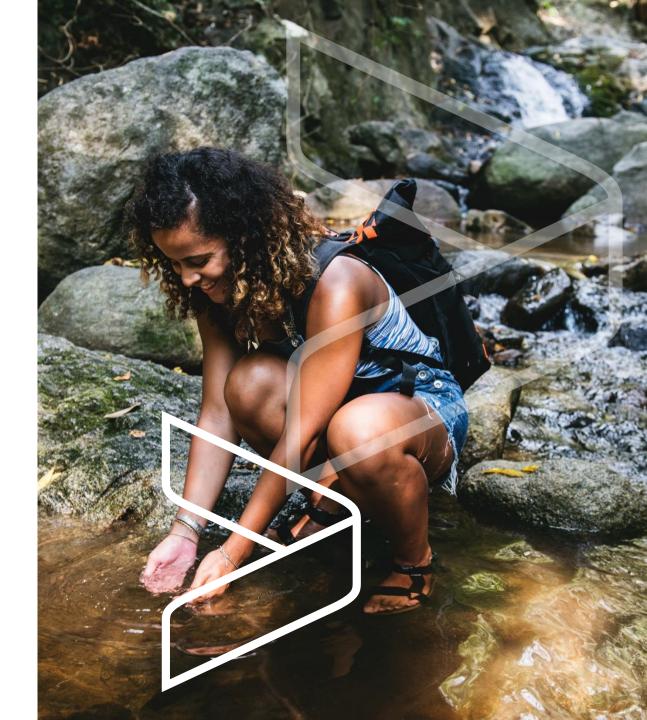
Valneva – Q1 2024 Analyst Presentation



# Second-Generation Zika Virus Vaccine Candidate

VLA1601





# VLA1601: Optimized Second-Generation Vaccine Candidate Against Zika Virus Entering Phase 1, further program evaluation planned



#### Vaccine Highlights



- Second-generation adjuvanted inactivated whole-virus vaccine
- Leverages Valneva's proven / licensed platform (VLA2001)
- Previous Phase 1 results from firstgeneration candidate showed excellent immunogenicity and safety results<sup>1</sup>

#### Market Opportunity



- Flaviviral disease transmitted by Aedes mosquitoes<sup>2</sup>
- Devastating effects<sup>3</sup>:
- Microcephaly & severe brain defects in newborns
- · Guillain-Barré syndrome in adults
- No vaccines or specific treatment available – PRV eligible; potential funding from public institutions

### **Upcoming Milestones**



- Execute Phase 1 clinical trial with enhanced process and optimized vaccine formulation
- Evaluate future development strategy in H1 2025 based on:
- Phase 1 results
- Market potential
- External, non-dilutive funding

1 Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus; 2 https://www.cdc.gov/zika/transmission/index.html; 3 https://www.who.int/mediacentre/factsheets/zika/en/



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# Q1 2024 Financials: Product Sales of €32.1 million

Commercial business on track for continued, significant growth



€m (audited)	Q1 2024	Q1 2023	% Change
IXIARO <sup>®</sup> /JESPECT <sup>®</sup>	16.6	17.4	-4%
DUKORAL®	11.3	10.2	10%
IXCHIQ®	0.2		
Third party products	4.1	4.5	-9%
Total product sales	32.1	32.1	0.1%



### **Q1 2024 Financials: Income Statement**



€m (unaudited)	Q1 2024	Q1 2023
Product sales	32.1	32.1
Other Revenues	0.6	1.4
Revenues	32.8	33.5
Cost of goods and services	(22.2)	(20.5)
Research and development expenses	(13.1)	(14.1)
Marketing and distribution expenses	(11.3)	(9.0)
General and administrative expenses	(11.7)	(10.0)
Gain from sales of Priority Review Voucher, net	90.8	
Other income / (expense), net	2.9	3.5
Operating loss	68.2	(16.6)
Finance, investment in associates & income taxes	(9.3)	(1.6)
Profit / (Loss) for the period	58.9	(18.1)
Adjusted EBITDA <sup>1</sup>	73.0	(12.3)

1 Q1 2024 Adjusted EBITDA was calculated by excluding €14.0 million (Q1 2023: €5.8 million) of income tax expense, finance income/expense, foreign exchange gain/(loss), results from investments in associates, depreciation, amortization and impairment (excluding impairment loss of disposal) from the €58.9 million profit (Q1 2023: € 18.1 million loss) for the period as recorded in the consolidated income statement under IFRS. Click here for important information about Non-IFRS measures such as Adjusted EBITDA and a reconciliation of Adjusted EBITDA to net loss, the most directly comparable IFRS measure.



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# **Commercial Business Expected to Deliver Substantial Growth** Driven by Portfolio of Differentiated Products<sup>1</sup>





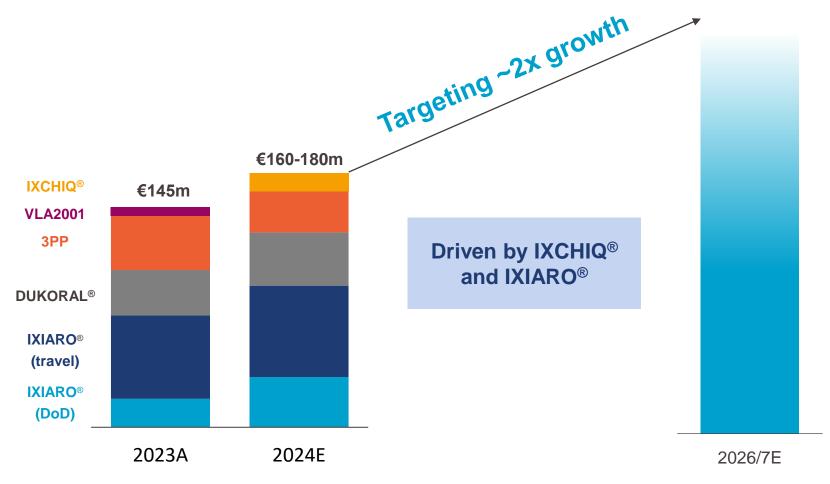
Only Japanese encephalitis vaccine approved in U.S. and Europe; vaccine requirement for U.S. military deployed to parts of Asia

**IXCHIQ**<sup>®</sup>

First and only approved single-shot chikungunya vaccine

DUKORAL

**Only** Cholera and ETEC<sup>2</sup> vaccine approved



1 Please refer to Product / Prescribing Information (PI) / approved in your respective country for complete information about this vaccine; 2 ETEC indication in some markets only



# **Reiterating Strong Mid-Term Outlook**

Valneva is Solidly Funded with a Clear Pathway Toward Sustained Profitability<sup>1</sup>



### 2024 Guidance

- Product Sales: €160 €180 million<sup>2</sup>
- Total Revenues: €170 €190 million
- Other Income: €100 €110 million
- R&D Expense: €60 €75 million
- Significantly lower cash burn vs. 2023
  - Expect to complete contribution to Phase 3 Lyme disease trial in H1 2024
  - Commercial business expected to be cash-flow positive (excluding IXCHIQ<sup>®</sup>)

# **Mid-Term Outlook**

- Commercial business expected to cash-flow positive (including IXCHIQ<sup>®</sup>) from 2025
  - Continued travel sales growth for IXIARO<sup>®</sup> and **DUKORAL<sup>®</sup>**
  - Double-digit CAGR for IXIARO<sup>®</sup> for at least the next 3 years
  - IXCHIQ<sup>®</sup> sales to exceed €100 million in year 3 of launch, even assuming competitive product entry
- Focused and strategic investments in R&D Next Phase 3 program entry post Lyme data
- Gross margin improvement
  - Focus on proprietary sales
  - Cost-efficient manufacturing leveraging new facilities
- Expect further R&D support: sizable non-dilutive funding

1 Subject to successful development, licensure and launch of the Company's Lyme disease vaccine candidate partnered with Pfizer; 2 Assumes ~20-30% reduction in third party sales due to external supply constraints



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# **Key Upcoming Catalysts and News Flow**

#### Chikungunya vaccine

- Upcoming potential approvals: EMA, Health Canada, Anvisa (Brazil)
- Initiate Phase 3 immunocompromised individuals study in H1 2024
- Report 6-month follow up results and file for initial label extension (adolescents)
- Initiate Phase 4 clinical program in early 2025

#### Lyme disease vaccine candidate VLA15

- VALOR trial: complete booster vaccination for Cohort 1 in Q2 2024
- VALOR trial: complete initial three-dose vaccination for Cohort 2 in Q2 2024
- Complete Valneva contribution to Phase 3 trial costs in Q2 2024
- Phase 2 two-year antibody persistence and booster results expected in Q3 2024

#### **Additional newsflow**

- New U.S. Department of Defense supply contract for IXIARO<sup>®</sup> in H2 2024
- Further advance select R&D programs

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Thank you Merci Danke Tack



