

Valneva A Leading Specialty Vaccine Company

Company Presentation
May 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.

A Leading Specialty Vaccine Company

Focused on vaccines that make a difference

We **develop, manufacture, & commercialize** prophylactic vaccines for infectious diseases addressing unmet medical needs



- **Proven Expertise:** Three in-house vaccine approvals; three proprietary commercialized travel vaccines
- **Focus on Innovation:** Advancing first-, only- or best-in-class vaccine candidates; Experience across multiple vaccine platforms
- **De-risked Blockbuster Lead Program:** Phase 3 Lyme disease vaccine candidate partnered with Pfizer
- **Growing Commercial Revenues:** €145m in 2023 vaccine sales (+26% YoY) to support R&D investments; Expected to ~double by 2026 with launch of IXCHIQ®
- **Targeting profitability by 2026:** based on continued commercial growth plus Lyme commercial entry in 2027

Valneva's Commercial and R&D Portfolio

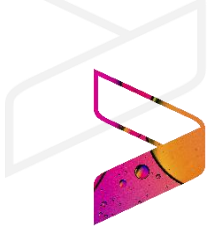
Further extending a unique, best-in class portfolio



	Program	Vaccine Design	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial
Commercial products	IXIARO®	Only U.S./ EU approved vaccine against Japanese encephalitis					
	DUKORAL®	Established Cholera (ETEC*) vaccine approved in >30 countries					
	IXCHIQ®	World's first and only approved chikungunya vaccine (U.S.); Review ongoing in Europe, Canada & Brazil					
Clinical Programs	VLA15: Lyme disease	Most clinically advanced Lyme vaccine program worldwide					
	VLA1553: Chikungunya	Phase 3 adolescent study (Brazil) and Phase 2 pediatric study support potential label expansion					
	VLA1601: Zika	Potential for first/best-in-class					
Pre-Clinical Programs	VLA1554: hMPV	For partnering (e.g. RSV combo)					
	VLA2112: EBV						
	Enteric diseases						

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® 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

R&D

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The World's First and Only Chikungunya Vaccine

IXCHIQ® / VLA1553

*IXCHIQ® 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® in the U.S. is contingent upon verification of clinical benefit in confirmatory studies.

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Chikungunya: A Major Public Health Threat

Mosquito-transmitted outbreak disease with potentially debilitating consequences



Aedes aegypti



Aedes albopictus

Often causes **large, explosive outbreaks**

Affecting **up to 75%** of the local population¹

Substantial quality-of-life and **health-economic impact**

Nearly half (43%) of those infected develop **severe chronic symptoms**³

Potential for **outbreaks in U.S. and Europe** where *Aedes* mosquitoes are established^{2,3}

Returning infected travelers can trigger local transmissions

Identified in **>100 countries** across five continents

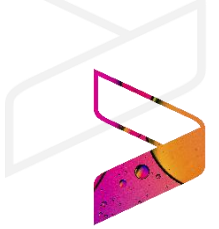


75% of world population lives in areas at-risk of CHIKV

1. Staples et al. CDC Yellow Book 2020, Chapter 4; 2. Bettis et al, PLOS Neglected Tropical Diseases 16(1): e0010069. 3. Silva LA et al. J Clin Invest. 2017 Mar 1;127(3):737-749

IXCHIQ®: The World's First and Only Licensed Chikungunya Vaccine

FDA-approved in adults, with potential additional regulatory approvals in 2024



Vaccine Highlights



- Live-attenuated: offers strong and long-lasting protection from a single shot
- FDA approved (Nov 2023) – PRV sold for \$103 million (Feb 2024)
- ACIP recommended vaccine for certain travelers and laboratory workers
- U.S. launch underway: sales through Valneva's commercial infrastructure

Market Opportunity



- Travelers
 - Military
 - Outbreak preparedness
- 
- Partnership for Latin America and certain LMICs¹ (Insituto Butantan)
 - Estimated global market to exceed \$500 million per year²; \$300-\$400 represented by travel segment

Upcoming Milestones



- Potential upcoming approvals: EMA, Health Canada, Anvisa (Brazil)
- Initiate regulatory process in the UK
- Initiate further clinical trials, including Phase 4 clinical program
- Filings for potential label extension

¹ Low- and middle-income countries; ² VAMV005. Chikungunya virus vaccines. Global demand analysis. Feb 2020

IXCHIQ® Key Features and Differentiators



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

- **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 safety¹**

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

Only CHIKV vaccine to achieve target immunogenicity with a single shot

Differentiated vaccine shows rapid, long-lasting immunity across all age groups tested^{1,2,5}



Immunogenicity Data

- 99% Seroresponse³ Rate (SRR) after single vaccination → maintained at 97% after 24 months^{4,5}
- Similar SRR and antibody titers in age 65+ adults as younger adults^{1,4}
- 100% SRR after 14 days and sustained to Month 12²
- Adolescent trial met primary endpoint⁶: highly immunogenic in baseline-negative individuals; 99% SRR



Safety Data

- Generally well tolerated by >3,600 adults and 754 adolescents
- Pivotal Safety (solicited systemic AEs):
 - ~50% of participants, most commonly headache, fatigue, myalgia
 - Majority mild or moderate; 2.0% reported as severe, most commonly fever
- Adolescent trial suggests favorable safety profile regardless of previous CHIKV infection⁷

1. [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#); 2. Re-testing of Phase 1 sera (vaccinated with liquid formulation of VLA1553) using the final assay/threshold used for the pivotal endpoint; data presented at CISTM18, May 2023; 3. CHIKV neutralizing antibody titer of ≥ 150 by μ PRNT₅₀ (Micro Plaque Reduction Neutralization Test), agreed with regulators to be used as a surrogate endpoint in Phase 3; 4. [Valneva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate](#); 5. [Valneva Reports Positive 24-Month Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ®](#); 6. [Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate](#); 7. [Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate](#)

IXCHIQ® is FDA approved for adults under the accelerated pathway¹

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



Post-Marketing Effectiveness² (Phase 4)

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

Pragmatic randomized controlled effectiveness and safety study³: 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

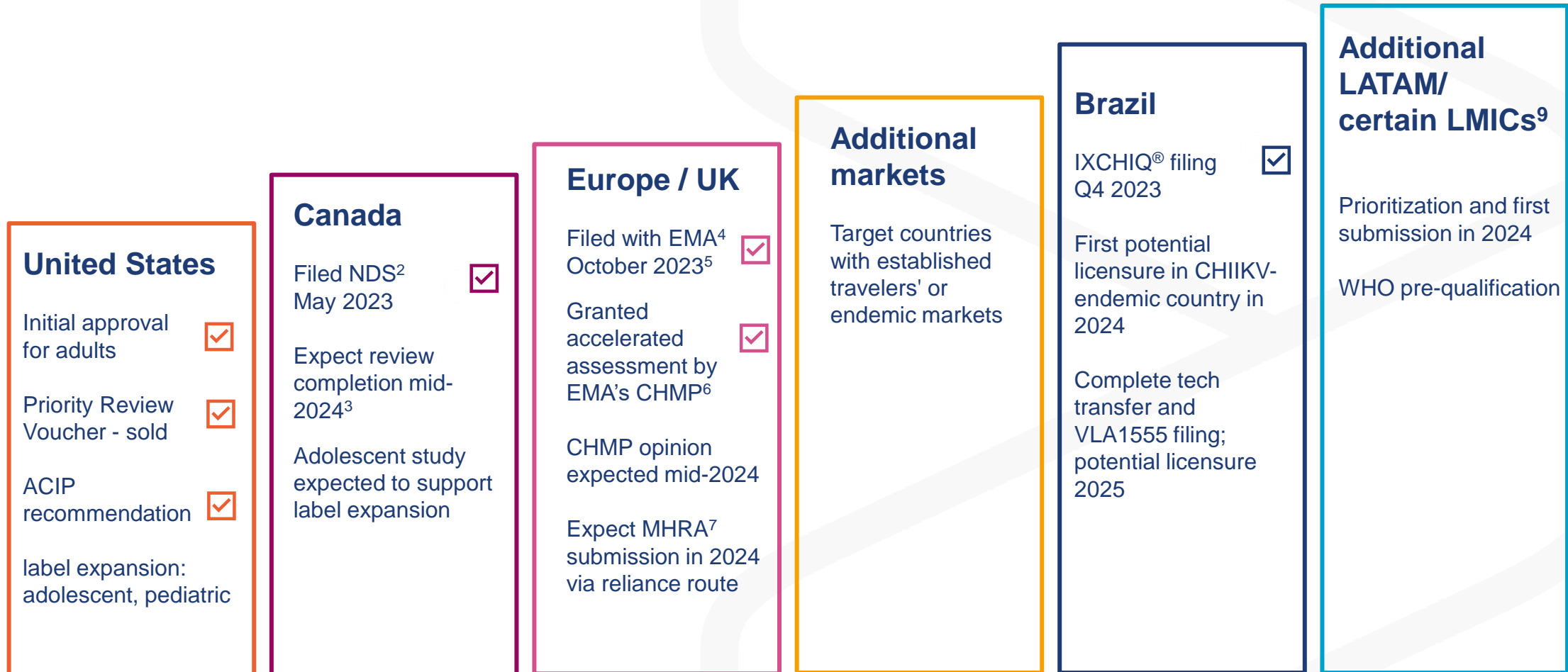
Phase 3: Open-label safety and immunogenicity study in moderately immunocompromised adults infected with HIV; starting soon

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>



Preparing for Global Market Launches

Planned additional and future regulatory processes¹

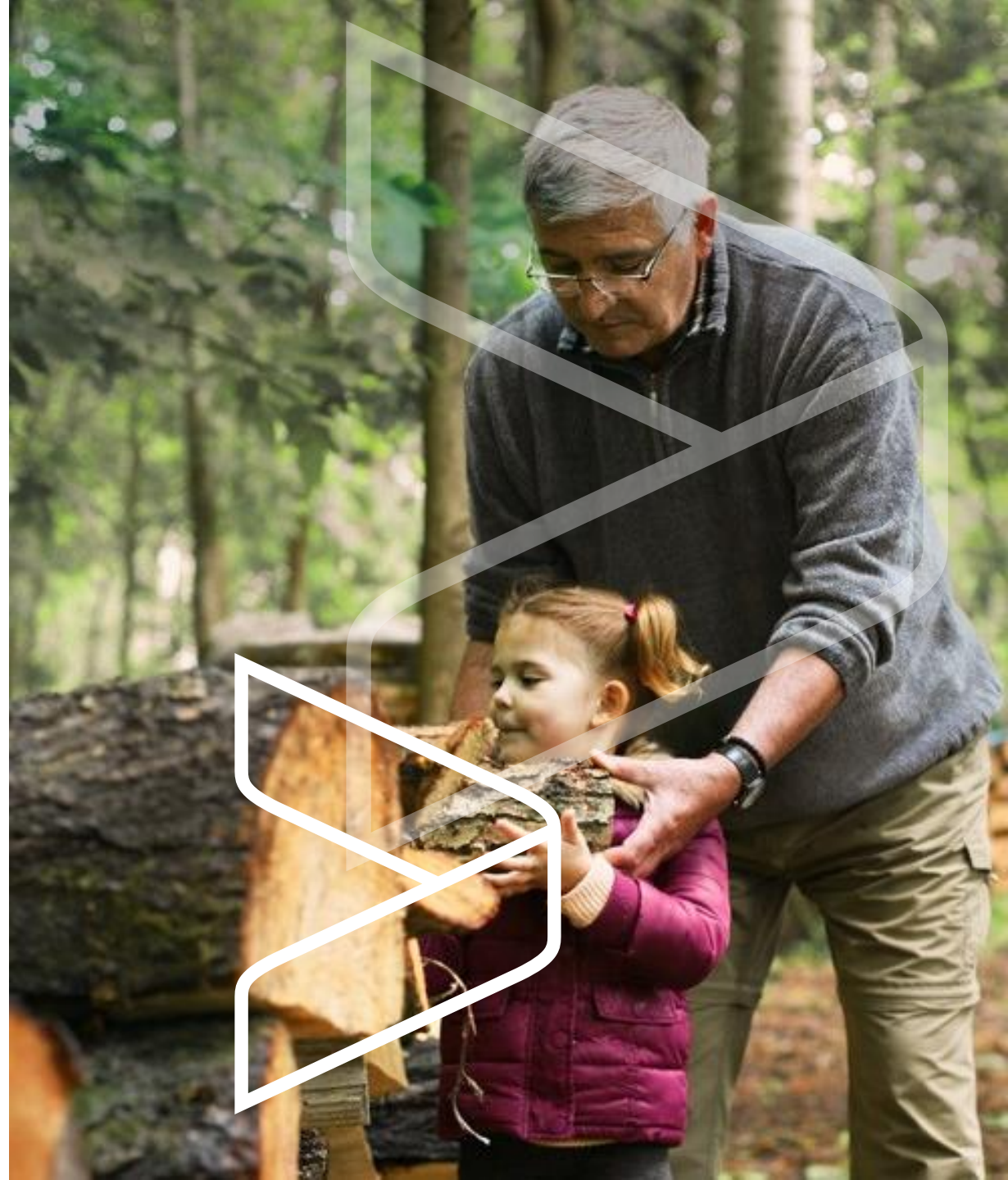


1. IXCHIQ[®] is not currently approved in any other country or jurisdiction outside of the U.S.; 2. New drug submission; 3. Based on Health Canada's performance standards of approx. 300 days from acceptance; 4. European Medicines Agency; 5. Valneva Submits Chikungunya Vaccine Marketing Application to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

World's leading Lyme Disease Vaccine Candidate

VLA15

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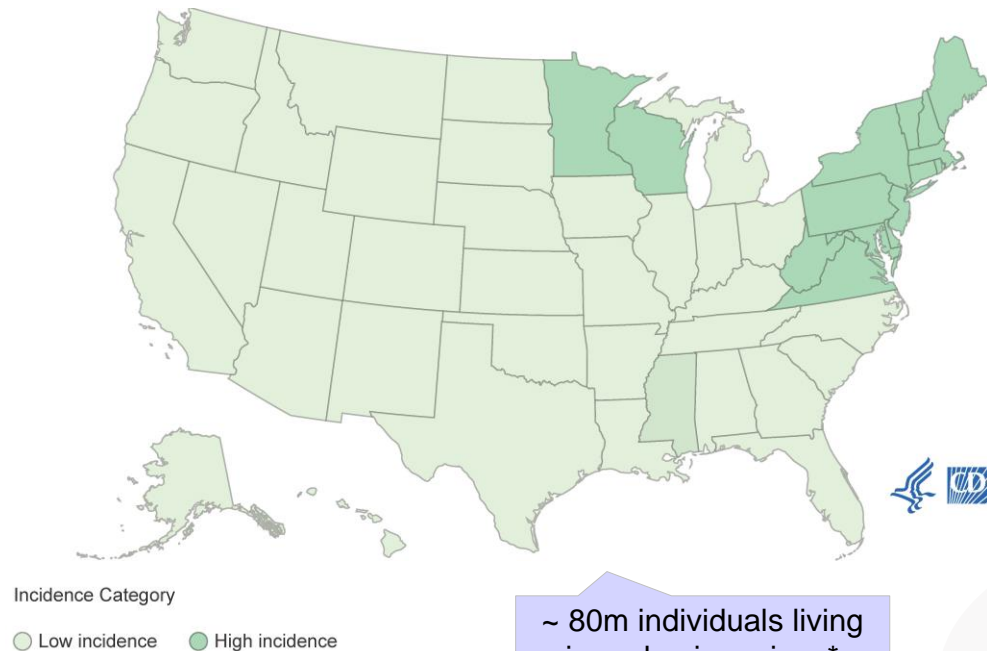
Lyme Disease is a Major Health Issue

Severe Tick-transmitted Infection, Increasingly Common in the U.S. and Europe

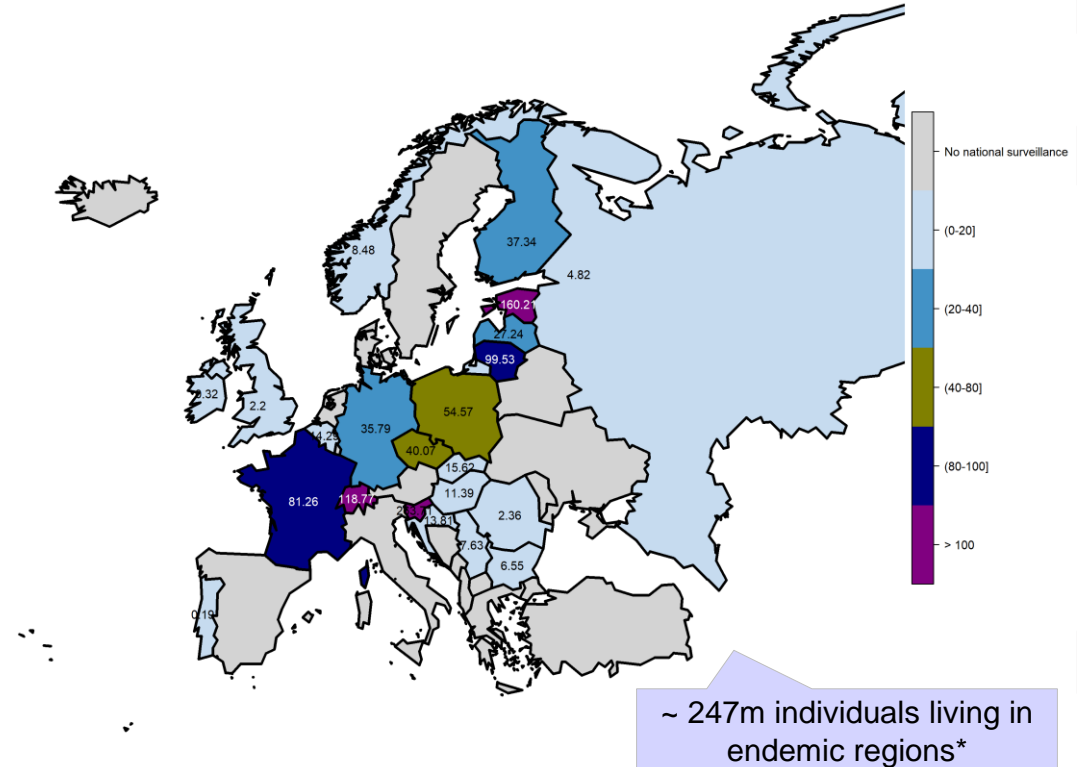


Epidemiology – Seasonal (peaking in ~ July)

National Surveillance by Incidence Category
(~475,000 annual cases)



Incidence for three most recent available years
(cases/100,000 persons) (> 130,000 annual cases)

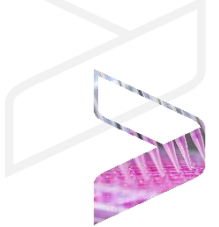


US: CDC <https://www.cdc.gov/lyme/stats/maps.html>, EU: Pfizer internal analysis of national surveillance system data

* Endemic regions are defined by an incidence of >10/100.000 population

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 partnership¹



- >\$1billion estimated global market²
- Valneva eligible for milestones up to \$408 million (\$165 million received)
- Tiered sales royalties 14-22%

Upcoming Milestones

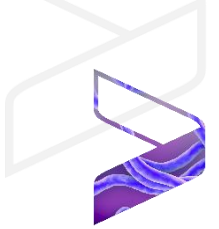


- Complete Valneva contribution to Phase 3 trial costs in H1 2024
- Phase 3 trial execution (Q2 2024):
 - Complete full vaccination for Cohort 1
 - Complete primary vaccination for Cohort 2
- Two-year antibody persistence and booster results in Q3 2024
- Efficacy results from Phase 3 trial (end 2025); Regulatory filings (U.S. + EU) in 2026³

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;

VLA15 Demonstrated Strong Immunogenicity Across 1,030 Adults and Children

Three Phase 2 studies optimized dose and schedule across age groups



2020: First positive immunogenicity data¹

Immunogenic (all serotypes & dose groups)
Higher doses elicited higher antibody responses
Encouraging profile in older adults (ages 50-65)

2021: First positive booster data²

High antibody response confirmed after primary vaccination
12-month booster dose elicited strong anamnestic response

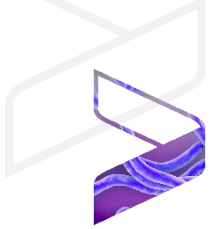
2022: First positive pediatric data³

Strong immunogenicity profile in adults² (18-65yo) & children (5-17yo)
More immunogenic in children on both 2-dose & 3-dose schedules; 3-dose schedule selected for all in Phase 3
Confirmed booster response (all serotypes & age groups)

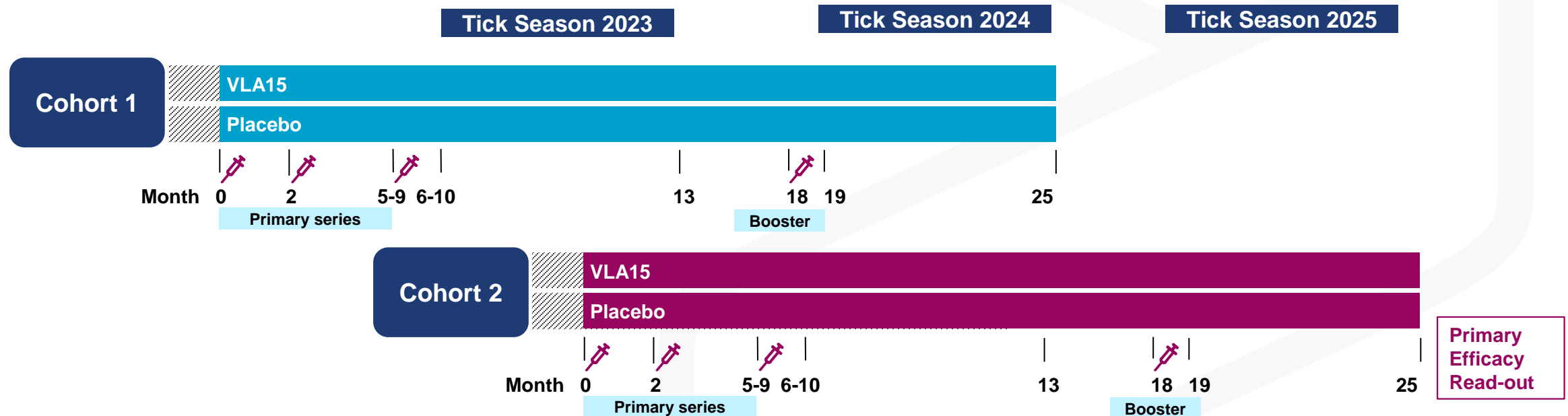
¹ Study VLA15-201; ² Study VLA15-202; ³ Study VLA15-221

Phase 3 Efficacy Study Fully Enrolled

Pfizer aims to submit regulatory applications in U.S. and Europe in 2026¹



- **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 cases² after two consecutive tick seasons (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed¹ 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

Second-Generation Zika Virus Vaccine Candidate

VLA1601

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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 first-generation candidate showed excellent immunogenicity and safety results¹

Market Opportunity



- Flaviviral disease transmitted by *Aedes* mosquitoes²
- Devastating effects³:
 - 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 <http://www.who.int/mediacentre/factsheets/zika/en/>

Valneva Commercial Business

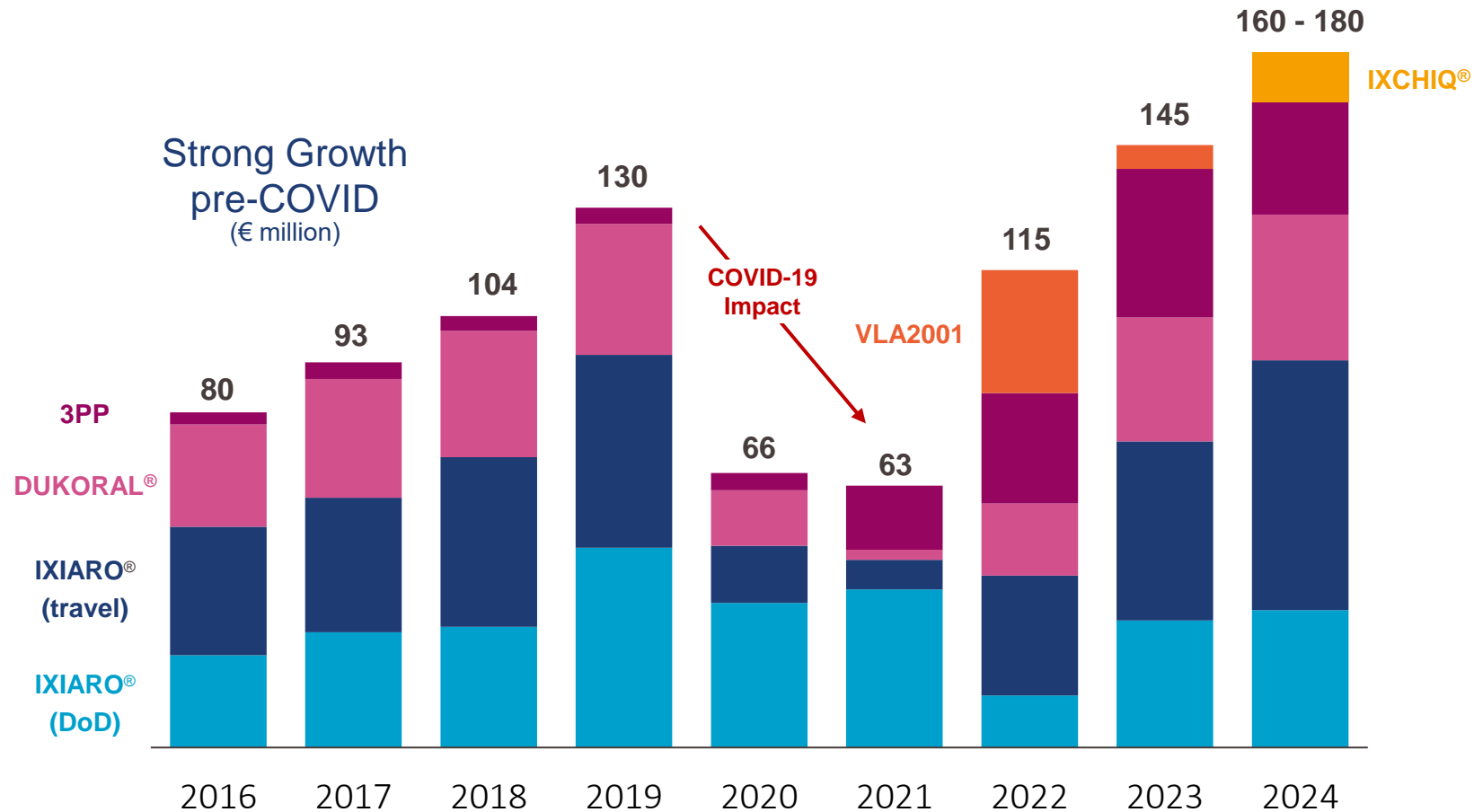
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Product Sales: Continued Growth Anticipated, Driven by Travel Recovery^{1,2}

Revenues Surpassed Pre-Pandemic Levels by 12% in 2023¹



¹ Valneva Reports Full Year 2023 Revenue and Cash, Provides First 2024 Guidance ² IATA/ Tourism Economics (July 2022); ³ Valneva Announces Sale of Priority Review Voucher for \$103 Million; 2022 and 2023 revenues included €29.6 million and €7.7 million in COVID-19 vaccine sales, respectively (not shown)

Commercial Business Expected to Deliver Substantial Growth over Mid-Term Driven by Portfolio of Differentiated Products*



IXIARO®

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

IXCHIQ®

First and only approved single-shot chikungunya vaccine

DUKORAL®

Only Cholera and ETEC** vaccine approved

IXCHIQ®

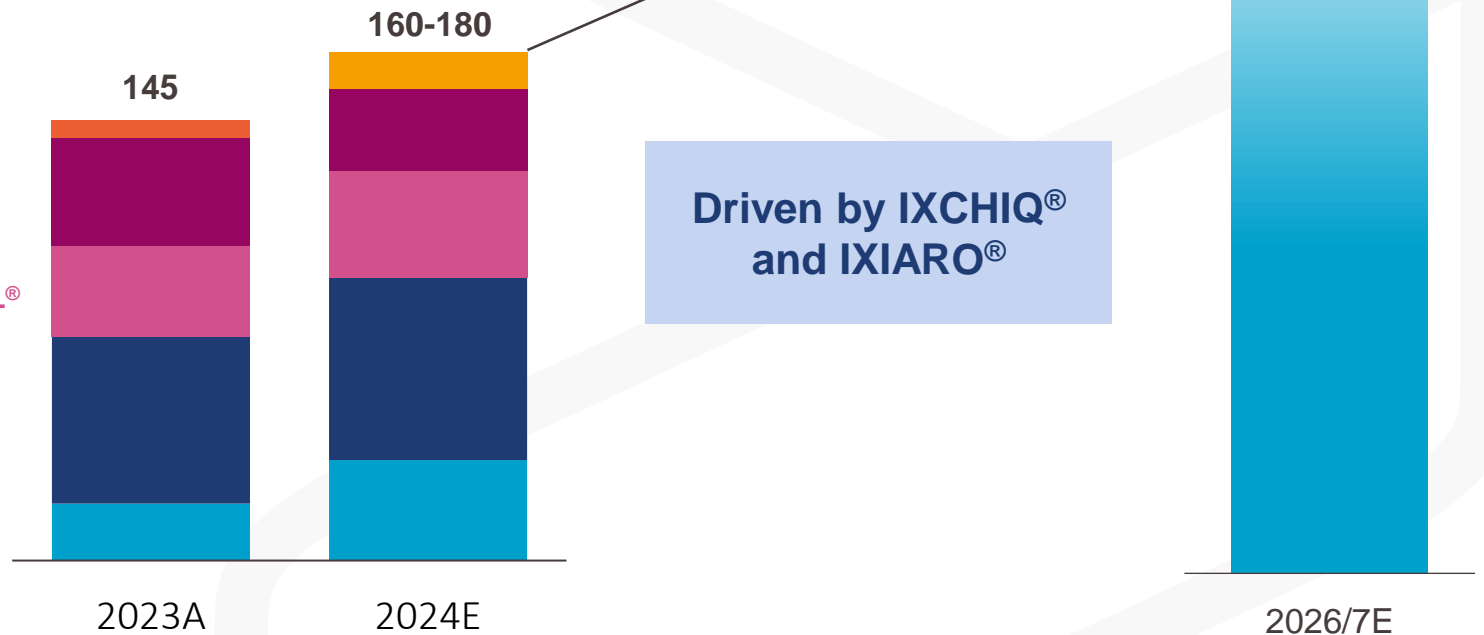
VLA2001

3PP

DUKORAL®

IXIARO®
(travel)

IXIARO®
(DoD)



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

Valneva is Solidly Funded with Strong Near- and Mid-term Financial Outlook



Improved 2024 Guidance

- Product Sales: €160 - €180 million*
- 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®)



Mid-Term Outlook

- Commercial business expected to cash-flow positive (including IXCHIQ®) from 2025
 - Continued travel sales growth for IXIARO® and DUKORAL®
 - Double-digit CAGR for IXIARO® for at least the next 3 years
 - IXCHIQ® 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

* Due to improved outlook regarding IXIARO® supply constraints; assumes ~20-30% reduction in third party sales (external supply constraints)

Key Upcoming Catalysts and News Flow



Chikungunya vaccine

- Initiate Phase 3 immunocompromised individuals study in H1 2024
- Upcoming potential approvals: EMA, Health Canada, Anvisa (Brazil)
- File for potential label extension
- Initiate Phase 4 clinical program

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 H1 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® in H2 2024
- Further advance select R&D programs

Thank you
Merci
Danke
Tack

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