

# Valneva A Leading Specialty Vaccine Company

April 2025



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This presentation presents information about 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
- **Key Value Driver – De-risked Blockbuster Lead Program:** Lyme disease vaccine candidate partnered with Pfizer; first Phase 3 data readout at the end of 2025
- **Growing Commercial Revenues:** Targeting €170 - €180 million of vaccine sales in 2025 to support continued R&D investments; Strong cash position of €168 million (Dec. 31, 2024)
- **Targeting profitability in 2027:** based on continued commercial growth plus Lyme vaccine commercial entry

# Valneva's Augmented Commercial and R&D Portfolio

Further extending a unique, differentiated portfolio

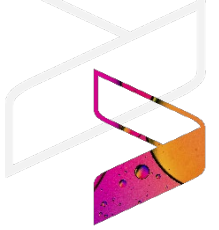


	Program	Vaccine Design	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial
<b>Commercial Products</b>	<b>IXIARO®</b>	Only U.S./ EU approved vaccine against Japanese encephalitis					
	<b>DUKORAL®</b>	Established Cholera (ETEC <sup>1</sup> ) vaccine approved in >30 countries					
	<b>IXCHIQ®</b>	World's first approved chikungunya vaccine (U.S., Europe, UK, Canada); Review ongoing in Brazil					
<b>Clinical Programs</b>	<b>VLA15:</b> Lyme disease	Most clinically advanced Lyme vaccine program worldwide					
	<b>VLA1553:</b> Chikungunya	Phase 3 adolescent study (Brazil) and Phase 2 pediatric study support potential label expansion					
	<b>S4V2:</b> Shigellosis	Phase 2 CHIM <sup>2</sup> underway; Phase 2 pediatric study starting in H1 25					
	<b>VLA1601:</b> Zika	Potential for first/best-in-class					
<b>Key Pre-Clinical Activities</b>	<b>VLA2112:</b> EBV						
	Various Enteric diseases						

<sup>1</sup> ETEC indication in some markets only; <sup>2</sup> Controlled human infection model

# 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

- Leverage proven R&D engine and strategic partnerships
- Continue to focus on vaccines that can make a difference: (first-, only-, best-in-class)
- Execute efficiently to generate meaningful clinical catalysts

## 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 Lyme disease vaccine candidate partnered with Pfizer



**R&D**

**valneva**



# World's leading Lyme Disease Vaccine Candidate

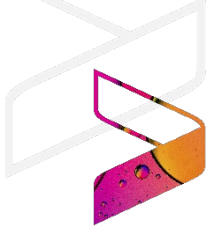
VLA15

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# Lyme Disease Represents A Major Medical Need And Market Opportunity

No vaccine is currently available to prevent Lyme disease in humans



## Annual Burden of Disease

**U.S.<sup>1</sup>**  
**~476K** cases

**Europe<sup>2</sup>**  
**>129K** cases

### Severe Manifestations<sup>3</sup>

**10-30%**  
cases develop



Lyme carditis  
Lyme neuroborreliosis  
Lyme arthritis

### Persistent Symptoms<sup>4,5</sup>

**5-10%**

cases continue to have persistent symptoms following treatment

## Commercial opportunity for Valneva



**U.S.**  
**87 million**



**Europe**  
**202 million**

**Population Living in Endemic Regions<sup>1,2</sup>**

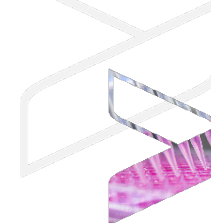
**>\$1 billion estimated global market<sup>6</sup>**

<sup>1</sup> Kugeler et al. Emerging Infectious Disease, 2021 (doi.org/10.3201/eid2702.202731); <sup>2</sup> Burn et al. Vector Borne and Zoonotic Disease, 2023 (DOI: 10.1089/vbz.2022.0071); <sup>3</sup> Schwartz et al. Morbidity and Mortality Weekly Report Nov. 10, 2017; <sup>4</sup> Ursinus: [https://www.thelancet.com/journals/lanepi/article/PIIS2666-7762\(21\)00119-8/fulltext](https://www.thelancet.com/journals/lanepi/article/PIIS2666-7762(21)00119-8/fulltext); <sup>5</sup> Aucott, J.N., et al., Risk of post-treatment Lyme disease in patients with ideally-treated early Lyme disease: A prospective cohort study. Int J Infect Dis, 2022. 116: p. 230-237.; <sup>6</sup> Lyme Disease research and analysis conducted by an independent market research firm



# 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 (>97% coverage)
- Established mechanism of action
- U.S. FDA Fast Track Designation
- Phase 3 fully recruited; primary vaccination completed<sup>1</sup>

## Market Opportunity

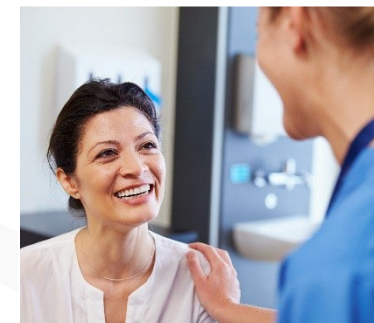


- Exclusive, worldwide partnership<sup>2</sup>



- >\$1billion estimated global market<sup>3</sup>
- Valneva eligible for upfront and milestone payments up to \$408 million (\$165 million received)
- Tiered sales royalties 14-22%

## Upcoming Milestones

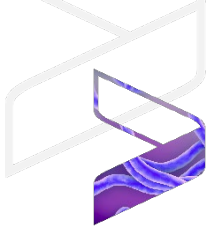


- On track for first Phase 3 study results (end 2025); Regulatory filings (U.S.+ EU) in 2026<sup>4</sup>
- Completed Valneva contribution to Phase 3 trial costs in H1 2024
- Reported two-year antibody persistence and booster results

<sup>1</sup> Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion; <sup>2</sup> Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; <sup>3</sup> Lyme Disease research and analysis conducted by an independent market research firm; <sup>4</sup> 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 data<sup>1</sup>

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

## 2021: First positive booster data<sup>2,3</sup>

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

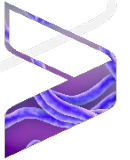
## 2022: First positive pediatric data<sup>4,3</sup>

- Strong immunogenicity profile in adults<sup>2</sup> (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 1<sup>st</sup> and 2<sup>nd</sup> booster responses (all serotypes & age groups)

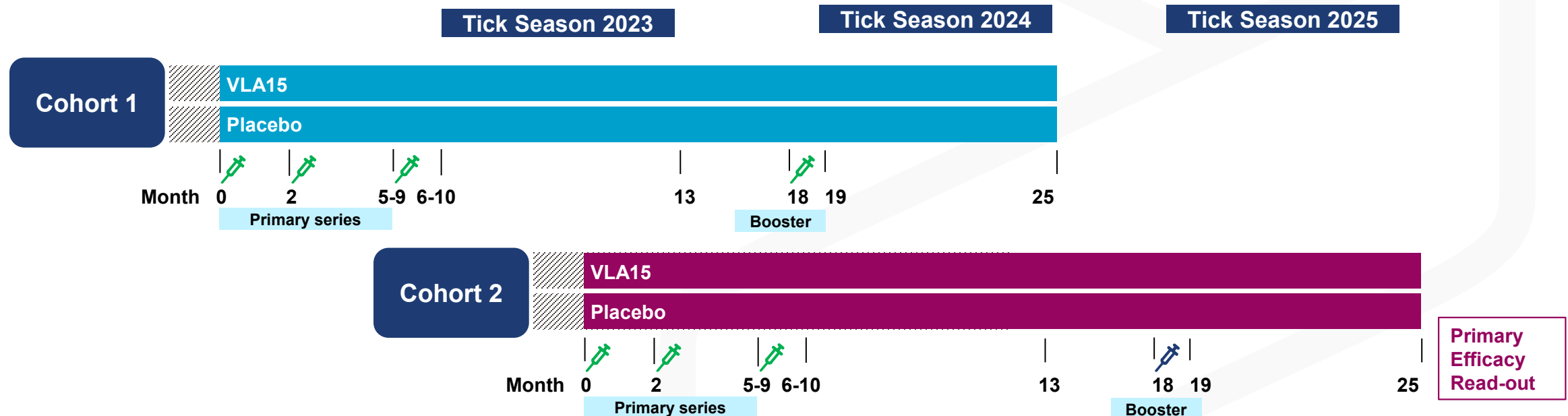
<sup>1</sup> Study VLA15-201; <sup>2</sup> Study VLA15-202; <sup>3</sup> Phase 2 VLA15-201 and -202 study results [published](#) in *The Lancet Infectious Disease* (June 2024); <sup>4</sup> Study VLA15-221

## Phase 3: First Data Readout Expected at the End of 2025

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



- **Population:** ~9,400 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 2nd consecutive tick season (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed<sup>1</sup> LD cases after 1st tick season (i.e., after completion of primary vaccination series) amongst other secondary endpoints as defined in Phase 3 protocol



<sup>1</sup> Subject to positive data; <sup>2</sup> Cases are evaluated and confirmed by an Endpoint Adjudication Committee



# The World's First Chikungunya Vaccine

**IXCHIQ® / VLA1553**

IXCHIQ® is currently approved by the U.S. Food & Drug Administration (FDA), European Medicines Agency (EMA), The UK's Medicines and Healthcare products Regulatory Agency (MHRA) and Health Canada for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older. It is approved as well for adolescents age 12+ years by EMA.

Continued approval of IXCHIQ® is contingent upon verification of clinical benefit in confirmatory studies.

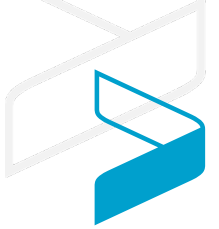
 **valneva**





# 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 population<sup>1</sup>

Substantial quality-of-life and **health-economic impact**<sup>2</sup>

**Nearly half (43%)** of those infected develop **chronic symptoms**<sup>3</sup>

**~460,000 cases and 170 deaths** associated with chikungunya disease worldwide in 2024<sup>4</sup>;

Most cases reported in **Brazil, Paraguay, Argentina and Bolivia**

**Four-fold increase** in India from 2023<sup>4</sup>

Identified in **>110 countries** across five continents

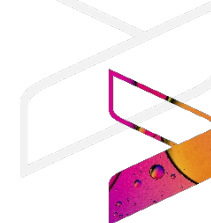


**75% of world population lives in areas at-risk of chikungunya**

1. Staples et al. CDC Yellow Book 2020, Chapter 4; 2. The global health and economic burden of chikungunya from 2011 to 2020: a model-driven analysis on the impact of an emerging vector-borne disease; 3. Bettis et al, PLOS Neglected Tropical Diseases 16(1): e0010069. 4. As of September 30<sup>th</sup>; <https://bluedot.global/vaccines-on-the-table-as-chikungunya-outbreak-intensifies-in-india/>

# IXCHIQ®: The World's First Licensed Chikungunya Vaccine

Approved in adults in U.S., EU, UK, Canada - additional approvals expected in 2025




## Vaccine Highlights



- Live-attenuated: offers strong and long-lasting protection with a single shot
- Approved for adults by the U.S. FDA, EMA, MHRA and Health Canada; For adolescents as well by EMA.
- U.S. launch underway: sales through Valneva's commercial infrastructure; Launches commencing in Europe, Canada and the UK
- Filed for additional adolescent label extensions and including two-year persistence data

## Market Opportunity



- Travelers 
- Military
- Outbreak preparedness
- Estimated global market to exceed \$500 million per year<sup>2</sup>; \$300-\$400 represented by travel segment
- Partnership for Latin America and certain LMICs<sup>1</sup> (Insituto Butantan)
- Partnership for LMICs in Asia with Serum Institute of India (SII)

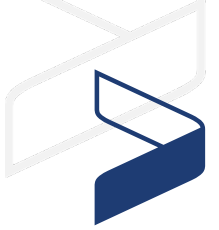
## Upcoming Milestones



- Potential upcoming approval in Brazil
- Reported Positive Phase 2 pediatric results (Q1 2025); Phase 3 pediatric study to commence in Q4 2025
- Initiate Phase 4 clinical program with support from recent \$41.3m CEPI grant

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

# IXCHIQ® Builds on Key Differentiators to Drive Growth



The 1<sup>st</sup> vaccine against chikungunya  
providing a strong and persistent immune response  
with only one dose

- 98.9% seroresponse rate at Day 29 - Sustained seroresponse rate at 96% after three years<sup>1</sup>
- Strong and persistent immune response in adults 18-64 yrs and 65+<sup>2</sup>, as well as adolescents
- Generally well tolerated among the >3,600 adults, 754 adolescents and 304 children evaluated for safety<sup>3</sup>
- Convenient single dose

1. Two-year antibody persistence (97%) included in current EU label; submitted for inclusion in U.S. and Canadian labels; 2. Included in current U.S., EU, UK, and Canadian labels; 3. No adverse drug reaction reported since approval of IXCHIQ® indicate any changes compared to knowledge from clinical trials.

# Only CHIKV Vaccine to Achieve Long-Lasting Immunogenicity with a Single Shot

Differentiated vaccine shows rapid, persistent immunity across all age groups tested<sup>1,2,5</sup>



## Immunogenicity Data

- 99% Seroresponse<sup>3</sup> Rate (SRR) after single vaccination → maintained at 96% after 36 months<sup>4,5,6</sup>
- Similar SRR and antibody titers in age 65+ adults as younger adults<sup>1,4</sup>
- 100% SRR after 14 days and sustained for 12 months<sup>2</sup>
- Adolescent trial met primary endpoint<sup>7</sup>: highly immunogenic in baseline-negative individuals; 99% SRR sustained at 98% after 12 months<sup>8</sup>



## 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<sup>9</sup> and pediatric<sup>10</sup> trials demonstrated favorable safety profile regardless of previous CHIKV infection

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  $\geq 150$  by  $\mu$ PRNT<sub>50</sub> (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 Three-Year Antibody Persistence Data for its Single-Shot Chikungunya Vaccine IXCHIQ®](#); 7. [Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate](#); 8. [Valneva Reports High Sustained Immune Response in Adolescents One Year After Single Vaccination with its Chikungunya Vaccine](#); 9. [Valneva Reports Positive Initial Phase 3 Safety Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate](#); 10. [Valneva Reports Positive Phase 2 Results in Children for its Chikungunya Vaccine and Announces Phase 3 Dose Decision](#)



# IXCHIQ®: Focused on Expanding Access, Label Extension, Product Profile

Robust clinical program supported by new \$43.1 million CEPI grant<sup>1</sup>



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

*To confirm effectiveness following licensure based on an immunological surrogate of protection and to optimize description of the safety profile*

- Observational effectiveness study in Brazil
- Pragmatic randomized controlled effectiveness and safety study<sup>3</sup>: adults (and adolescents - tbc) in endemic countries
- Prospective safety cohort study and pregnancy surveillance in Brazil

## Additional Label Extension

*To expand access to the vaccine for all age groups*

- Phase 3: Randomized, controlled study in adolescents aged 12 to 17 years
- Phase 3: Randomized, controlled study in children aged 1 to 11 years

Reported positive data up to Month 12

Starting Q4 2025, based on (+) Ph2<sup>4</sup>

## Product Profile

*To confirm the long-term durability of the immune response and further differentiate the vaccine*

- Phase 3: Ongoing antibody persistence and long-term safety study in adults; reported positive 36-month results to date

1. <https://valneva.com/press-release/cepi-expands-partnership-with-valneva-with-a-41-3-million-grant-to-support-broader-access-to-the-worlds-first-chikungunya-vaccine/>; 2. <https://www.fda.gov/media/173759/download>;  
3. <https://www.fda.gov/media/172166/download>; 4. Valneva Reports Positive Phase 2 Results in Children for its Chikungunya Vaccine and Announces Phase 3 Dose Decision

# World's Most Clinically Advanced Tetravalent *Shigella* Vaccine Candidate

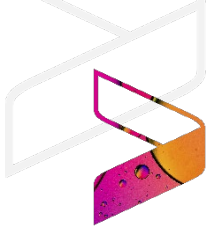
S4V2

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# S4V2: Opportunity to Develop First-in-Class Vaccine for a Life-Threatening Disease

Tetravalent bioconjugate vaccine with potential to cover up to ~85% of shigellosis infections<sup>1</sup>



## Vaccine Highlights



- World's most clinically advanced tetravalent *Shigella* vaccine candidate
- Exclusive global license from  (LMTB)<sup>2</sup>
- Includes four most common pathogenic *Shigella* bacteria serotypes: *S. flexneri* 2a, 3a, 6, and *S. sonnei*
- Positive Phase 1/2 clinical data reported<sup>3</sup>
- Awarded FDA Fast Track designation

## Market Opportunity



- Global market expected to exceed \$500 million annually<sup>4</sup>
- Travelers and military
- Endemic countries (LMICs<sup>5</sup>)
- Second-leading cause of fatal diarrheal disease; Up to estimated 165 million cases and 600,000 deaths annually<sup>6</sup>
- Identified as a priority vaccine by World Health Organization (WHO)<sup>7</sup>

## Upcoming Milestones



- Ongoing Phase 2 CHIM<sup>8</sup> study aiming to provide early look at potential efficacy
- Phase 2 pediatric study to launch in 2025; to be conducted by LMTB
- Valneva to assume all further R&D, CMC<sup>9</sup> and regulatory activities; worldwide commercialization upon potential approved

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8878964/pdf/vaccines-10-00212.pdf>; 2. Valneva and LimmaTech Enter into a Strategic Partnership to Accelerate the Development of the World's Most Clinically Advanced Tetravalent Shigella Vaccine Candidate; 3. [20240221\\_LimmaTech\\_Shigella-Interim-Data-PR\\_Final.pdf](https://www.limma.com/2024/02/21/limmatech-shigella-interim-data-pr-final.pdf) (lmtbio.com); 4. LEK 2024; Appox. 7 years after launch; 5. Low-and-Middle-Income Countries; 6. *Shigellosis* | CDC Yellow Book 2024; 7. Immunization, Vaccines and Biologicals (who.int); 8. Controlled Human Infection Model; 9. Chemistry, Manufacturing and Controls

# Valneva Gains Exclusive Worldwide Rights to Tetravalent *Shigella* Vaccine

Strategic partnership with LimmaTech Biologics (“LMTB”)



## Vaccine candidate “S4V2”

- World’s most clinically advanced tetravalent Shigellosis vaccine candidate
- Tetravalent bioconjugate vaccine for prevention of disease caused by *Shigella* bacteria (O-antigens of *S. flexneri* 2a, 3a, 6 and *S. sonnei*)
- Developed following positive proof-of-concept clinical data with monovalent vaccine candidate, which demonstrated promising efficacy in challenge model
- LMTB reported positive Phase 1/2 clinical data on S4V2, including robust immunogenicity against all strains; favorable safety and tolerability<sup>1</sup>
- FDA Fast Track granted in October 2024



## Key Aspects of Partnership

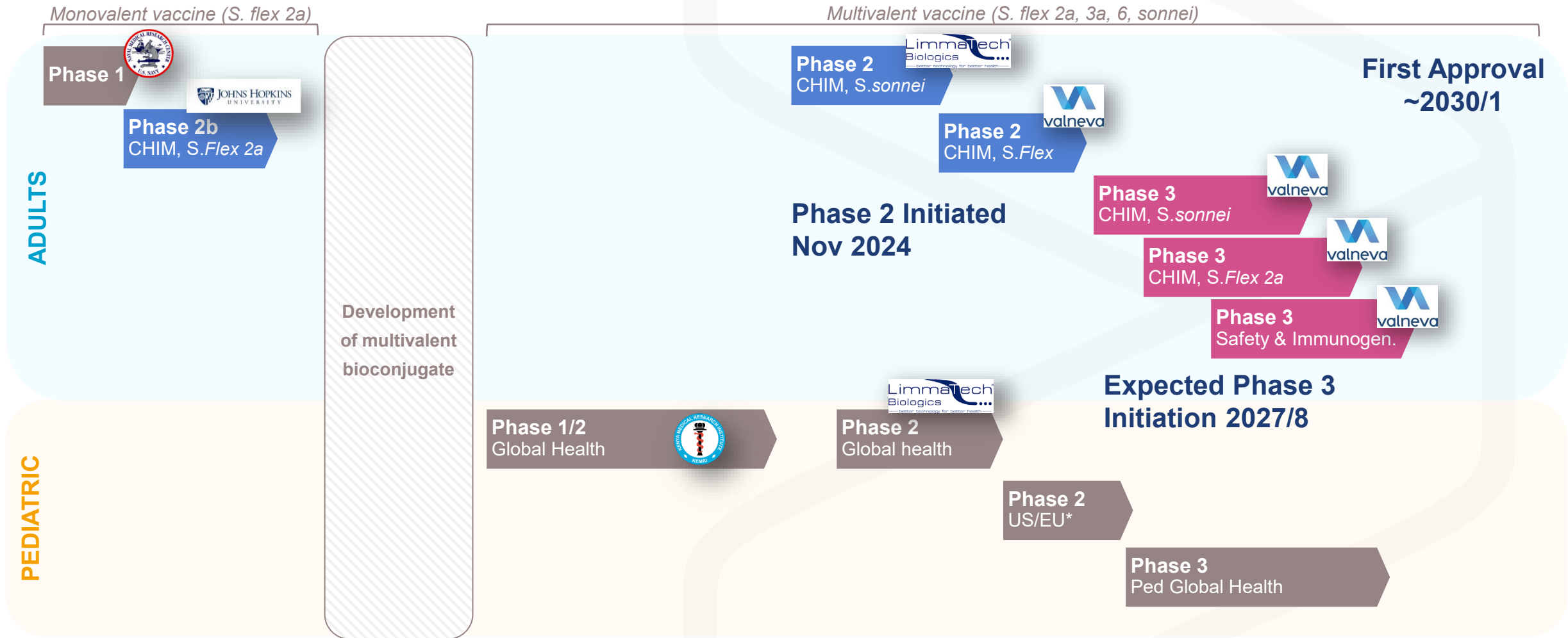
- €10 million upfront payment to LMTB
- Up to €40 million in future development, regulatory and sales-based milestones
- Low double-digit royalty on net sales (travel)
- Additional payments and single-digit royalties based on net sales (LMICs)
- Clinical collaboration through Phase 2
  - LMTB: Phase 2 CHIM<sup>2</sup> study (*S. Sonnei*) and pediatric immunogenicity study
  - Valneva: Phase 2 CHIM study (*S. flexneri* 2a)
- Valneva to lead all Phase 3, licensure, and commercial activities

<sup>1</sup> [https://lmtbio.com/wp-content/uploads/2024/02/20240221\\_LimmaTech\\_Shigella-Interim-Data-PR\\_Final.pdf](https://lmtbio.com/wp-content/uploads/2024/02/20240221_LimmaTech_Shigella-Interim-Data-PR_Final.pdf); <sup>2</sup> Controlled Human Infection Model



# Historical and Planned Clinical Studies

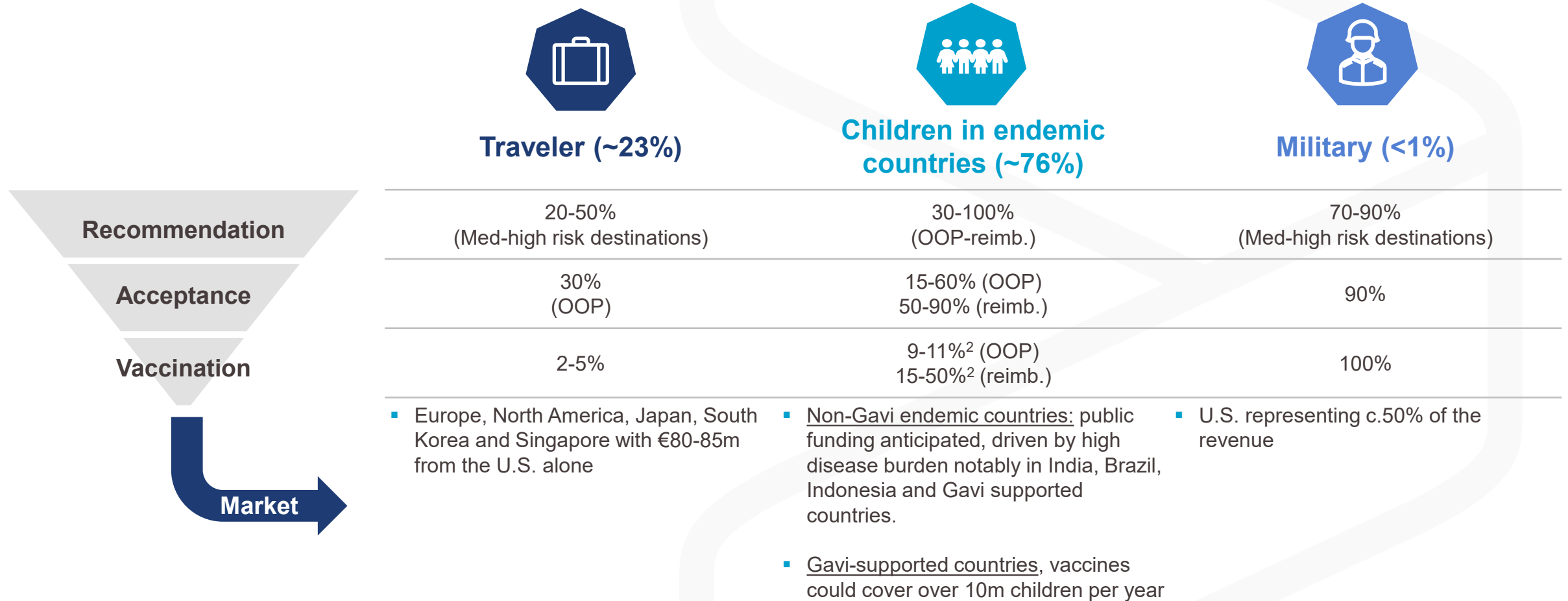
Multiple catalysts and decision points for envisaged development strategy



\* If needed

# Commercial Assessment of Shigella vaccine

Shigella vaccine market estimated to peak at ~€500 million<sup>1</sup>



Source: Market Study: LEK 2024, 1 Appox. 7 years after launch; 2 Converted to vaccination rate by applying the yearly vaccination penetration every year over a cohort of 5 years

# Novel Zika Virus Vaccine Candidate

VLA1601

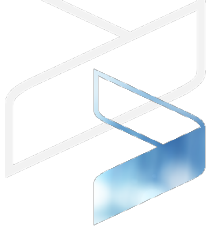
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# VLA1601: Optimized Vaccine Candidate Against Zika Virus

Phase 1 results expected this year



## Vaccine Highlights



- Novel adjuvanted inactivated whole-virus vaccine
- Leverages Valneva's proven / licensed platform (VLA2001)
- Phase 1 results from previous 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 based on:
  - Phase 1 results
  - Market potential
  - External, non-dilutive funding

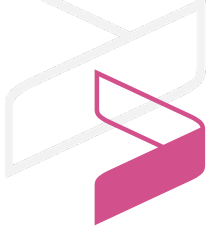
<sup>1</sup> Emergent Biosolutions and Valneva Report Positive Phase 1 Results for Their Vaccine Candidate Against the Zika Virus; <sup>2</sup> <https://www.cdc.gov/zika/transmission/index.html>; <sup>3</sup> <http://www.who.int/mediacentre/factsheets/zika/en/>



# Valneva Commercial Business

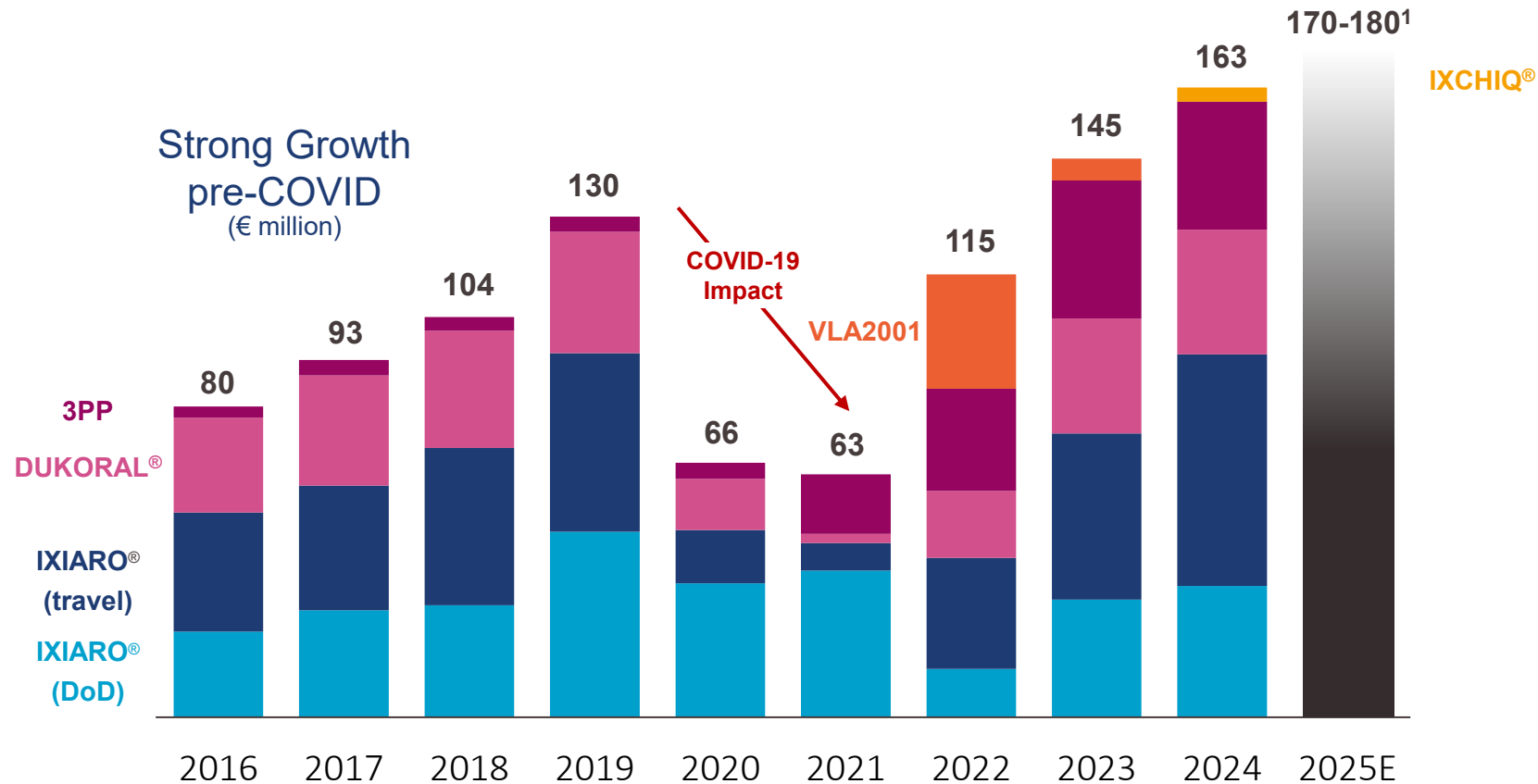
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# Continued Product Sales Growth Fuels Investments into R&D

+13% in 2024; Commercial business expected to be cash-flow positive in 2025



<sup>1</sup> Valneva Reports Preliminary Unaudited 2024 Revenue and Cash and Provides 2025 Outlook

# Valneva Remains Solidly Funded with Strong Financial Outlook



## 2025 Guidance

- Product Sales: €170 - €180 million<sup>1</sup>; Commercial business expected to be cash-flow positive
- Total Revenues: €180 - €190 million
- R&D Expense: €90 - €100 million, partially offset by grand funding and anticipated R&D tax credits
- Targeting >50% lower operational cash burn:
  - <€30 (vs. >€60 in 2024)
- Stringent focus on cash management supporting sufficient cash runway to reach key inflection points



## Financial Outlook

- Continued revenue growth and cash flows from commercialized vaccines
- Focused and strategic investments in R&D
  - Next Phase 3 program entry post Lyme data
  - Further R&D support: potential non-dilutive funding
- Gross margin improvement
  - Focus on proprietary sales
  - Cost-efficient manufacturing leveraging new facilities
- Potential for sustained profitability from 2027 based on successful Lyme disease vaccine approval and commercialization

1. Assumes continued wind down of third-party sales business; 2. Low- and middle-income countries

# Valneva Outlook: Growth Drivers for 2025 and Beyond



## VLA15 success case

- Potential for sustained profitability upon potential approval and commercialization\*, driven by substantial milestones and royalties starting in 2027

## Growing commercial revenues

- Near term: continued growth trajectory of IXIARO<sup>®</sup> and DUKORAL<sup>®</sup>
- Further growth as IXCHIQ<sup>®</sup> gains global traction

## Realizing future pipeline value

- Shigella and Zika in ongoing and planned studies
- Goal to enter next Phase 3 post-Lyme

\*Subject to positive Phase 3 data



Thank you  
Merci  
Danke  
Tack

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