



valneva

**A LEADING SPECIALTY VACCINE
COMPANY**

COMPANY PRESENTATION

FEBRUARY 2024

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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 United States is contingent upon verification of clinical benefit in confirmatory studies. Regulatory review of the VLA1553 chikungunya vaccine candidate remains ongoing in other jurisdictions, and approval by the FDA does not guarantee approval in other jurisdictions, on similar terms or at all.

Valneva Summary and Core Strengths



Fully integrated specialty vaccine company focused on development, manufacturing and commercialization of **prophylactic vaccines for infectious diseases** with significant unmet medical need



- **Highly specialized and targeted approach to development of unique prophylactic vaccines**
 - **Advanced pipeline of differentiated clinical-stage assets** designed to address large populations
 - **Highly experienced leadership team with vaccine development and regulatory expertise;** successfully advanced three vaccines from early development to commercialization; recent IXCHIQ[®] approval
 - **Highly developed, nimble and sophisticated manufacturing infrastructure**
 - **Specialist sales infrastructure: three commercialized vaccines; distribution rights for third-party vaccines**
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- **Product Sales: €144.6M in 2023 (+26% vs 2022); 2024 sales guidance of €150 - €180M**
 - **Cash position of €126.1M at December 31, 2023; excludes €95M from sale of PRV in February 2024**

Valneva's R&D Pipeline Overview



	Program	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial	Next Inflection Point	Development Partners	
Clinical Portfolio	IXCHIQ®/VLA1553: Chikungunya	IXCHIQ®: FDA Approved PRV sold for \$103M							Product launched early 2024	CEPI/ Butantan (LMIC)
	VLA153: Lyme disease								Phase 3 fully enrolled; primary/booster vaccinations ongoing	
	VLA84: Clostridium difficile								Developed to EoP2/ on-hold	Open to partnering
	VLA1601: Zika								Expected clinical re-entry early 2024	-
	VLA1554: hMPV								Initial pre-clinical PoC completed	Partnering under evaluation
	VLA2112: EBV								Initial preclinical proof of concept by end 2024	-
	Other pre-clinical activities									



The World's First Chikungunya Vaccine

IXCHIQ® / VLA1553

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

Chikungunya: A Major Public Health Threat

Mosquito-transmitted disease with potentially debilitating consequences



Aedes aegypti



Aedes albopictus

- Chikungunya virus (CHIKV) is transmitted by ***Aedes*** mosquitoes¹
- Acute chikungunya, seen in up to 97% of those infected, typically presents with sudden onset of **high fever and joint pain**.¹
- Often causes **large, explosive outbreaks**, affecting one-third to three-quarters of the population¹; difficult to predict next outbreaks²
- High burden of disease: outbreaks can have substantial health-economic impact; infection can progress to **severe chronic symptoms** in many patients⁴
- **Outbreaks** have occurred in Asia, Africa and across Latin America¹ with the potential for it to happen in the U.S. and Europe^{2,4}; recent outbreak in Paraguay⁵ with PAHO issuing an epidemiological alert for the Americas⁶
- **Returning infected travelers** can trigger local transmission in areas where relevant mosquitoes are established (e.g. Southern U.S./Europe)²

1. Staples et al. CDC Yellow Book 2020, Chapter 4 . 2. Bettis et al, PLOS Neglected Tropical Diseases 16(1): e0010069. 3. Lindsey et al *Am J Trop Med Hyg.* 2018;98(1):192-197. doi:10.4269/ajtmh.17-0668 4. Silva LA et al. *J Clin Invest.* 2017 Mar 1;127(3):737-749; 5 [PAHO provides guidance to countries in response to increased chikungunya cases](#); 6 [Epidemiological Alert: Chikungunya increase in the Region of the Americas](#)



IXCHIQ®: The World's First Approved Chikungunya Vaccine

FDA-approved, live-attenuated vaccine with potential additional regulatory approvals in 2024

Pioneering Vaccine Development in an Area of High Unmet Need – Preparing for Success

- **First** chikungunya vaccine to be **approved by the FDA** (November 2023) – PRV sold for \$103 million (February 2024)
- **Additional filings** under review by EMA, Health Canada and Anvisa (Brazil)
- Live-attenuated vaccine approach: believed to be **particularly well suited to target long-lasting protection** compared to clinical-stage chikungunya vaccine candidates
- Preparing for launch: IXCHIQ® **fits perfectly within Valneva's existing commercial infrastructure**
- **Additional clinical trials to expand current label:** Phase 3 Adolescent study completed; Phase 2 pediatric study ongoing

IXCHIQ®: Target Populations/Geographies

- **Non-endemic** countries: travelers / military / outbreak preparedness in U.S., EU, CAN
- **Endemic** use in Latin America and certain LMICs¹: Partnered with CEPI and Instituto Butantan, including future local manufacturing

1. Low- and middle-income countries

Upcoming Milestones

- ACIP meeting end February 2024
- Potential upcoming approvals: EMA, Health Canada, Anvisa (Brazil) and UK



VLA1553: Clinical Data Highlights^{1,2,5}

Live-attenuated CHIKV vaccine demonstrates rapid and long-lasting immunity with a single shot

Immunogenicity Data

- 99% Seroresponse³ Rate (SRR) after a single vaccination
- Immunogenicity profile maintained over time: 99% SRR after 12 months⁴ and 97% after 24 months⁵
- Older adults (≥ 65 years) achieved similar SRR and neutralizing antibody titers as younger adults (<65 years)^{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

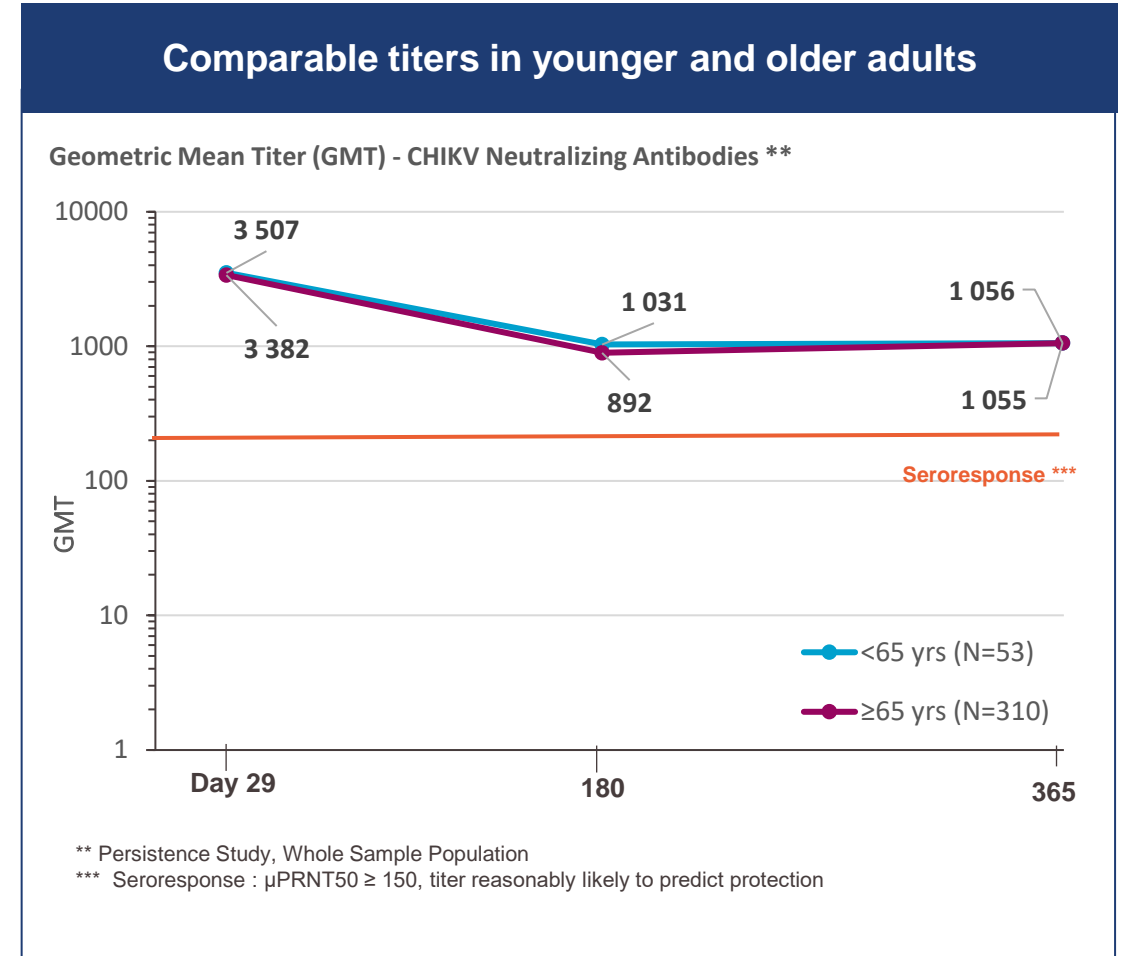
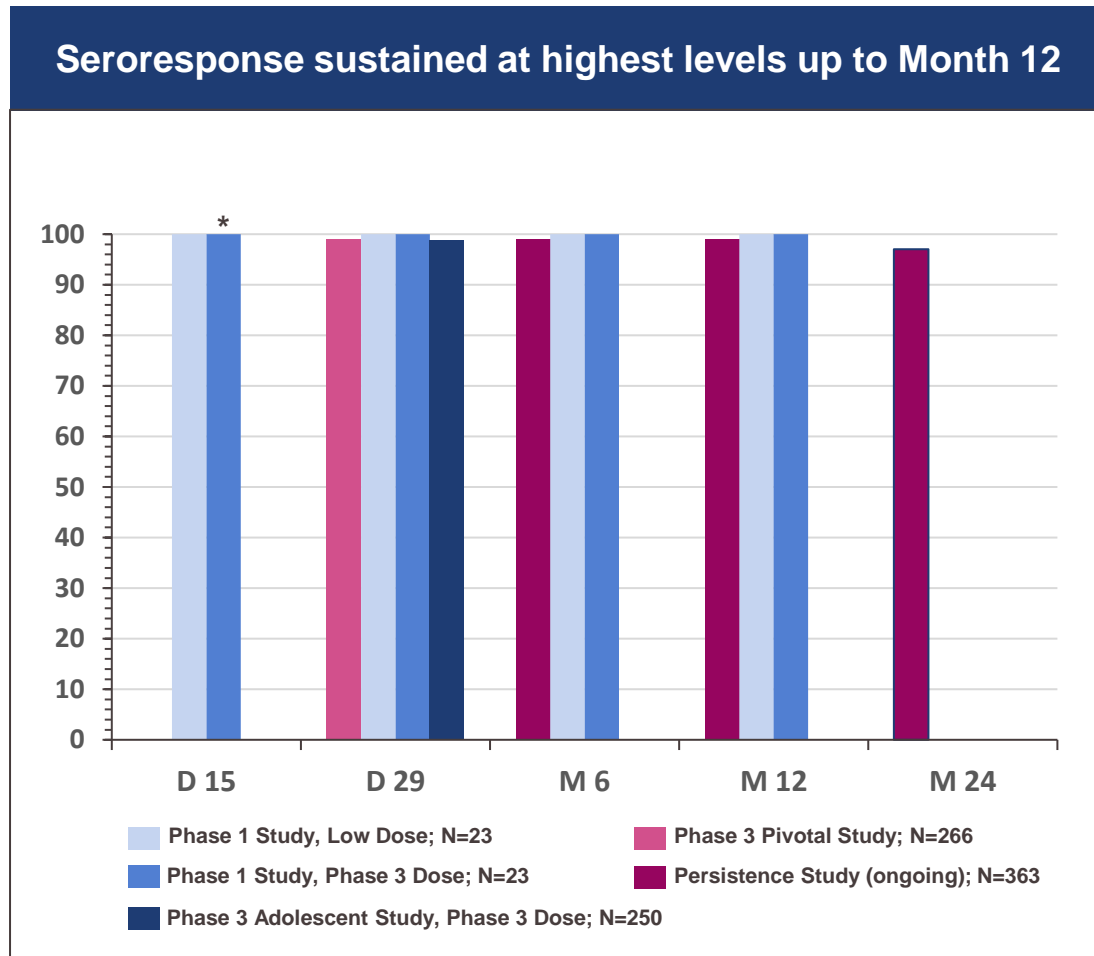
- VLA1553 was generally well tolerated among the >3,600 adults and 754 adolescents evaluated for safety
- Pivotal Safety Data:
 - ~50% of study participants had solicited systemic adverse events, most commonly headache, fatigue and myalgia
 - Majority of solicited adverse events mild or moderate. 2.0% of study participants reported severe solicited adverse events, most commonly fever.
- Adolescent trial in Brazil 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 μPRNT₅₀ (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](#)



VLA1553 Induces Early and Sustained Response Regardless Of Age

High seroresponse rates across studies

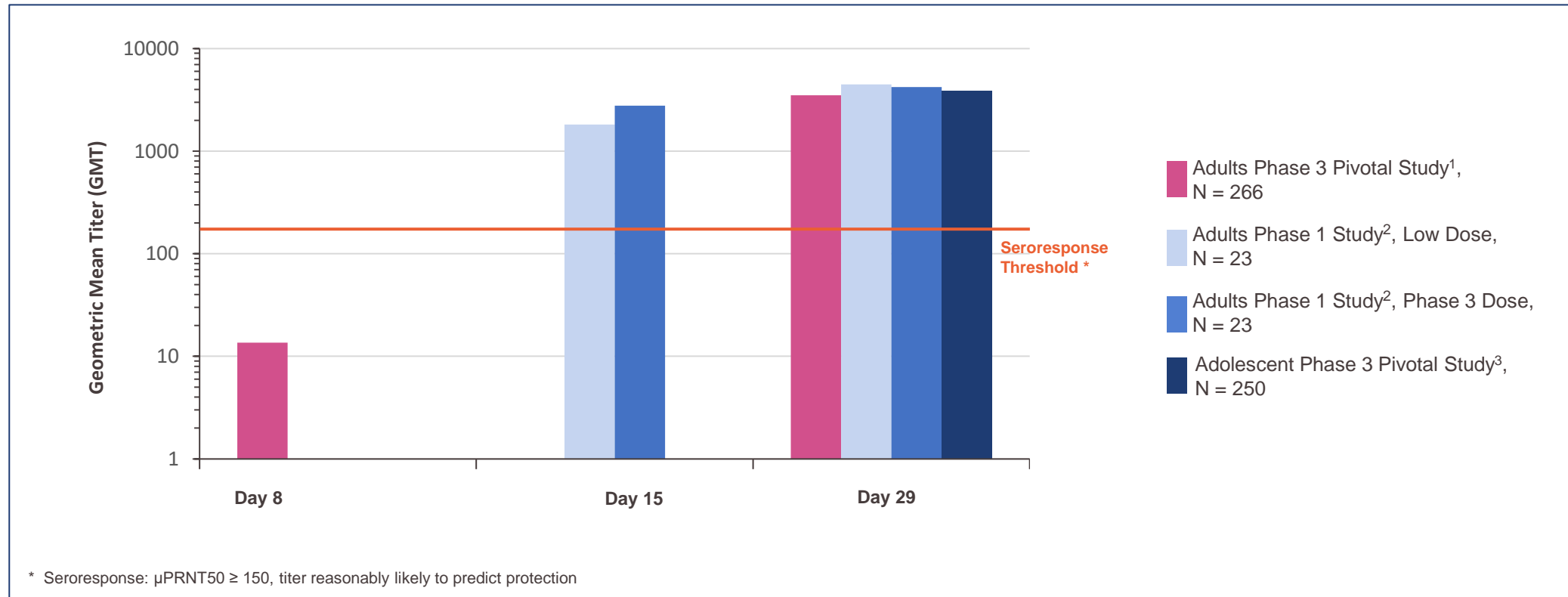


* Wressnigg et al, Lancet ID: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30238-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext); Re-testing of Phase 1 sera (vaccinated with liquid formulation of VLA1553) using the final assay/threshold used for the pivotal endpoint; data presented at CISTM18, May 2023



VLA1553: Fast and Robust Induction of Neutralizing CHIKV Antibodies

High neutralizing antibody titers at Day 15 in Phase 1; by Day 29 for pivotal trial endpoint



Note: All GMT used same, validated μ PRNT assay

1. [Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate](#); 2. Wressnigg et al, Lancet ID: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30238-3/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext); 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. [Valneva Reports Positive Pivotal Phase 3 Immunogenicity Data in Adolescents for its Single-Shot Chikungunya Vaccine Candidate](#)



IXCHIQ[®] is approved under the accelerated licensure pathway¹

Phase 4 aims to verify the clinical benefit in two² key post-marketing effectiveness studies

VLA1553-402

Observational effectiveness study in population > 12 years of age in endemic areas of Brazil

- To estimate the efficacy of IXCHIQ[®] (VLA1553) in the prevention of symptomatic laboratory-confirmed CHIKV cases after a single vaccination
- Test-negative case control study (RT-PCR case confirmation), ~450 cases / 890 controls
- Municipality selection based on CHIKV risk, test infrastructure
- Pilot vaccination period to ensure est. >15% vaccination coverage
 - Safety evaluation (incidence of medically attended AESIs) (n ~ 5000)
 - Serosurvey (Pre-exposure assessment)

2025 – 2028 (including pilot phase)

VLA1553-404

Pragmatic randomized controlled effectiveness and safety study in adults in an endemic country (n ~ 20.000)

- To assess efficacy of IXCHIQ[®] (VLA1553) in the prevention of symptomatic laboratory-confirmed CHIKV cases after a single vaccination compared to control participants during the same trial period
- 1:1 randomization
- Safety evaluation (n ≥10.000) for severe chikungunya-like adverse reactions and prolonged arthralgia
- Statutory requirement³ for well-controlled clinical investigation introduced to address potential biases associated with an observational design

2025 - 2029

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>



Chikungunya Global Market Segments

Global market for chikungunya vaccines estimated to exceed \$500 million per year by 2032¹

Segments Targeted Directly by Valneva

Travelers from Non-Endemic Regions

Travel vaccine for individuals travelling to areas with risk of chikungunya

Military from Non-Endemic Regions

Vaccine for troops stationed in areas with risk of chikungunya

Outbreak Preparedness Non-Endemic Regions

Vaccine in areas in response to / at risk for a domestic outbreak

Segments Targeted via Partnership

Endemic Region Use

Vaccine in Latin America / certain LMIC markets, Targeted via **CEPI / Instituto Butantan Partnership**

CHIKV identified in >110 countries across five continents



¹ VAMV005. Chikungunya virus vaccines. Global demand analysis. Feb 2020



IXCHIQ® Fits Perfectly Within our Existing Commercial Infrastructure

High-caliber team with significant experience in the vaccine space

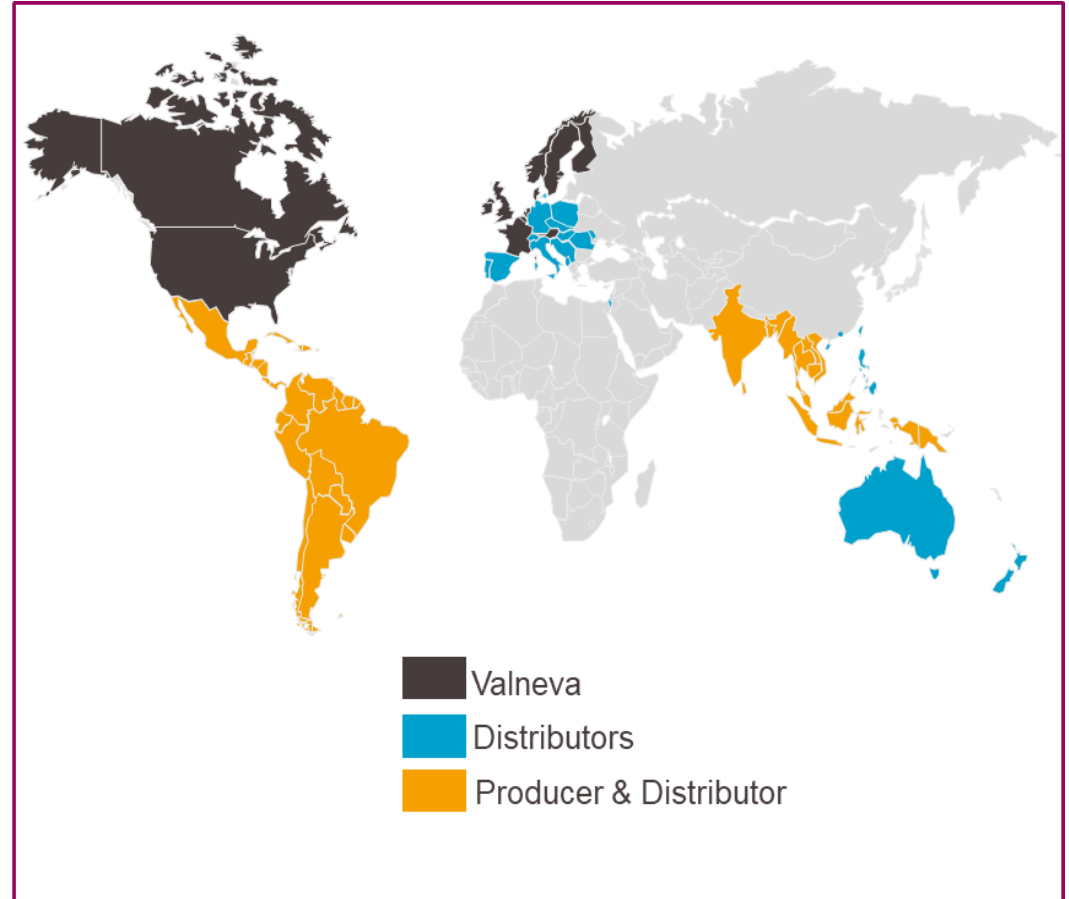
Highly experienced teams with deep expertise in vaccine market segments

Commercial infrastructure in most key markets; footprint extended through distribution partners

Integrated sales, marketing, medical and access/government affairs capabilities focused on increasing awareness and unlocking brand potential

Leverage data-driven insights and digital tools to enhance commercial capabilities

Commercial Footprint

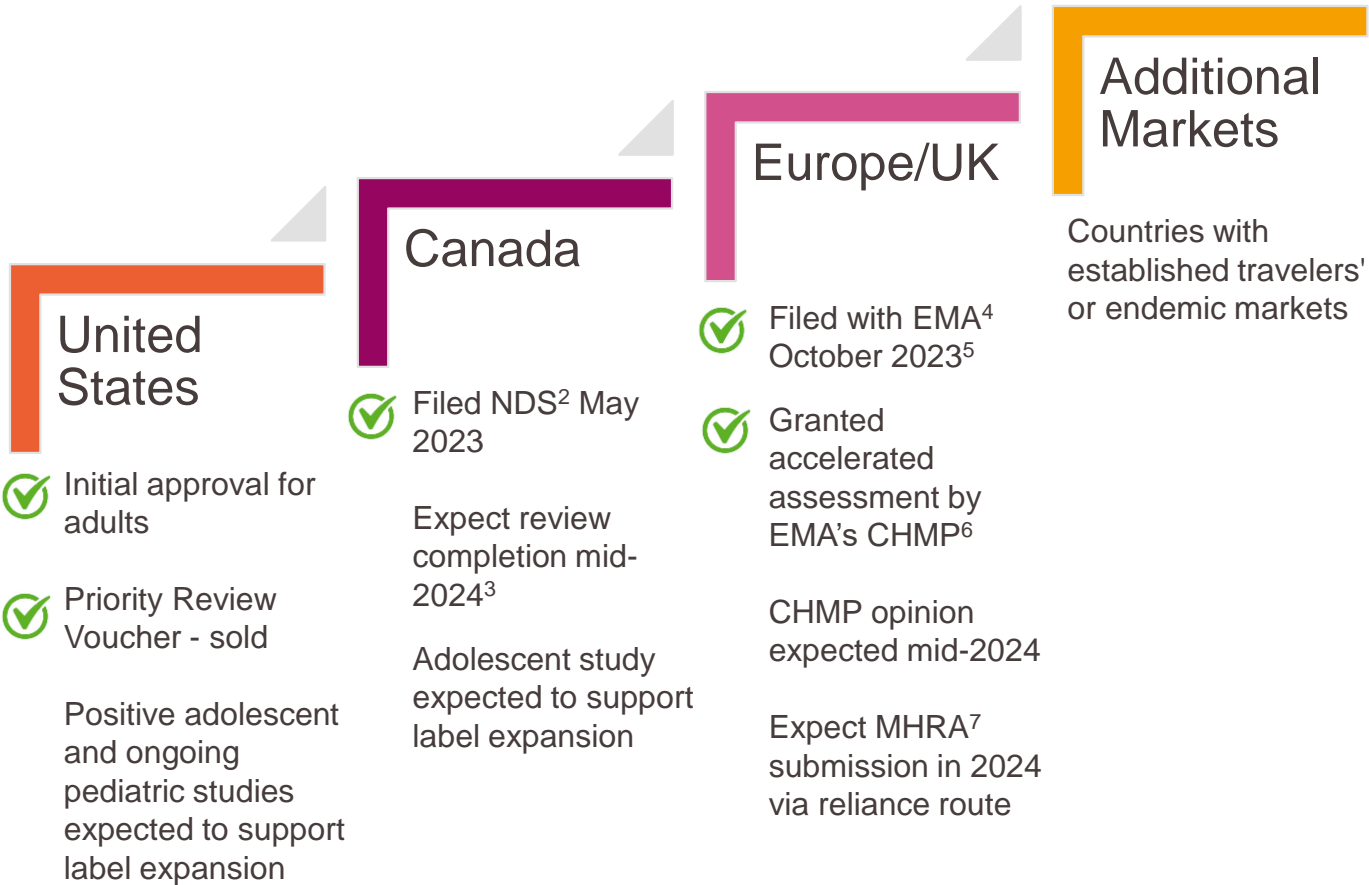




Preparing for Global Market Launches

Planned additional and future regulatory processes¹

IXCHIQ®: Valneva



Instituto Butantan



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



Lyme Disease Vaccine Candidate – VLA15



Multivalent Recombinant Protein Vaccine Candidate for Lyme Disease

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



1

Phase 3 study ongoing, sponsored by Pfizer¹ and supported by positive results for three Phase 2 clinical trials^{2,3,4}, incl. first pediatric/adolescent data (priming and 12-mo booster)^{5,6}

2

Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 (\$95) million equity investment in Valneva⁷

3

Investigational multivalent vaccine targeting the six most prevalent serotypes causing Lyme disease in the United States and Europe

4

Follows established mechanism of action for a Lyme disease vaccine candidate

5

Fast Track Designation granted by U.S. FDA in July 2017

¹ Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; ² Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate; ³ Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15. ⁴ Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate ; ⁵ Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate/; ⁶ Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate; ⁷ Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15.

Valneva's and Pfizer's Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine VLA15



Established	April 2020
Updated	June 2022; Equity Investment of \$95 Million by Pfizer; Phase 3 cost split 40/60% (Valneva/Pfizer)*
Rationale	Maximize Lyme disease opportunity by leveraging Pfizer's outstanding development and commercial expertise
Scope	Pfizer leading late-stage development and will have sole control over global commercialization
Key Financial Terms	<p>Valneva eligible to receive up to \$408 million (\$165 million received)</p> <ul style="list-style-type: none"> • \$130 million upfront payment (received) • \$35 million in development milestone payments (received) • \$143 million in early commercialization milestones • \$100 million in cumulative sales milestones <p>Tiered sales royalties ranging 14-22%</p>
Co-development costs	Valneva responsible for 40%; Pfizer 60%
Status	Pivotal Phase 3 efficacy study fully enrolled (adult and pediatric)

* As of 1st May 2022



VLA15 Demonstrated Strong Immunogenicity Across 1,030 Adult and Pediatric Participants

VLA15-221: First positive pediatric data (April 2022¹)

- Strong immunogenicity profile in adult² (ages 18-65) and pediatric participants (ages 5-17)
- More immunogenic in pediatric participants than in adults, with both two-dose and three-dose vaccination schedules; three-dose schedule selected for all ages in Phase 3
- Antibody levels remained above baseline six months after primary vaccination³; strong anamnestic antibody response across all serotypes and age groups (age 5 - 65), one month after booster dose (Month 19)⁴

VLA15-202: First positive booster data (September 2021)⁴

- High antibody responses confirmed across all serotypes and dose groups after primary vaccination series (primary endpoint)⁶
- 12-month booster dose elicited strong anamnestic response

VLA15-201: First positive immunogenicity data (July 2020)⁷

- Immunogenic across all serotypes and dose groups; higher doses elicited higher antibody responses
- Encouraging immunogenicity profile confirmed, including in older adults (ages 50-65)

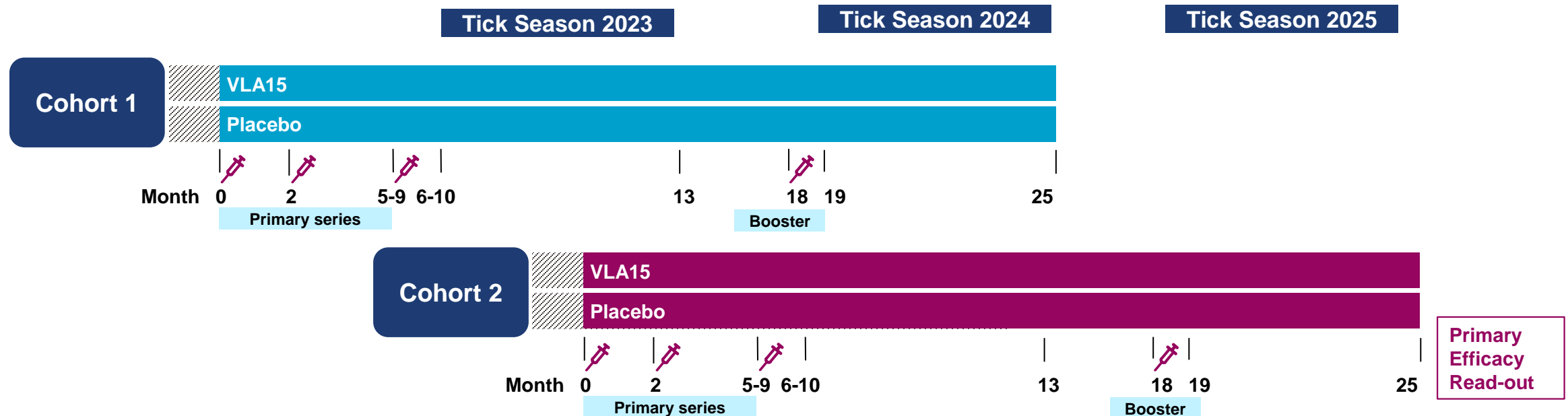
¹ Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate; ² Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; ³ Valneva and Pfizer Report Six-Month Antibody Persistence Data in Children and Adults for Lyme Disease Vaccine Candidate; ⁴ Valneva and Pfizer Report Positive Pediatric and Adolescent Phase 2 Booster Results for Lyme Disease Vaccine Candidate; ⁵ Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate; ⁶ Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15; ⁷ Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate



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



Zika Virus Vaccine Candidate – VLA1601



VLA1601: Potential to be a Differentiated Zika Virus Vaccine

Adjuvanted, inactivated whole virus vaccine candidate

Zika viral disease

- Flaviviral disease transmitted by *Aedes* mosquitoes¹
- Common flu-like symptoms, lasting between 2 -7 days
- Devastating effects in newborns and adults:
 - Microcephaly and severe brain defects in newborns
 - Guillain-Barré syndrome² in adults
- **No vaccines or specific treatment available**

Valneva's vaccine candidate

- Highly purified
- Adjuvanted inactivated whole-virus vaccine
- Leverages Valneva's proven/ licensed platform(s):
 - IXIARO®, VLA2001



Final Phase 1 data confirmed excellent safety profile^{3,4}

- Met primary endpoint showing excellent safety profile in all tested doses and schedules
 - Comparable to IXIARO® and other clinical stage Zika vaccines
- Immunogenic at all doses and schedules tested
 - Dose- and schedule-dependent

Expect to re-initiate Phase 1 clinical trial in Q1 2024 with updated formulations

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

⁴ Valneva Reports H1 2019 Results Marked by Strong Operational Performance and Major Corporate Progress



Valneva Commercial Products

Current Commercial Portfolio



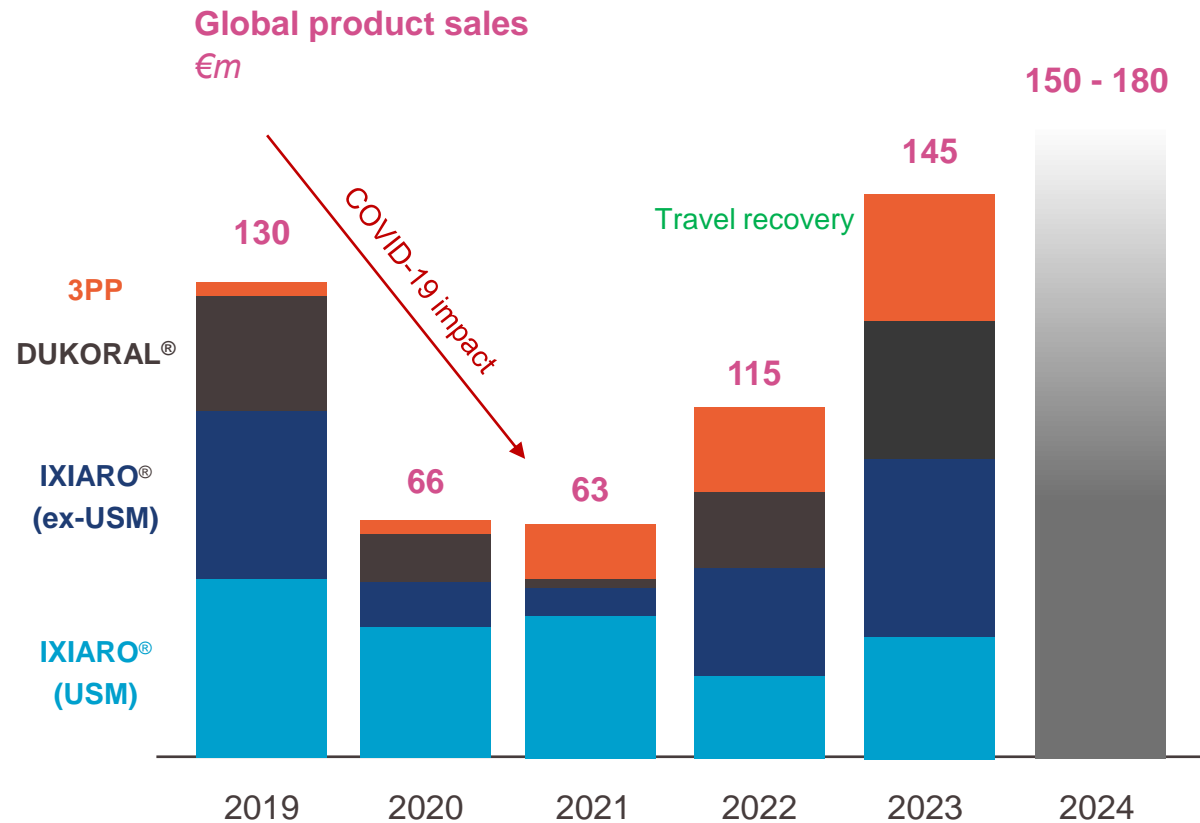
	Brand	Indication*	Partner / Year	Valneva commercial rights & key markets
Proprietary		Active immunization against Japanese encephalitis from 2 months of age	Global Rights	Valneva direct markets : US, CA, UK, FR, Nordics, BE, NL, AT Key markets addressed by Partners: DE, AU, IL
		Active immunisation against Cholera and ETEC** from 2 years of age	Global Rights	Valneva direct markets : CA, UK, FR, Nordics, AT Key markets addressed by Partners: DE, AU, IL, PL
		Prevention of disease caused by chikungunya virus in individuals 18yo and older who are at increased risk of exposure	Global Rights	Valneva direct markets : US Regulatory processes ongoing: EU, CA, Brazil
3rd-Party Distribution		Active immunization against Flu	2016	Rights licensed from Seqirus in Austria
		Passive, transient post-exposure prevention of rabies infection	2018	Rights licensed from Kamada in Canada
		Active immunization against rabies in individuals of all ages	2020	Rights licensed from Bavarian Nordic in select markets: CA, UK, FR, BE, NL, AT
		Active immunization against tick-borne encephalitis in adults and children	2020	Rights licensed from Bavarian Nordic in select markets: Austria & France
		Active immunization against hepatitis B virus in adults	2022	Rights licensed from VBI in select markets: UK, Nordics, Netherlands, & Belgium

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

Product Sales: Strong Growth Anticipated, Driven by Continued Travel Recovery



Revenues Surpassed Pre-Pandemic Levels by 12% in 2023¹; Continued growth expected in 2024^{1,2}



2024 guidance¹

Product sales of €150 million to €180 million

Other income of €95 million to €105 million, including:

- €95 million in proceeds from PRV sale³

R&D expense of €65 million to €90 million

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)



Financial Overview



Balance sheet strengthened by successful capital raises

May 2021: U.S. Initial Public Offering with gross proceeds of \$107.6 million

2021-2023: Follow on offerings and debt financing

- Most recent upsized Global Offering brought in €102.9 million in gross proceeds; led by new U.S. investor¹, with strong support from existing holders in the U.S. and Europe
- Increased the principal amount of existing debt financing agreement² and secured add-on facility³ (fully drawn)

June 2022: €90.5 (\$95) million investment by Pfizer⁴ to support Valneva's contribution to Phase 3 trial of VLA15

Cash position of €126.1 million (December 31, 2023)⁵;

- Excludes €95 million in proceeds from sale of PRV in February 2024



Nasdaq: VALN – Euronext Paris: VLA

¹ Valneva Announces Pricing of €102.9 Million Global Offering of American Depositary Shares and Ordinary Shares; ² Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed; ³ Valneva Announces Extension of Existing Loan Agreement; ⁴ Valneva and Pfizer Announce Closing of Equity Investment; ⁵ Valneva Reports Nine-Month 2023 Financial Results and Provides Corporate Updates; ⁵ Valneva Reports Full Year 2023 Revenue and Cash, Provides First 2024 Guidance



Key Upcoming 2024 Catalysts and News flow

Chikungunya vaccine

- ACIP recommendation expected Q1 2024
- Initiation Phase 3 immunocompromised individuals studies expected in H1 2024
- Upcoming potential approvals: EMA, Health Canada, Anvisa (Brazil) and UK
- Initiation of Phase 4 clinical program by year end 2024
- Filing for potential label extension

Lyme disease vaccine candidate VLA15

- VALOR trial: completion of booster vaccination for Cohort 1 expected Q2 2024
- VALOR Trial: completion of primary vaccination for Cohort 2 expected in Q2 2024
- Completion of Valneva contribution to Phase 3 trial costs in H1 2024
- Phase 2 two-year antibody persistence and booster results expected in Q3 2024

Additional news flow

- Initiation of VLA1601 Zika vaccine Phase 1 clinical trial in Q1 2024
- Advancement of select pre-clinical programs

Thank you
Merci
Danke
Tack

