



**valneva**

**A LEADING SPECIALTY VACCINE  
COMPANY**

**COMPANY PRESENTATION  
JEFFERIES HEALTHCARE  
CONFERENCE 2023**

# Disclaimer



This presentation does not contain or constitute an offer of, or the solicitation of an offer to buy or subscribe for, Valneva SE shares to any person in the USA or in any jurisdiction to whom or in which such offer or solicitation is unlawful.

Valneva is a European company. Information distributed is subject to European disclosure requirements that are different from those of the United States. Financial statements and information may be prepared according to accounting standards which may not be comparable to those used generally by companies in the United States.

This presentation includes only summary information provided as of the date of this presentation only and does not purport to be comprehensive. Any information in this presentation is purely indicative and subject to modification at any time without notice. Valneva does not warrant the completeness, accuracy or correctness of the information or opinions contained in this presentation. None of Valneva, or any of its affiliates, directors, officers, advisors and employees is under any obligation to update such information or shall bear any liability for any loss arising from any use of this presentation. The information has not been subject to independent verification and is qualified in its entirety by the business, financial and other information that Valneva is required to publish in accordance with the rules, regulations and practices applicable to companies listed on Euronext Paris and the NASDAQ Global Select Market, including in particular the risk factors described in Valneva's universal registration document filed with the French Financial Markets Authority (Autorité des Marchés Financiers, or AMF) on March 30, 2023 (document d'enregistrement universel 2022) under number D. 23-0199 (the "2022 URD"), and in the Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 30, 2023, as well as the information in any other periodic report and in any other press release, which are available free of charge on the websites of Valneva ([www.valneva.com](http://www.valneva.com)) and/or the AMF ([www.amf-france.org](http://www.amf-france.org)) and SEC ([www.sec.gov](http://www.sec.gov)).

Certain information and statements included in this presentation are not historical facts but are forward-looking statements, including statements with respect to revenue guidance, the progress, timing, completion, and results of research, development and clinical trials for product candidates and estimates for future performance of both Valneva and certain markets in which it operates. The forward-looking statements (a) are based on current beliefs, expectations and assumptions, including, without limitation, assumptions regarding present and future business strategies and the environment in which Valneva operates, and involve known and unknown risk, uncertainties and other factors, which may cause actual results, performance or achievements to be materially different from those expressed or implied by these forward-looking statements, (b) speak only as of the date this presentation is released, and (c) are for illustrative purposes only. Investors are cautioned that forward-looking information and statements are not guarantees of future performances and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Valneva.

This presentation presents information about VLA1553, an investigational vaccine candidate that has not been approved for use and has not been determined by any regulatory authority to be safe or effective.

## 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;** clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization
  - **Highly developed, nimble and sophisticated manufacturing infrastructure**
  - **Specialist sales infrastructure: three commercialized vaccines; distribution rights for third-party vaccines**
- **Product Sales of €114.8M in 2022 (+82.3% increase vs 2021); On track for 2023 guidance of €130 - €150M**
  - **Cash position of €254.5M at March 31, 2023**

# Advanced, Focused and Differentiated Clinical Pipeline and Promising Early-Stage Targets



	Program	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Commercial	Next Inflection Point	Development Partners
Clinical Portfolio	VLA1553: Chikungunya						Potentially eligible for PRV	Potential BLA approval 3Q 2023	CEPI/ Butantan (LMIC)
	VLA15: Lyme disease							Additional enrollment starting in 2Q 2023	
	VLA84: Clostridium difficile							Developed to EoP2/ on-hold	Open to partnering
	VLA1601: Zika							Potential clinical re-entry end 2023/ early 2024	-
	VLA1554: hMPV							Initial pre-clinical PoC completed	Partnering under evaluation
	VLA2112: EBV							Antigen identification by end 2023	-
	Campylobacter							Pre-clinical entry subject to gating criteria	
	Parvovirus							Pre-clinical entry subject to gating criteria	



# Chikungunya Vaccine Candidate – VLA1553\*

\*VLA1553 is an investigational chikungunya vaccine candidate and is not approved for use in the United States or any other jurisdiction

# Chikungunya: A Major Public Health Threat

Mosquito-transmitted disease with potentially debilitating consequences



*Aedes aegypti*



*Aedes albopictus*

- Chikungunya virus (CHIKV) is transmitted by ***Aedes*** mosquitoes<sup>1</sup>
- Acute chikungunya, seen in up to 97% of those infected, typically presents with sudden onset of **high fever and joint pain**.<sup>1</sup>
- Often causes **large, explosive outbreaks**, affecting one-third to three-quarters of the population<sup>1</sup>; difficult to predict next outbreaks<sup>2</sup>
- High burden of disease: outbreaks can have substantial health-economic impact; infection can progress to **severe chronic symptoms** in many patients<sup>4</sup>
- **Outbreaks** have occurred in Asia, Africa and across Latin America<sup>1</sup> with the potential for it to happen in the U.S. and Europe<sup>2,4</sup>; current outbreak in Paraguay<sup>5</sup> with PAHO issuing an epidemiological alert for the Americas<sup>6</sup>
- **Returning infected travelers** can trigger local transmission in areas where relevant mosquitoes are established (e.g. Southern U.S./Europe)<sup>2</sup>

No curative treatment and no vaccines available to date

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](#)



## Potential to Deliver the World's First Chikungunya Vaccine in Q3

VLA1553\* - Live-attenuated vaccine candidate under FDA priority review

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

- **First and only** chikungunya vaccine candidate to report positive Phase 3 data – met all trial endpoints
- **First to submit a biologics license application (BLA)** to the FDA for potential approval; filed with Health Canada
- Live-attenuated vaccine approach: believe is **particularly well suited to target long-lasting protection** compared to other chikungunya assets being evaluated in clinical trials
- Pivotal immunogenicity/safety data, antibody persistence **results demonstrate long-lasting, high sero-response** with a single dose
- Preparing for launch: VLA1553 **fits perfectly within Valneva's existing commercial infrastructure**

### Target Populations & Geographic Reach

- **Non-endemic** countries: travelers / military / outbreak preparedness in U.S., EU, CAN
- **Endemic** use in LMICs<sup>1</sup>: Partnered with CEPI and Instituto Butantan, including local manufacturing

<sup>1</sup> Low- and middle-income countries

### 2023 Regulatory & Clinical Catalysts

- PDUFA date **confirmed: end of August 2023**
- Potential award/sale of PRV upon approval: **~\$100M**
- Adolescent trial: first results **expected mid-2023**
- Expect to commence **additional regulatory processes in 2023**, including EMA, MHRA



## VLA1553: Clinical Data Highlights<sup>1,2</sup>

Live-attenuated CHIKV vaccine candidate targeting long-lasting immunity with a single shot

### Immunogenicity Data

- Seroresponse<sup>3</sup> Rate (SRR) in 99% of participants after a single vaccination
- Immunogenicity profile maintained over time: 99% SRR after 12 months<sup>4</sup>
- Older adults ( $\geq 65$  years) achieved similar SRR and neutralizing antibody titers as younger adults ( $<65$  years)<sup>1,4</sup>
- 100% seroconversion after 14 days and sustained to Month 12 in preceding trial<sup>2</sup>

### Safety Data<sup>1</sup>

- VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety
- Approximately 50% of study participants experienced 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.

<sup>1</sup> Valveva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate. <sup>2</sup> 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); <sup>3</sup> 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; <sup>4</sup> Valveva Reports Positive 12-Month Antibody Persistence Data for Single-Shot Chikungunya Vaccine Candidate





# Chikungunya Global Market Segments

Global market for chikungunya vaccines estimated to exceed \$500 million per year by 2032<sup>1</sup>

## 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

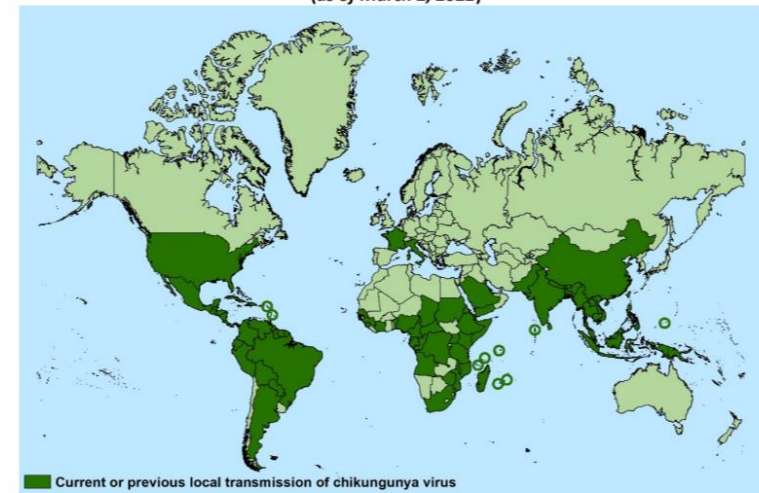
### Outbreak Preparedness Non-Endemic Regions

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

## Endemic Region Use

Vaccine in endemic / LMIC markets, Targeted via **CEPI / Instituto Butantan Partnership**

Countries and territories where chikungunya cases have been reported\*  
(as of March 2, 2022)



\*Does not include countries or territories where only imported cases have been documented.

<sup>1</sup> VAMV005. Chikungunya virus vaccines. Global demand analysis. Feb 2020



# VLA1553 Fits Perfectly Within our Existing Commercial Infrastructure

High-caliber team with significant experience in the vaccine space

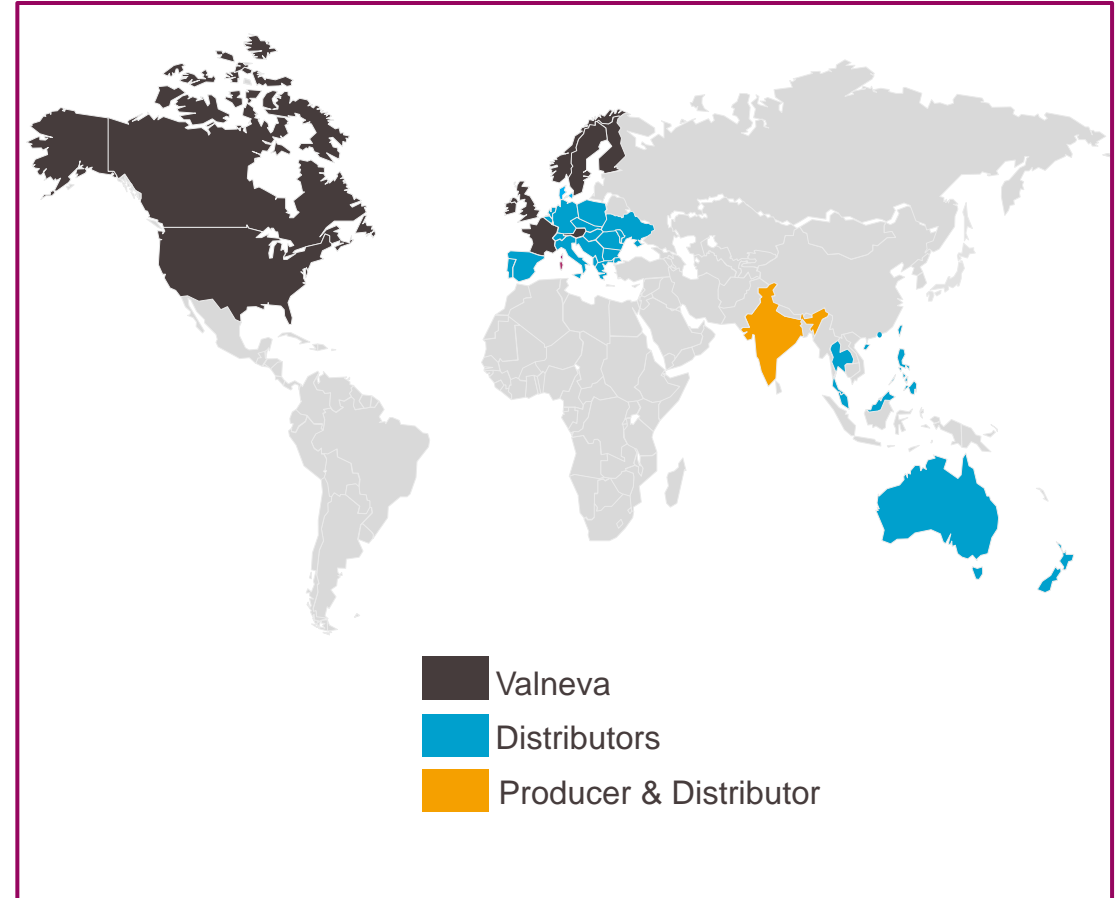
Highly experienced teams with deep expertise in vaccine commercialization

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

Integrated sales, marketing, medical and government affairs capabilities focused on unlocking brand potential

Leverage data driven insights and digital tools to enhance commercial capabilities

## Commercial Footprint





## **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 initiated by Pfizer<sup>1</sup> supported by positive results for three Phase 2 clinical trials<sup>2,3,4</sup>, including first pediatric data<sup>5</sup>; Pivotal trial design and timeline confirmed after uncovering GCP violations by 3rd-party operator<sup>6</sup>

2

Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 (\$95) million equity investment in Valneva<sup>6</sup>

3

Investigational multivalent vaccine (six serotypes) to help protect against 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 Reports First Quarter 2023 Financial Results and Provides Corporate Updates](#); [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

## Key features

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

\* As of 1<sup>st</sup> May 2022



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

## VLA15-221: First positive pediatric data (April 2022)<sup>1</sup>

- Strong immunogenicity profile in adult<sup>2</sup> (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 vaccination<sup>3</sup>

## VLA15-202: First positive booster data (September 2021)<sup>4</sup>

- High antibody responses confirmed across all serotypes and dose groups after primary vaccination series (primary endpoint)<sup>5</sup>
- 12-month booster dose elicited strong anamnestic response

## VLA15-201: First positive immunogenicity data (July 2020)<sup>6</sup>

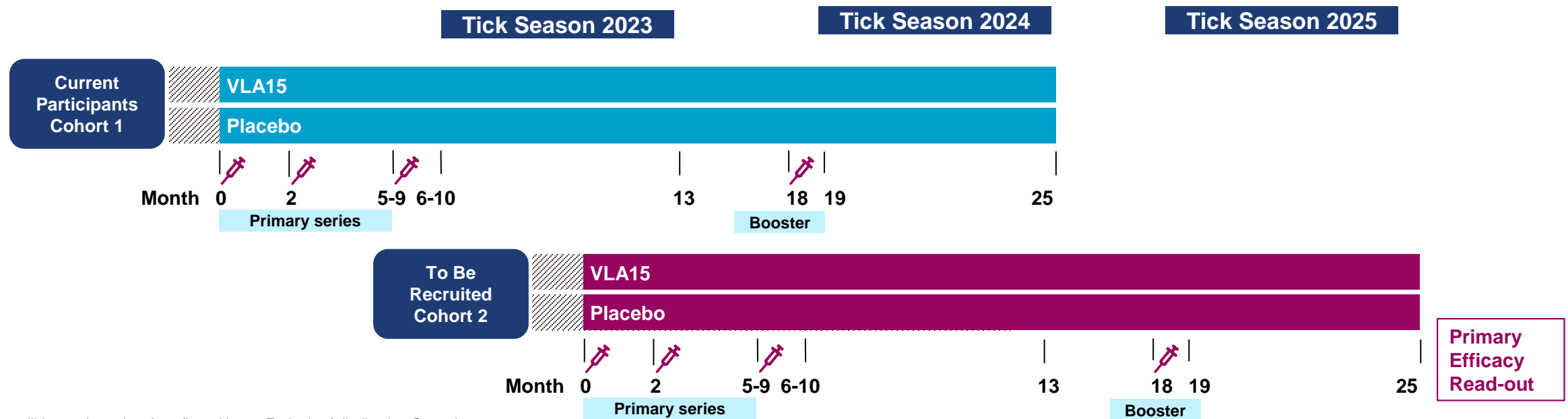
- Immunogenic across all serotypes and dose groups; higher doses elicited higher antibody responses
- Encouraging immunogenicity profile confirmed, including in older adults (ages 50-65)

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



## Phase 3 Efficacy Study

- **Population:** ~9000 total participants  $\geq 5$  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 U.S./EU)
- **Primary endpoint:** Rate of confirmed<sup>1</sup> LD cases 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



<sup>1</sup> Cases will be evaluated and confirmed by an Endpoint Adjudication Committee

**Pfizer now aims to submit regulatory applications in U.S. and Europe in 2026**



## **Valneva Commercial Products**



# Current Commercial Portfolio



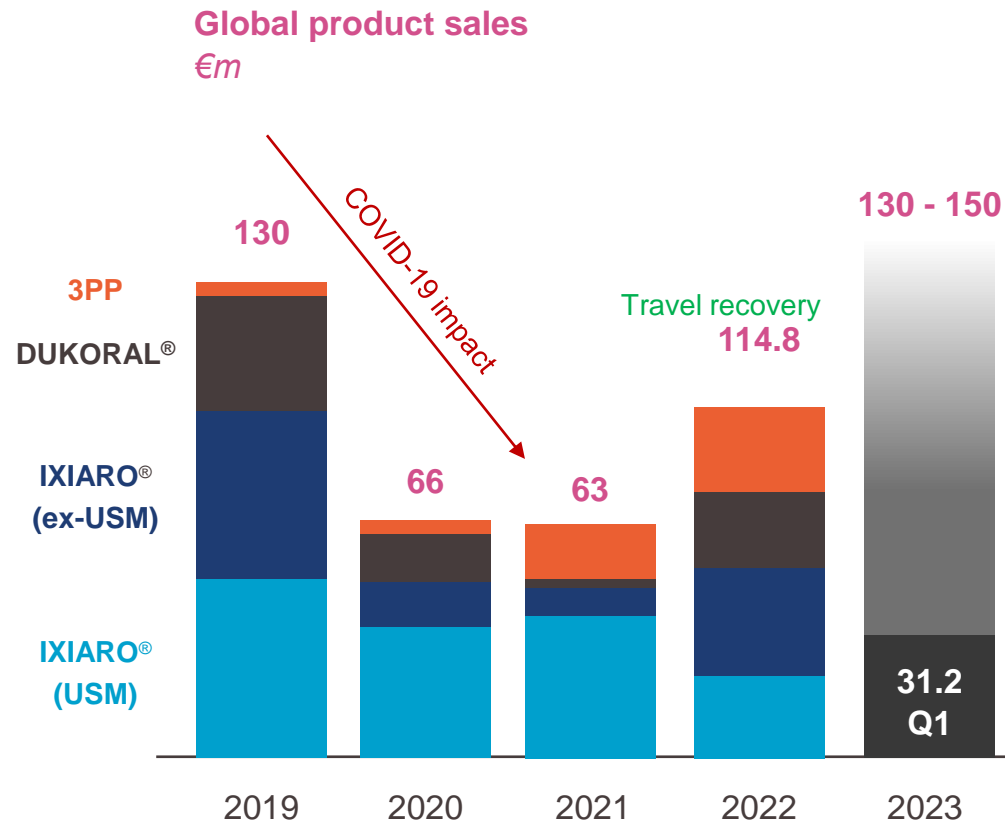
	Brand	Indication*	Partner / Year	Valneva commercial rights & key markets
Proprietary		Active immunization against <b>Japanese encephalitis</b> from 2 months of age	Global Rights	<b>Valneva direct markets</b> : US, CA, UK, FR, Nordics, BE, NL, AT <b>Key markets addressed by Partners:</b> DE, AU, IL
		Active immunisation against <b>Cholera and ETEC**</b> from 2 years of age	Global Rights	<b>Valneva direct markets</b> : CA, UK, FR, Nordics, AT <b>Key markets addressed by Partners:</b> DE, AU, IL, PL
3 <sup>rd</sup> -Party Distribution		Active immunization against <b>Flu</b>	2016	Rights licensed from <b>Seqirus</b> in <b>Austria</b>
		Passive, transient <b>post-exposure</b> prevention of <b>rabies</b> infection	2018	Rights licensed from <b>Kamada</b> in <b>Canada</b>
		Active immunization against <b>rabies</b> in individuals of all ages	2020	Rights licensed from <b>Bavarian Nordic</b> in select markets: <b>CA, UK, FR, BE, NL, AT</b>
		Active immunization against <b>tick-borne encephalitis</b> in adults and children	2020	Rights licensed from <b>Bavarian Nordic</b> in select markets: <b>Austria &amp; France</b>
		Active immunization against <b>hepatitis B virus</b> in adults	2022	Rights licensed from <b>VBI</b> in select markets: <b>UK, Nordics, Netherlands, &amp; Belgium</b>

\*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 Recovery of Travel Segment



Revenues Expected to Recover to Pre-Pandemic Levels in 2023<sup>1</sup>; and on volume basis by 2024<sup>2</sup>



## DRIVERS

- + Pent-up travel demand
- + Re-establishment of Travel Medicine clinics/ ramping up of resources
- + Elevated concern of infectious diseases amongst travelers
- + DoD: new contract; increased deployment to Asia

## BARRIERS

- + Airline capacity/staff shortages
- + Slowing economic growth and rising inflation
- + Impact of new COVID-19 waves
- + Strong demand led to temporary supply constraints in the later part of 2022 and Q1 2023

<sup>1</sup> Valneva Reports Full Year 2022 Revenue and Cash, Provides First 2023 Guidance <sup>2</sup> IATA/ Tourism Economics (July 2022)

# Commercial Portfolio: Strong Sales Performance of €114.8 Million in 2022



## 2022 product sales grew by 82.3% vs. prior period

### Significant recovery in travel markets

- Product sales of the **Japanese encephalitis vaccine** in the travel market increased to €28.8 million compared to €7.1 million (FY 2021)
- Product sales of the **cholera vaccine** increased 610.3% to reach €17.3 million compared to €2.4 million (FY 2021)
- **Third-party product** sales increased to €26.5 million from €15.4 million (FY 2021)
- Strong growth offset by IXIARO<sup>®</sup> sales to U.S. Department of Defense of €12.5 million vs €38 million (FY 2021); **expect new supply contract in 2023**
- The **COVID-19 vaccine** generated sales of €29.6 million

## 2023 guidance

**Product sales of €130 million to €150 million, including:**

- Marginal COVID-19 vaccine sales under an existing supply agreement

**Other income of €90 million to €110 million**

**R&D expense between €70 million and €90 million**



# Executing Our Commercial Strategy

Three key levers to accelerate commercial performance

## Travel health recovery

### *Customer engagement through Valneva Travel Health*

- Building brand identity
- Elevate Valneva's reputation as a committed travel health partner for HCP and travelers
- Provide tools and services to customers supporting acceleration of travel health recovery



## Expand vaccine portfolio

### *Evaluation of new in-licensing and product acquisitions*

### *Distribution partnerships in selected regions*

- Bavarian Nordic for Rabies and TBE vaccines
- Seqirus for flu vaccines
- Kamada for Rabies IgG
- VBI for Hep B vaccine
- Adding complementary distribution partnerships



## VLA1553 launch preparedness

### *Evolution of commercial infrastructure*

- Optimize commercial infrastructure to support launch excellence
- Market access/recommendations
- Market and brand development





# Financial Overview



## Company is Well Capitalized to at Least 2024

Balance sheet strengthened by successful capital raises

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

**2021-2022: Follow on offerings and debt financing**

- Most recent upsized Global Offering brought in €102.9 million in gross proceeds; led by new U.S. investor<sup>1</sup>, with strong support from existing holders in the U.S. and Europe
- Increased the principal amount of existing debt financing agreement<sup>2</sup>

**June 2022: €90.5 (\$95) million investment by Pfizer<sup>3</sup> to support Valneva's contribution to Phase 3 trial of VLA15**

**Cash position of €254.5 million (March 31, 2023)<sup>4</sup>**



Nasdaq: VALN – Euronext Paris: VLA

<sup>1</sup> Valneva Announces Pricing of €102.9 Million Global Offering of American Depositary Shares and Ordinary Shares; <sup>2</sup> Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed; <sup>3</sup> Valneva and Pfizer Announce Closing of Equity Investment; <sup>4</sup> Valneva Reports First Quarter 2023 Financial Results and Provides Corporate Updates



## Key Upcoming Catalysts and News Flow in 2023

### Chikungunya vaccine candidate VLA1553

- First adolescent study results mid-2023
- Potential BLA approval and first launch; Potential PRV sale in H2 2023
- Initiate additional ex-U.S. regulatory submissions in 2023

### Lyme disease vaccine candidate VLA15

- Additional enrollment for primary immunization to begin in 2Q 2023
- Additional antibody persistence results in H2

### Additional news flow

- Potential DoD contract for IXIARO® in the coming months
- Potential augmenting clinical pipeline through program acquisition or partnering
- Progression of selected pre-clinical programs towards clinical entry



# Valneva is Poised for Substantial Growth

Led by potential new product launches

## Additional potential growth drivers:

- Continued recovery of travel volumes toward pre-COVID levels and beyond
- New U.S. DoD contract for IXIARO<sup>®</sup> expected in the coming months
- Potential in-licensing or acquisition of additional clinical assets
- Potential U.S. reimbursement for CDC-recommended travel vaccines

