valneva

# Advancing Vaccines for Better Lives

Company Presentation

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# Valneva in Summary

**Fully integrated specialty vaccine company** focused on development 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 target 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: Two commercialized vaccines; distribution rights for 3rd-party vaccines**

- **Total revenues of €348.1 million in 2021, compared to €110.3 million in 2020**
- **Strong cash position of €311.3 million at March 31, 2022**
- **€430-€590 million in total revenues expected in 2022**

# Research & Development

# Valneva has an Advanced Clinical Pipeline and Three Approved Products[1]

[1] As of May 6, 2022, VLA2001 has been granted emergency use authorization by the Bahraini NHRA and Conditional Marketing Authorization by the UK MHRA. [2] VLA15 received Fast Track designation from the FDA. [3] VLA1553 received Fast Track designation from the FDA, PRIME designation from the European Medicines Agency and is also potentially eligible for a U.S. Priority Review Voucher. [4] Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium

# Lyme Disease Vaccine – VLA15

# Lyme Disease is a Major Health Issue

## Severe Tick-transmitted Infection, Increasingly Common in the US and Europe

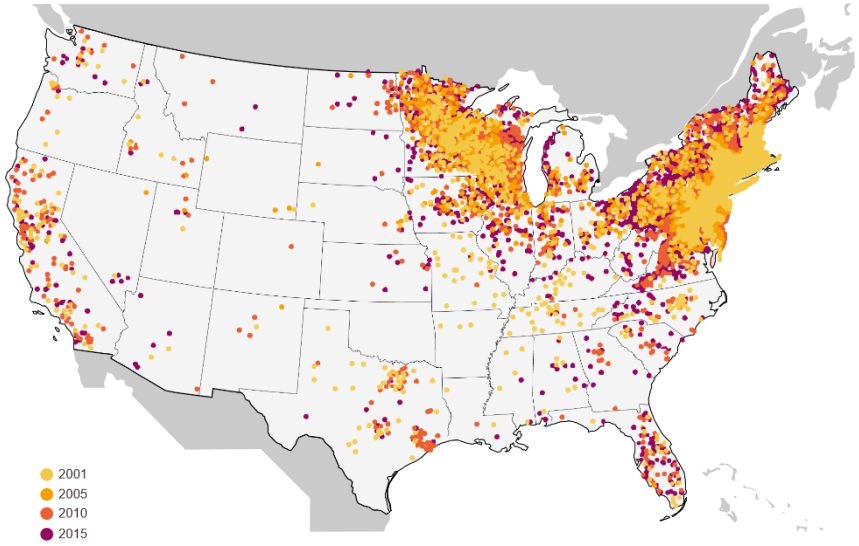
Early signs include **flu-like symptoms**[1] and **Erythema migrans rash**[2] which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

**No available treatment to protect against Lyme disease**

**Global market estimated to reach $1 billion by 2030**

**Direct medical costs in the U.S. estimated up to $1.3 billion each year – indicating an attractive health economic benefit**[3]

**Spread of Lyme Across the US**[4]




[1] Fever, chills, headache, fatigue, muscle and joint aches, swollen lymph nodes. [2] Occurs in approx. 70-80% of infected persons. [3] Adrion, E. et al PLOS ONE Feb 2015.
[4] Centers for Disease Control and Prevention

# VLA15: Multivalent Lyme Disease Vaccine Candidate

## Only Lyme Disease Program in Advanced Clinical Development Today

1. **FDA Fast Track Designation granted**
2. **Exclusive, worldwide partnership with Pfizer**
3. **Positive results reported from Phase 2 trials[1,2,3], incl. first pediatric data and booster response[4]; Phase 3 schedule selected**
4. **Multivalent vaccine (six serotypes) to help protect against Lyme disease in the United States and Europe**
5. **Follows proven Mechanism of Action for a Lyme disease vaccine**

**1** Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate**; 2** Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15. **3** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate **; 4** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

# VLA15: Development Progress and Outlook

## Positive Phase 2 Results in Adults[1,2,3,4] and Pediatric Participants[5] Reported

### VLA15-221 Phase 2 trial recruited 625 randomized participants, 5 to 65 years of age[2]

- Strong immunogenicity profile for both adult and pediatric participants reported in February [3] and April 2022[5], respectively
- VLA15 was found to be more immunogenic in pediatric participants (5-17 years old) than in adults with both two-dose or three-dose vaccination schedules

### Phase 3 clinical trial planned to start in the third quarter of 2022

- Based on the latest Phase 2 immunogenicity and safety data, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule for both adult and pediatric participants[5]
- Clinical readout, based on one tick season, projected by end of 2023
- $25 million milestone payment due to Valneva upon trial initiation

**1** Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate., **2** Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate; **3** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; **4** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate, **5** Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate

# Chikungunya Vaccine – VLA1553

# VLA1553: Single Shot Chikungunya Vaccine Candidate

## Most Clinically Advanced Chikungunya Vaccine Program Worldwide

1. **Final positive pivotal Phase 3 results[1] and topline lot-to-lot data[2] reported; Adolescent Phase 3 trial initiated in January 2022[3]**
2. **FDA Breakthrough Therapy[4], Fast Track[5] and EMA PRIME[7] designations granted; Potentially eligible for Priority Review Voucher[6]; FDA Pre-submission process initiated**
3. **Single shot, live attenuated[8] prophylactic vaccine targeting chikungunya virus neutralization**
4. **Up to $23.4 million awarded to Valneva for R&D by CEPI; Partnership with Instituto Butantan for LMICs[9]**
5. **Excellent fit with existing commercial and manufacturing capabilities**
6. **Global market, including endemic regions, estimated to exceed $500 million annually by 2032[10]**

Note: Photo credit: James Gathany. **1** Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; **3** Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate **;** **4** Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate; **5** Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate; **6** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program; **7** Valneva's Chikungunya vaccine candidate awarded EMA prime designation; **8** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase); **9** Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-Income countries ; **10** VacZineAnalytics Chikungunya virus vaccines Global demand analysis. February 2020.

# VLA1553: Development Outlook

## Pre-submission Discussions with the US FDA Initiated

### First and only program to have reported positive Phase 3 results worldwide

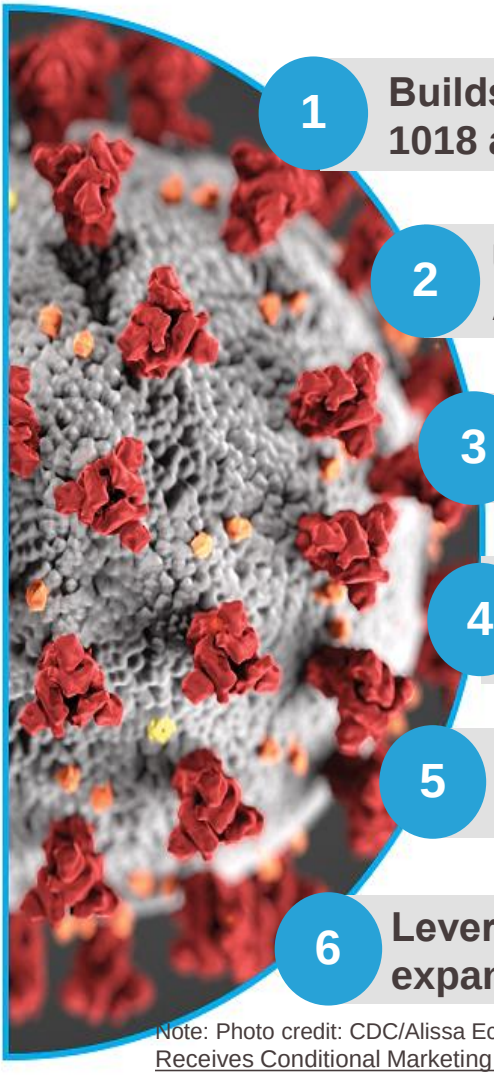
- Six-month follow-up completed - all Phase 3 immunogenicity and safety endpoints met - seroprotection in 98.9% of participants after one month and 96.3% after six months - good safety and tolerability profile confirmed
- Positive topline lot-to-lot consistency trial results reported (VLA1553-302)[2], final data expected in Q2 2022
- Antibody persistence follow-up trial (VLA1553-303) ongoing: up to 375 volunteers from the VLA1553-301 trial will be followed annually for five years
- Adolescent Phase 3 trial initiated in January 2022 to support potential label expansion, funded by the Coalition for Epidemic Preparedness Innovations (CEPI)[3]

**1** Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate; **3** Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate;

# SARS-CoV-2 (COVID-19) Vaccine – VLA2001

# VLA2001: Inactivated Whole Virus COVID-19 Vaccine Candidate

## Only Inactivated COVID-19 Vaccine Program in the Clinic in Europe



1. **Builds on Valneva's IXIARO® manufacturing technology, combined with Dynavax's CpG 1018 adjuvant[1]**
2. **UK MHRA Conditional Marketing Authorization[2] and Bahraini NHRA Emergency Use Authorization received[3]; EMA rolling review ongoing**
3. **Advance purchase agreements for up to 60 million doses with European Commission[4] and for one million doses with Bahrain[5]**
4. **Pivotal Phase 3 trial showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability[6]; Positive topline homologous booster data reported[7]; Shown to neutralize Omicron and Delta variants in laboratory studies[8]**
5. **Ongoing clinical trials aiming to gradually extend target product profile (label)**
6. **Leveraging Valneva's manufacturing sites in Scotland and Sweden; capacity being expanded, including CMO[9] – targeting >100m doses per annum[10]**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. **1** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; **2** Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine, **3** Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; **4** Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001; **5** Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; **6** Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001; **7** Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva; **8** Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant; **9** Valneva and IDT Biologika Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001; **10** Based on a combination of in-house capacity and external/contracted manufacturing.

# VLA2001: Pivotal Phase 3 “Cov-Compare Study” Results

## Immunogenicity

- **VLA2001 met its co-primary endpoints** vs AZD1222, demonstrating:
  - **Superiority** in terms of **geometric mean titer** for neutralization antibodies (GMT ratio = 1.39, p<0.0001), as well as
  - **Non-inferiority** in terms of **seroconversion rate**
- **VLA2001 induced broad** antigen-specific IFN-gamma producing **T-cells reactive against the S (74.3%), N (45.9%) and M (20.3%) proteins**

## Safety and Tolerability

- **VLA2001 was generally well tolerated:**
  - **Significantly more favorable profile** compared to AZD1222
  - Participants 30 years and above reported **significantly fewer solicited adverse events,** including **injection site reactions**, and **systemic reactions**
- Participants **18-29 years** old showed an **overall safety profile comparable to the older age group**

## COVID-19 Cases

- The **occurrence of COVID-19** cases (exploratory endpoint) was **similar between treatment groups** (age 30+)
- The **complete absence** of **any severe COVID-19 cases** could suggest that **both vaccines** used in the study **prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta)**

# VLA2001: Current Purchase Agreements and Grants

## European Commission

- Supply agreement signed with the European Commission in November 2021[1]

## Bahrain: One million doses of VLA2001 to be supplied in 2022-23[2]

- NHRA Emergency Use Authorization received[3]; first vaccines delivered in March 2022

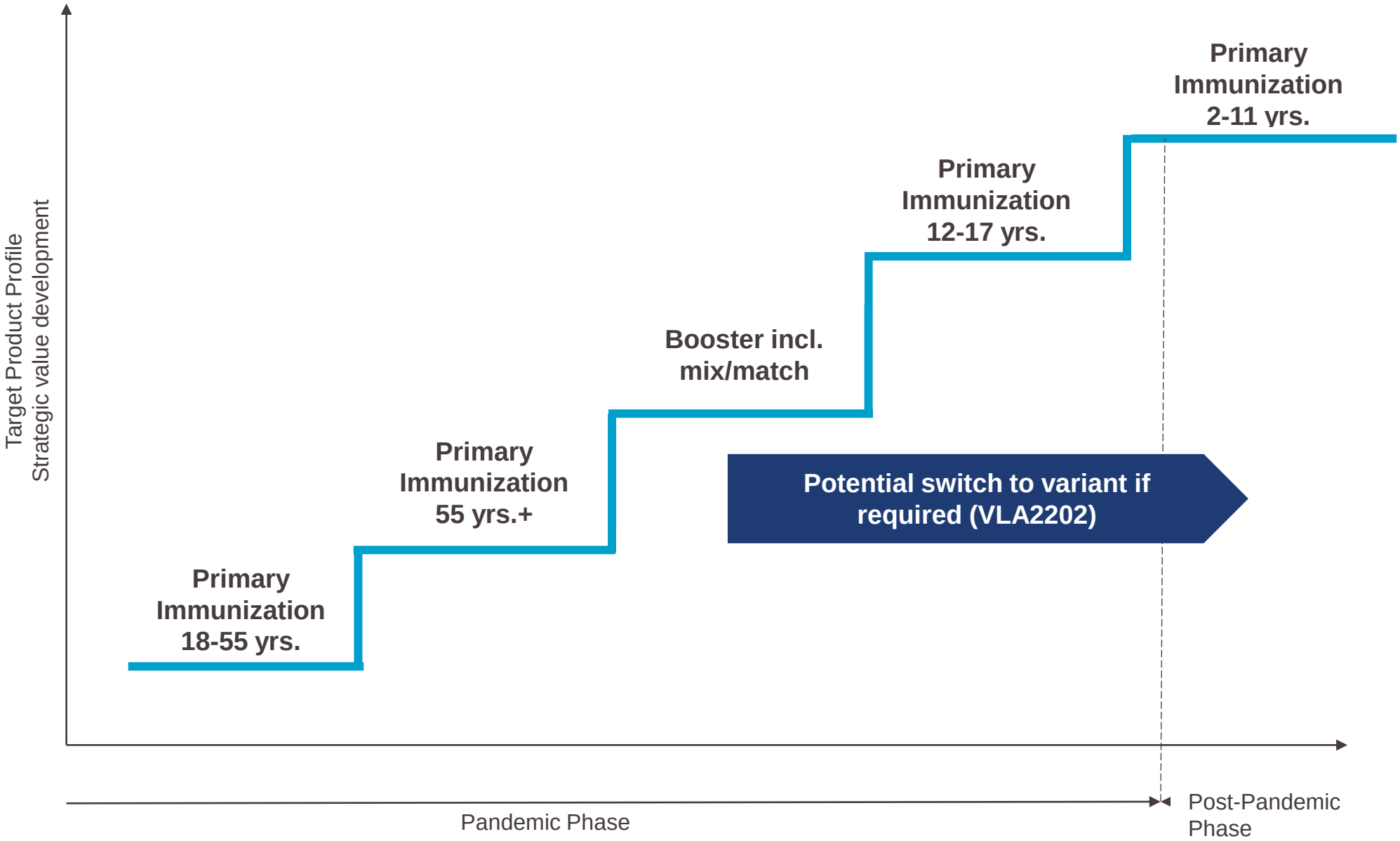
## Up to £20 Million awarded by Scottish Enterprise to advance vaccine development[4]

- Grants totaling up to £20 million expected to be received over the next three years, commencing March 2022
- The first grant of up to £12,500,000 will support R&D related to VLA2001 manufacturing; the second grant of up to £7,500,000 will support R&D connected to manufacturing of Valneva's other vaccine candidates

**1** Valneva Announces European Commission Approval of Advance Purchase Agreement for up to 60 Million Doses of Inactivated COVID-19 Vaccine VLA2001; **2** Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; **3** Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; **4** Valneva Awarded Up to £20 Million by Scottish Enterprise to Advance Vaccine Development

# VLA2001: Planned Label Extensions

## Ongoing and Future Clinical Studies Expected to Strengthen Product Profile



# Commercial Products

# Valneva has a Specialist Travel Vaccine Business and is a Contractor to the US Military

- **Prior to the pandemic, Valneva demonstrated a strong track record of sales growth** built upon the solid foundation of its business relationship with the US DoD
  - €129.5m of product sales in 2019 (+25% AER, +22% CER)[1]

- **Direct sales channels in the US and several key markets**
- **Distributors in Germany and smaller markets**
- **Marketing & Distribution of 3rd party specialty vaccines[2]**

- **Three year supply deal with US Military/Dept of Defense representing a base value of $118m if options are exercised. First year option exercised in Sep. 2021**

- **Valneva believes that the commercial business is a key asset for the future, e.g. chikungunya route to market, as the travel industry recovers**

[1] Valneva reports record product sales and major pipeline progress in 2019, [2]Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership

# Corporate Highlights and Newsflow

# Strong Financial Position with Substantial Product Revenues Expected in 2022

**Successfully raised ~$210 million in 2021**

- Nasdaq listing (Q2); $107.6 million[1]
- Follow-on (Q4); $102.0 million[2]

**Strong cash position of €311.3 million (March 31, 2022)[3]**

- Up to an additional $40 million made available in April 2022 as part of a recent upsized financing arrangement with leading US Healthcare Funds Deerfield and OrbiMed (of which $20 million conditioned to EMA's approval of VLA2001)

**Expected 2022 total revenues of €430-€590 million[3]**

**1** Gross proceeds from U.S. public offering and EU private placement; **2** Gross proceeds from global public offering in the U.S. and Europe; **3** Valneva Reports Q1 2022 Results and Provides Corporate Updates

# Key Upcoming Catalysts and Newsflow in 2022

## Lyme disease vaccine candidate VLA15

- Phase 3 trial initiation expected in Q3 2022

## Chikungunya vaccine candidate VLA1553

- Biologics License Application (BLA) expected in H2 2022

## COVID-19 vaccine candidate VLA2001

- Potential additional regulatory approvals
- Supplies and potential further purchase agreements
- Further clinical trials and data expected

Thank you
Merci
Danke
Tack

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