



 **valneva**

**Advancing Vaccines for Better Lives**

Company Presentation

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We are a **specialty vaccine company** focused on the **development and commercialization of prophylactic vaccines for infectious diseases** with significant unmet medical need

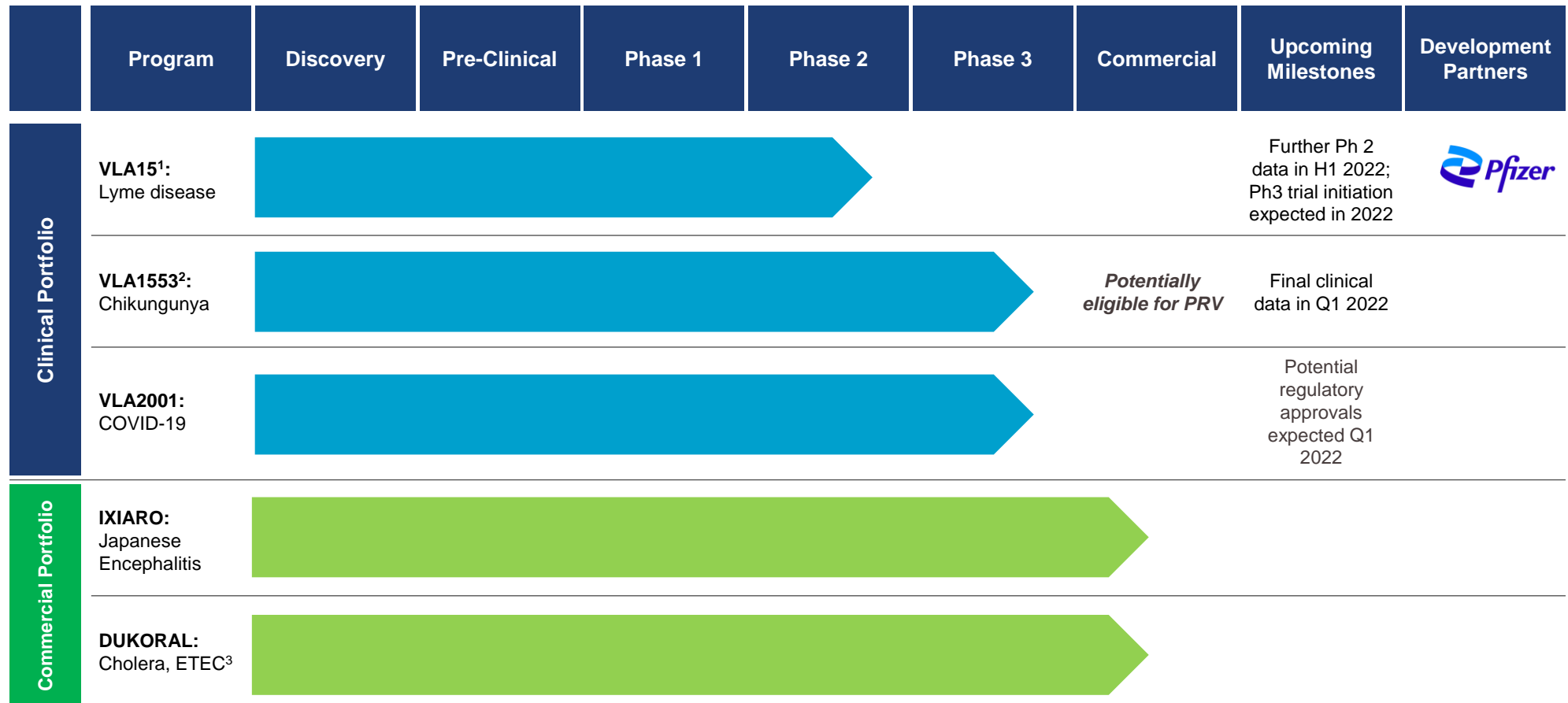


- **Highly specialized and targeted approach to development of unique prophylactic vaccines**
- **Advanced pipeline of differentiated clinical-stage assets** designed to address large target populations
- **Product development and regulatory expertise** with clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization
- **Highly developed, nimble and sophisticated manufacturing infrastructure**
- **Two commercialized vaccines, a specialist sales infrastructure and distribution rights for third-party vaccines**
- **Highly experienced leadership team with expertise in the vaccine space – Peter Bühler, 20+ years in the pharma and tech industries, joined the team as CFO on January 1, 2022.**

# Research & Development



# Valneva Has An Advanced Clinical Pipeline and Two Approved Products



<sup>1</sup> VLA15 received Fast Track designation from the FDA. <sup>2</sup> 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. <sup>3</sup> 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

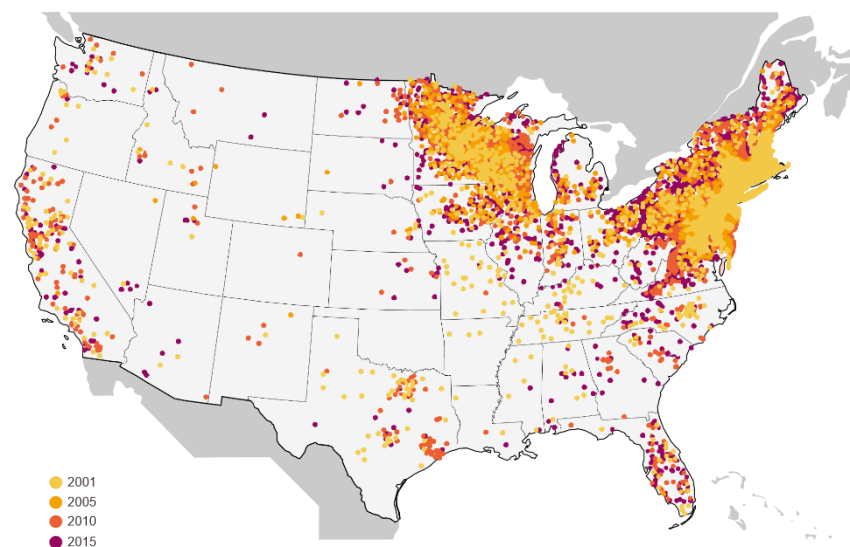
Early signs include **flu-like symptoms**<sup>1</sup> and **Erythema migrans rash**<sup>2</sup> which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

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<sup>3</sup>

### Spread of Lyme Across the US<sup>4</sup>



<sup>1</sup> Fever, chills, headache, fatigue, muscle and joint aches, swollen lymph nodes. <sup>2</sup> Occurs in approx. 70-80% of infected persons. <sup>3</sup> Adrion, E. et al PLOS ONE Feb 2015.

<sup>4</sup> 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 Topline results reported from Phase 2 trials<sup>1,2</sup>, incl. booster response<sup>3</sup>; Recruitment completed for Ph 2 trial VLA15-221 incl. pediatric group<sup>4</sup>
- 4 Multivalent vaccine (six serotypes) to 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 Results, Including Booster Response, for Lyme Disease Vaccine Candidate; 4 Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate





## **VLA15: Development Progress and Outlook**

### **Phase 2 trial<sup>1</sup> in Adults and Pediatric Subjects Ongoing**

**VLA15-221 recruitment completed in June 2021 with a total of 625 randomized participants, 5 to 65 years of age<sup>2</sup>**

- Topline results for VLA15-221 are expected in the first half of 2022
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the 6 Month dose<sup>1</sup>

**Further VLA15-202 results and topline booster data announced in Sep. 2021<sup>3</sup>**

- VLA15 immunogenic across all dose groups; elicited high antibody responses across all serotypes one month after primary vaccination series (primary endpoint)
- Booster dose elicited strong anamnestic response

**Phase 3 pivotal efficacy trial planned to commence pending positive readout from VLA15-221 in 2022<sup>1</sup>**

- Clinical readout, based on one tick season, projected by end of 2023
- \$25m milestone payment due to Valneva upon trial initiation

**Initial submission for regulatory approval anticipated in H2 2024, assuming positive data**

<sup>1</sup> Valneva and Pfizer Announce Initiation of Phase 2 Study for Lyme Disease Vaccine Candidate., <sup>2</sup> Valneva and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate ; <sup>3</sup> Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate

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



# VLA2001 – The Only Inactivated Vaccine Against COVID-19 in Clinical Development in Europe



1

**Builds on Valneva's IXIARO® manufacturing technology combined with Dynavax's CpG 1018 adjuvant<sup>1</sup>**

2

**EMA rolling review and UK MHRA, Bahraini NHRA rolling submissions ongoing**

3

**Advance purchase agreements for up to 60 million doses with European Commission<sup>2</sup> and for one million doses with Bahrain<sup>3</sup>;**

4

**Pivotal Phase 3 “Cov-Compare” trial showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability<sup>4</sup>; Positive topline homologous booster data reported<sup>5</sup>**

5

**Ongoing clinical trials aiming to gradually extend target product profile (label) and geographical reach**

6

**Small scale manufacturing ongoing, leveraging Valneva's sites in Scotland and Sweden; capacity being expanded, including CMO<sup>6</sup> – targeting >100mds per annum<sup>7</sup>**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. <sup>1</sup> Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; <sup>2</sup> Valneva Signs Purchase Agreement with European Commission for its Inactivated COVID-19 Vaccine VLA2001; <sup>3</sup> Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; <sup>4</sup> Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001; <sup>5</sup> Valneva Announces Positive Homologous Booster Data for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 – Valneva. <sup>6</sup> Valneva and IDT Biologika Announce Collaboration for Production of Inactivated COVID-19 Vaccine VLA2001; <sup>7</sup> Based on a combination of in-house capacity and external/contracted manufacturing.

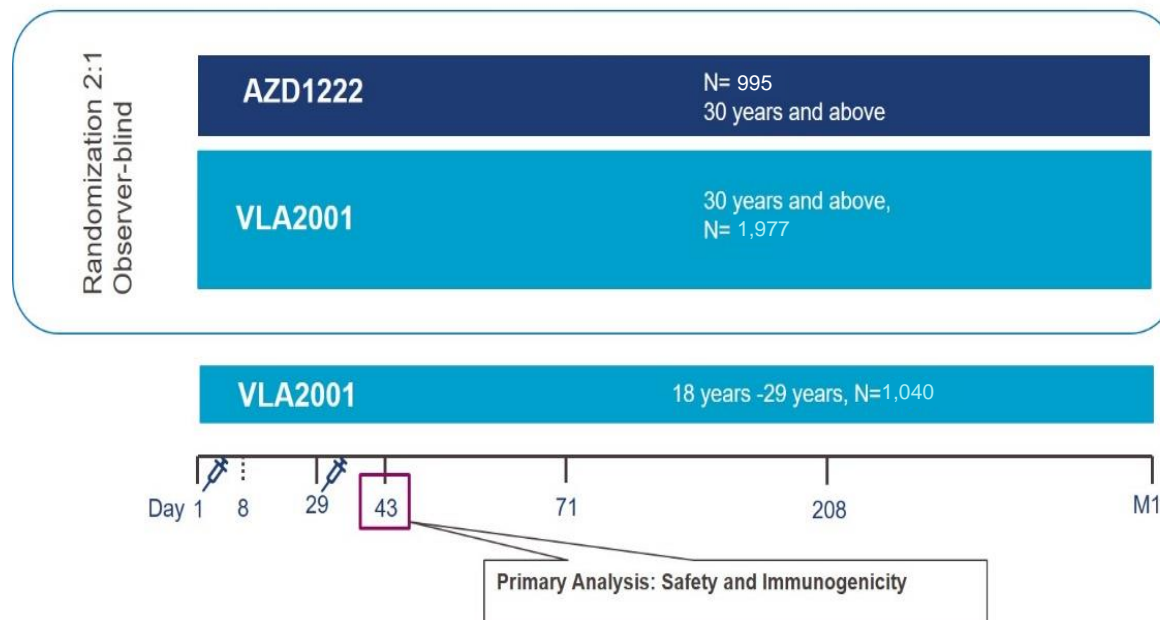
# Cov-Compare: Head-to-Head vs. AstraZeneca's Approved COVID-19 Vaccine AZD1222



## Study design and endpoints planned to support regulatory submissions

### Study Description

- **Randomized, observer-blind, controlled, immunogenicity trial** comparing VLA2001 to AstraZeneca's conditionally approved vaccine, AZD1222 (ChAdOx1-S)
- **2,972 participants 30 years of age and older** randomized (2:1) received two doses of either VLA2001 (n=1977) or AZD1222 (n=995) at the recommended dose level, 28 days apart
- **Also evaluating the safety and tolerability of VLA2001 in additional adults 18-29 years of age (n=1040)**, two weeks after the second vaccination



### Primary Objective - Compare VLA2001 to AZD1222 to determine:

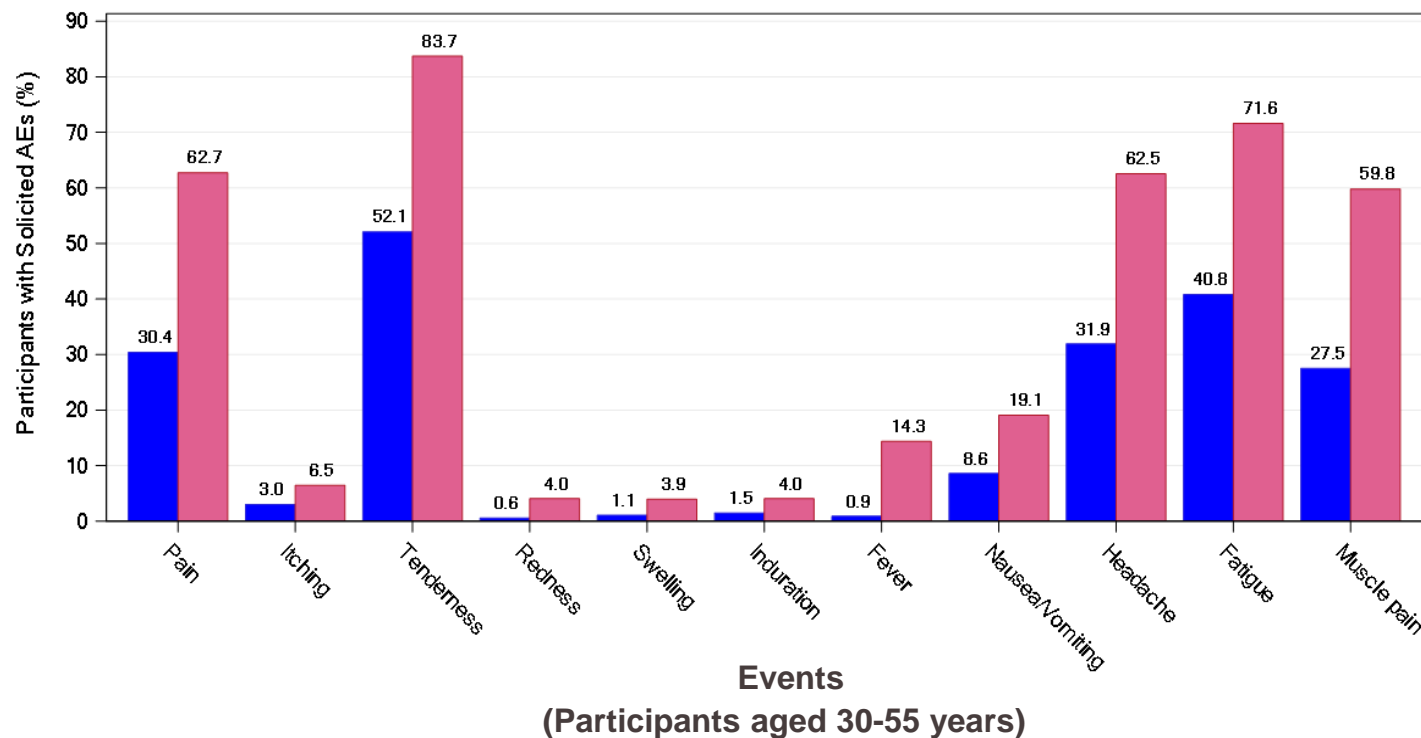
- **Superiority in terms of Geometric Mean Titer ratio** of SARS-CoV-2-specific neutralizing antibodies at two weeks after the second vaccination (Day 43) in adults aged 30 years and older; and
- **Non-inferiority in terms of seroconversion rate** and
- **Frequency and severity of any Adverse Event**



# VLA2001: Statistically More Favorable Tolerability Profile Compared to AZD1222

## Generally well tolerated across all tested age groups

### Solicited AEs within 7 days of vaccination



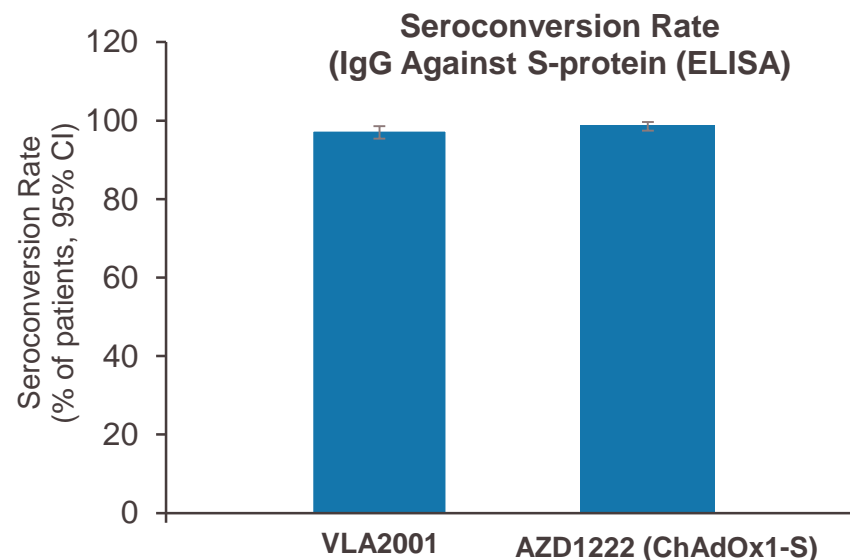
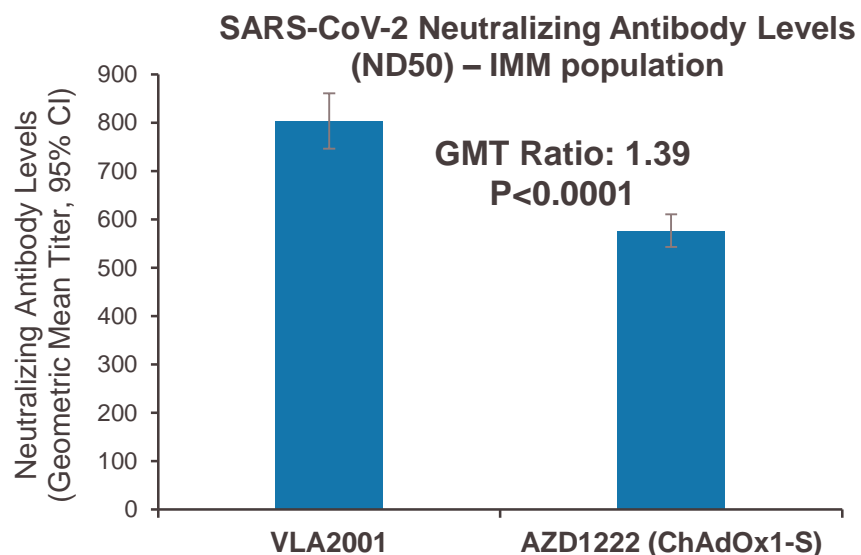
### Safety Conclusions

- Tolerability profile more favorable vs comparator vaccine in participants aged 30 years and above
- Well tolerated across all tested age groups
- Safety profile in younger age group comparable to older age group



## Co-Primary Immunogenicity Endpoints Met

### Superiority in neutralizing antibody levels (GMT ratio) & non-inferiority in seroconversion rate



### Positive Immunogenicity results at two weeks after second vaccination (Day 43) in adults aged 30+ years

- VLA2001 demonstrated superiority against AZD1222 by live virus microneutralization assay (ND50)
- (GMT ratio=1.39, p<0.0001) (VLA2001 GMT 803.5 (95% CI: 748.48, 862.59))
- VLA2001 demonstrated non-inferiority in terms of seroconversion rates (SCR >95% in both treatment groups)

# Overall “Cov-Compare Study” Conclusions



## 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)**



## Positive Topline Homologous Booster Data

77 participants, aged 18-55 years, received a third dose (booster dose) seven to eight months after completion of their primary immunization.

- **Excellent immune response after a booster dose of VLA2001 (GMT 9699.3 (95% CI: 8497.76, 11070.71))**
- **Antibody titers increased 42- to 106-fold two weeks after booster dose vs pre-booster levels Antibody titers were four-fold higher compared to two weeks after primary immunization**
- **Valneva is evaluating the sera from boosted participants for cross-neutralization against Variants of Concern, including Omicron**
- **Valneva to launch a dedicated heterologous booster trial, which will evaluate a VLA2001 booster shot provided at least six months after primary vaccination with other vaccines or following natural infection.**

<sup>1</sup> [Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate](#); <sup>2</sup> [Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate – Valneva](#); <sup>3</sup> <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>;





## European Commission: Up to 60 million doses of VLA2001 to be supplied in 2022-23<sup>1</sup>

- 24.3 million doses to be supplied in the second and third quarters of 2022; EC has the option to increase its initial purchase, the remainder of which would be delivered in 2023
- Deliveries expected to begin in April 2022, subject to approval by EMA

## Bahrain: One million doses of VLA2001 to be supplied in 2022-23<sup>2</sup>

- Deliveries expected to begin in the first quarter of 2022, subject to approval by NHRA

## Scottish Enterprise: Advanced discussions for multi-million pound grant funding and potential vaccine supply<sup>3</sup>

- Advanced discussions with Scottish Enterprise for grants totaling £10-20 million to fully complete VLA's strategic manufacturing site in Livingston, Scotland, and extend manufacturing capacity.
- Discussions between the Company and the Scottish Government also include potential supply of VLA2001 for Scotland, subject to regulatory approval.

<sup>1</sup> Valneva Announces European Commission Approval of Advance Purchase Agreement for up to 60 Million Doses of Inactivated COVID-19 Vaccine VLA2001; <sup>2</sup> Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001; <sup>3</sup> Valneva and Scottish Enterprise in Advanced Discussions for Major Grant to Complete Livingston Site – Valneva

# VLA2001: Potential to Protect Against Variants

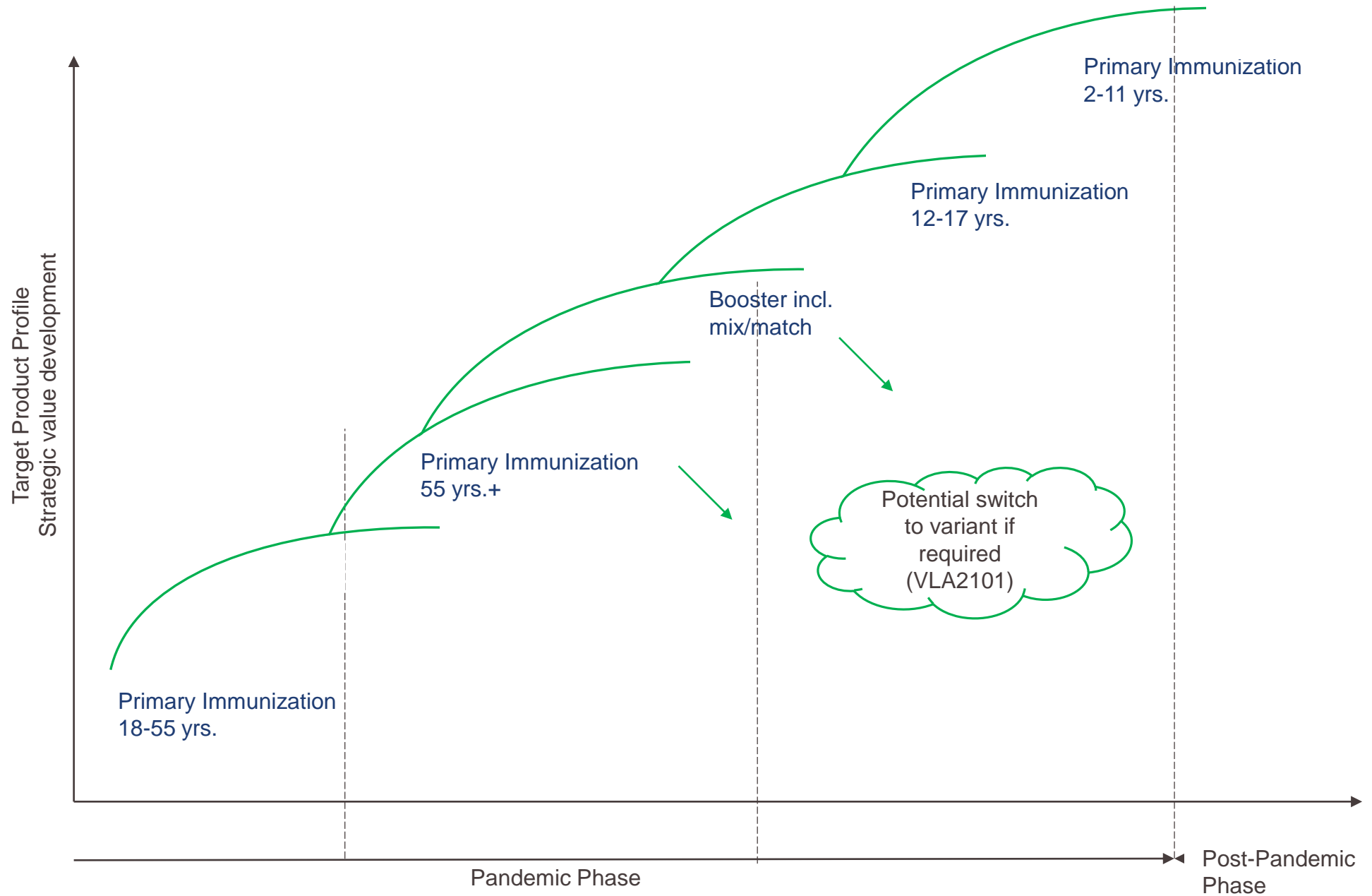


Valneva believes VLA2001 can potentially play a role in protecting against the new Omicron variant<sup>1</sup>

- VLA2001 is developed using the entire SARS-CoV-2 virus envelope (rather than targeting the spike protein alone)
  - › Preserving the whole virus envelope is expected to elicit a **broad immune response** and, together with the CpG1018 adjuvant, may provide an improved immunological profile by **boosting T-cell responses against additional SARS-CoV-2 proteins**
  - › **Valneva will test for cross-neutralization of VLA2001 against the Omicron variant**
  
- **Valneva's technology platform is adaptable for new variants, if required**
  - › Laboratory development and testing of variants has been undertaken, including the production of viral seedstock for **three earlier variants of concern, including Delta**
  - › A full scale pilot lot derived from the Alpha variant has been produced, validating the **suitability of Valneva's well-established manufacturing process for variant-based vaccines**

<sup>1</sup> [Valneva Confirms Initiation of Rolling Review with EMA and Provides Updates on its COVID-19 Vaccine Program VLA2001](#)

# VLA2001: Value Growth Through Continuous Extension of Label



# Chikungunya Vaccine – VLA1553



# VLA1553: The Most Advanced Chikungunya Vaccine Candidate



1

Positive topline Phase 3 data (VLA1553-301)<sup>1</sup> and lot-to-lot consistency results (VLA1553-302)<sup>2</sup> reported

2

Potentially eligible for Priority Review Voucher<sup>3</sup>; FDA Breakthrough Therapy<sup>4</sup>, Fast Track<sup>5</sup> and EMA PRIME<sup>6</sup> designations granted; FDA submission expected in 2022

3

Single shot, live attenuated<sup>7</sup> 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<sup>8</sup>

5

Excellent fit with existing commercial and manufacturing capabilities

6

Global market, including endemic regions, estimated to exceed \$500 million annually by 2032<sup>9</sup>

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

# VLA1553-301: Positive Topline Phase 3 Results



## Immunogenicity

- **VLA1553 met its primary endpoint:**
  - Protective CHIKV neutralizing **antibody titers reported in 98.5% of subjects** after a single shot
  - **Highly immunogenic** across all age groups, including the elderly

## Safety and Tolerability

- **VLA1553 was well tolerated across all age groups:**
  - Independent Data Safety Monitoring Board identified **no safety concerns**
  - **Majority of solicited adverse events were mild or moderate** and resolved within 3 days
  - **Equally good safety profile in the elderly**



## VLA1553: Development Outlook

### Pivotal Phase 3 Trial – Final Data Expected in Q1 2022

#### Most advanced chikungunya vaccine development program in the world

- Pivotal Phase 3 safety and immunogenicity trial progressing towards final analysis, in Q1 2022<sup>1</sup>
- Positive topline lot-to-lot consistency trial results reported (VLA1553-302)<sup>2</sup>, 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

**Ongoing discussions with the FDA to bring VLA1553 to potential licensure as soon as possible; FDA submission expected in 2022**

**The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a Priority Review Voucher**

<sup>1</sup> [Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate](#); <sup>2</sup> [Valneva Announces Positive Lot-to-Lot Consistency Trial Results for its Single-Shot Chikungunya Vaccine Candidate](#); <sup>3</sup> <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program>

# 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)<sup>1</sup>
- **Direct sales channels in the US and several key markets**
- **Distributors in Germany and smaller markets**
- **Marketing & Distribution of 3<sup>rd</sup> party specialty vaccines<sup>2</sup>**
- **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**

<sup>1</sup> [Valneva reports record product sales and major pipeline progress in 2019](#), <sup>2</sup>[Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership](#)

# Corporate Highlights and Newsflow



# VLA Successfully Raised ~ \$210 Million in 2021



- **Successful Nasdaq listing (Q2); \$107.6 million of gross proceeds**
  - Raised in initial US public offering and private placement in Europe
- **Successful follow-on (Q4); \$102.0 million of gross proceeds**
  - Raised in a global offering in the US and Europe





## Chikungunya vaccine candidate VLA1553

- Final Phase 3 trial results expected in Q1 2022 (including lot-to-lot consistency trial)
- Initiation of regulatory submissions with FDA and EMA

## Lyme disease vaccine candidate VLA15

- Remaining Phase 2 results and alignment with regulators
- Phase 3 trial initiation expected in H2/2022

## COVID-19 vaccine candidate VLA2001

- Regulatory submissions and supply contracts
- Further clinical trials and data

Thank you  
Merci  
Danke  
Tack

