valneva

Advancing Vaccines for Better Lives

Company Presentation

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Valneva in Summary

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**

Research & Development

Valneva Has An Advanced Clinical Pipeline and Two Approved Products

[1] VLA15 received Fast Track designation from the FDA. [2] 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. [3] 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

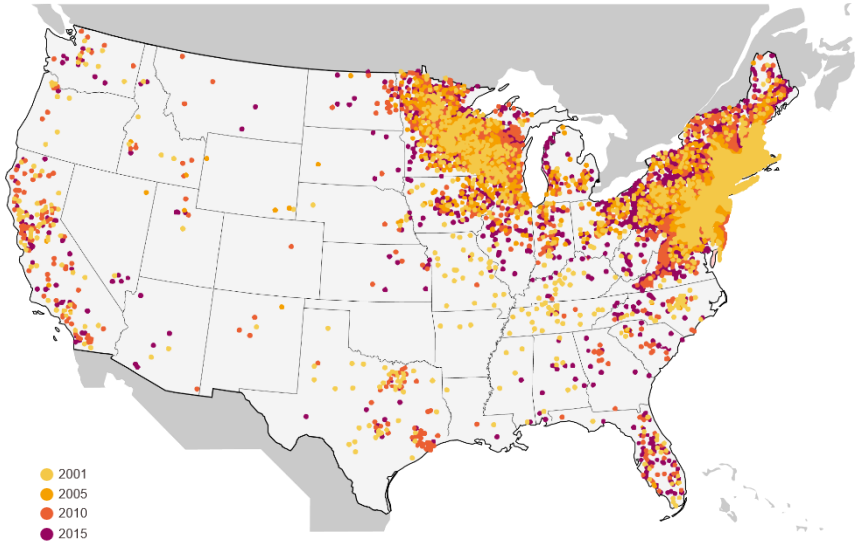
Early signs include **flu-like symptoms**[1] and **Erythema migrans rash**[2] which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

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 healtheconomic 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. **Topline results reported from Phase 2 trials [1, 2], incl. booster response[3]; Recruitment completed for Ph 2 trial VLA15-221 incl. pediatric participants[4]**
3. **Multivalent vaccine (six serotypes) to protect against Lyme disease in the United States and Europe**
4. **Follows proven Mechanism of Action for a Lyme disease vaccine**
5. **Exclusive, worldwide partnership with Pfizer**

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

Phase 2 trial[1] in Adults and Pediatric Subjects Ongoing

VLA15-221 recruitment completed in June 2021 with a total of 625 participants, 5 to 65 years of age, randomized[2]

- 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[1]

Further VLA15-202 results and topline booster data announced in Sep. 2021[3]

- 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[1]

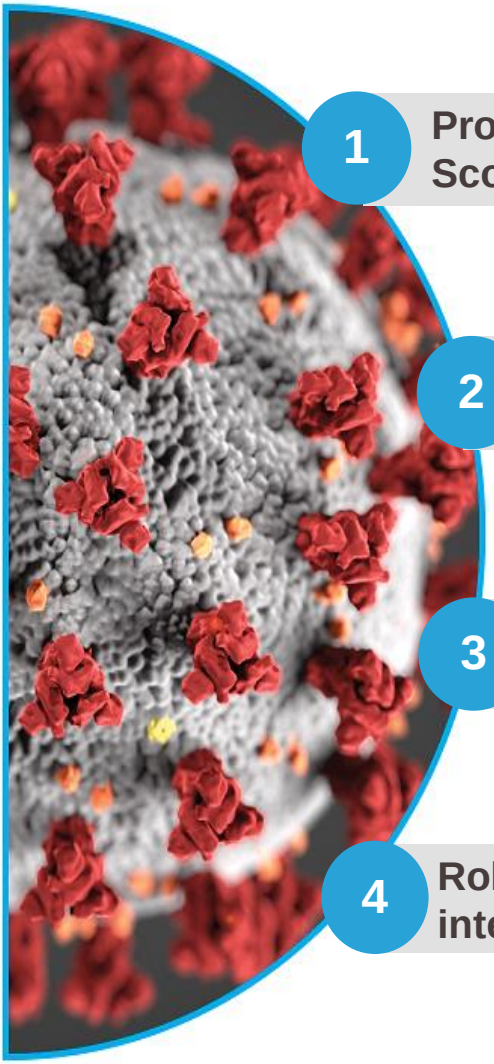
- Clinical readout, based on one tick season, projected by end of 2023
- $25m milestone payment due to Valneva upon trial initiation

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

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 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. **Program acceleration enabled through use of Valneva's FDA-registered facility in Scotland, where commercial manufacturing commenced January 2021[1]**
2. **Combines Valneva's proven approach of inactivated vaccines with Dynavax's advanced CpG 1018 adjuvant[2]**
3. **Positive Phase 3 Results from "Cov-Compare" reported in October 2021[3]**
4. **Rolling submission to MHRA commenced in Aug. 2021; Phase 3 "Cov-Compare" results intended to form the basis for potential regulatory approval in adults**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM.**1** Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment. **2** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; **3** Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001

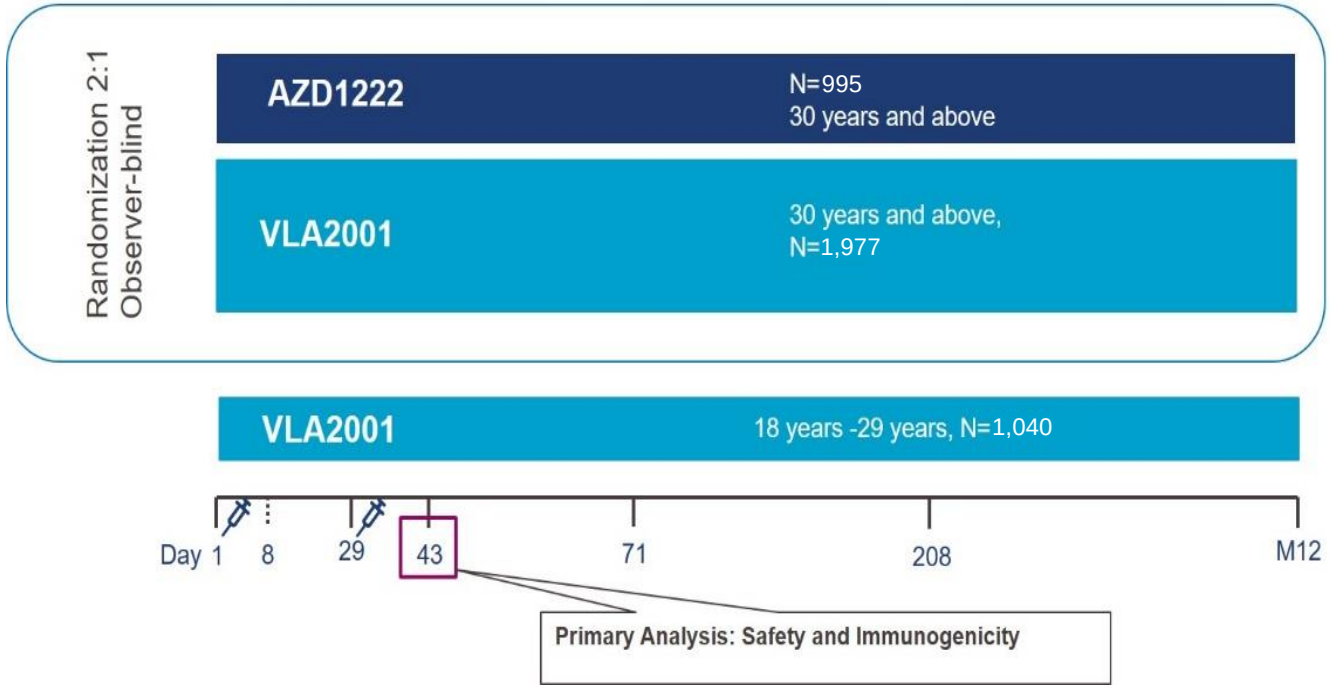
Phase 3 Cov-Compare Clinical Trial (VLA2001-301)

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 (ChAdOx1-S) (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



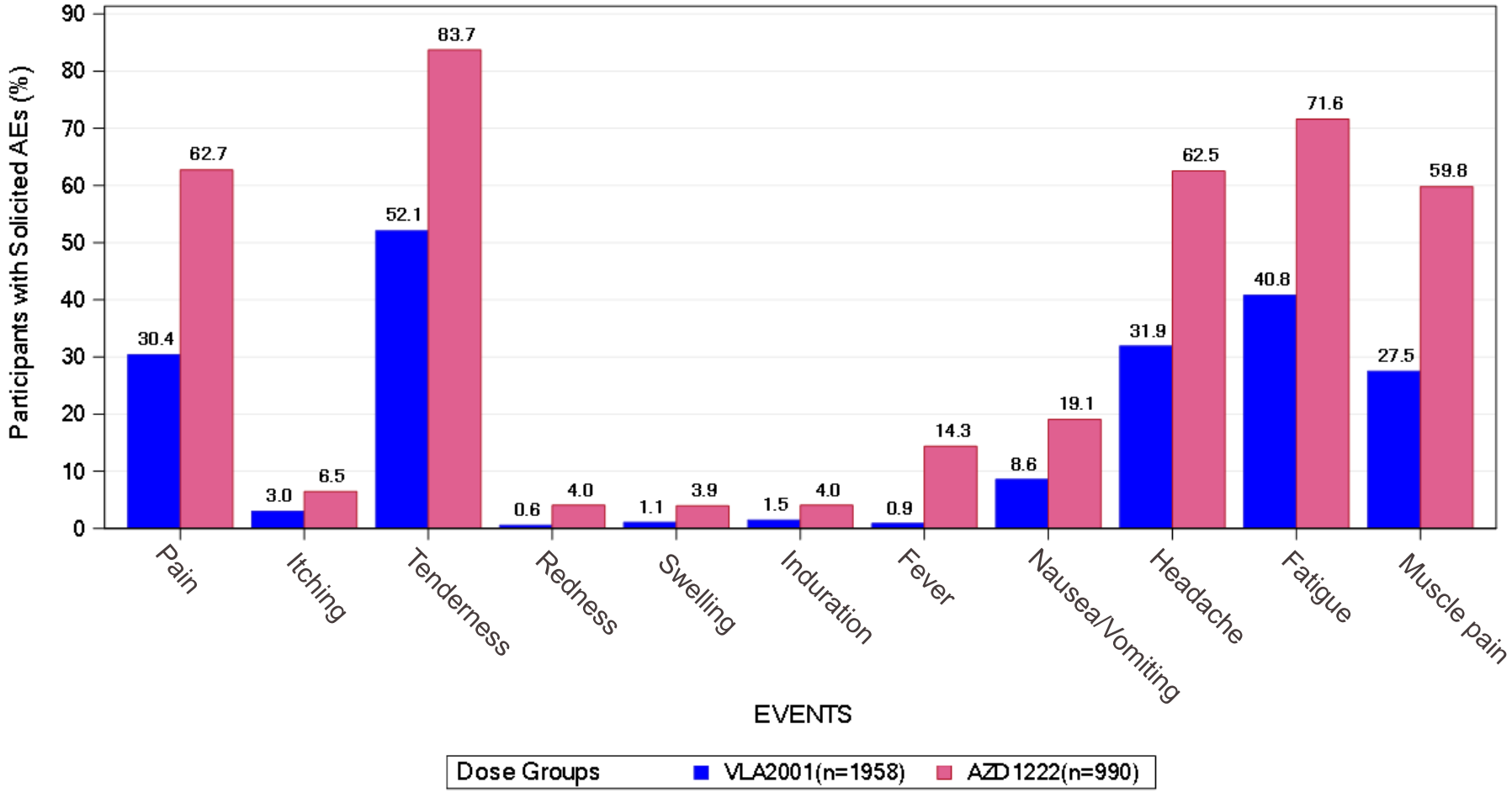
Primary Objective
Compare VLA2001 to AZD1222 (ChAdOx1-S) to determine:

- 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 Events

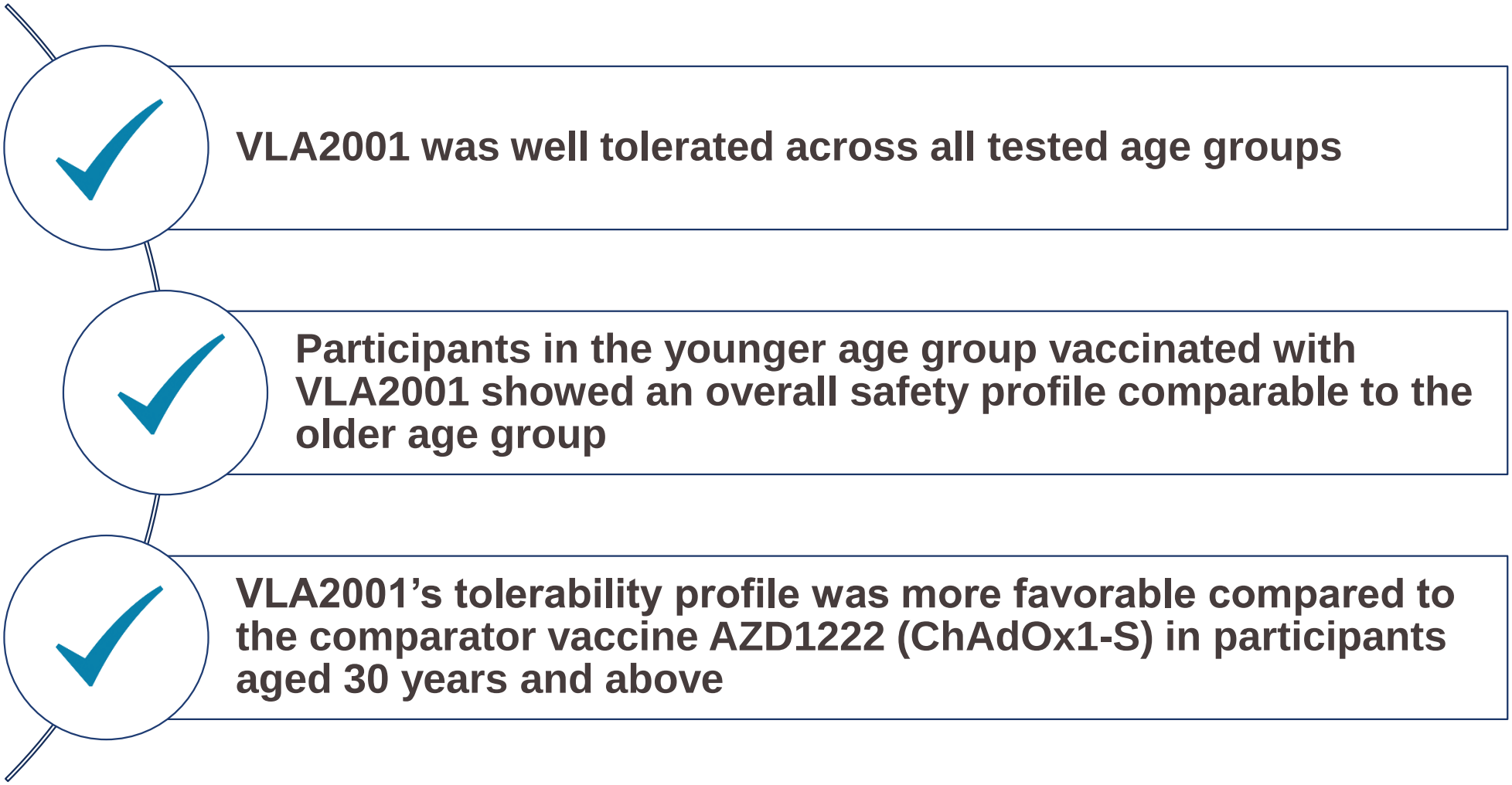
Safety and Tolerability Results - VLA2001 was Well Tolerated

Solicited Adverse Events within 7 Days of Vaccination

Participants aged 30-55 years



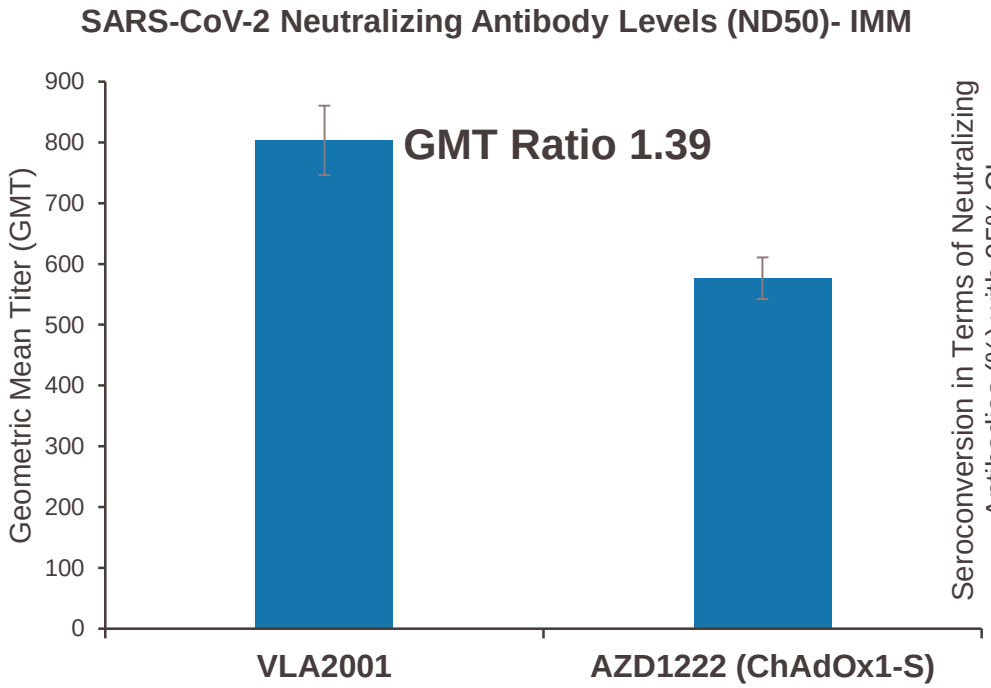
VLA2001-301 – Preliminary Safety Conclusions

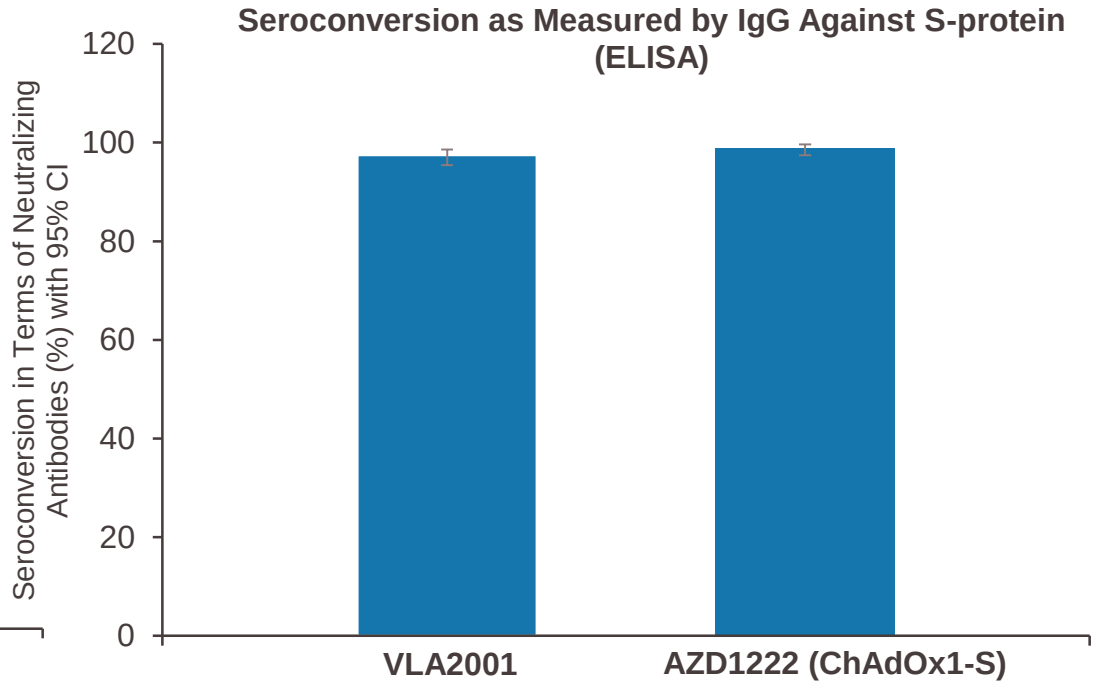


- VLA2001 was well tolerated across all tested age groups
- Participants in the younger age group vaccinated with VLA2001 showed an overall safety profile comparable to the older age group
- VLA2001's tolerability profile was more favorable compared to the comparator vaccine AZD1222 (ChAdOx1-S) in participants aged 30 years and above

Immunogenicity Results – Primary Endpoints Met

VLA2001 superiority in GMT ratio & non-inferiority in SCR against AZD1222 (ChAdOx1-S)



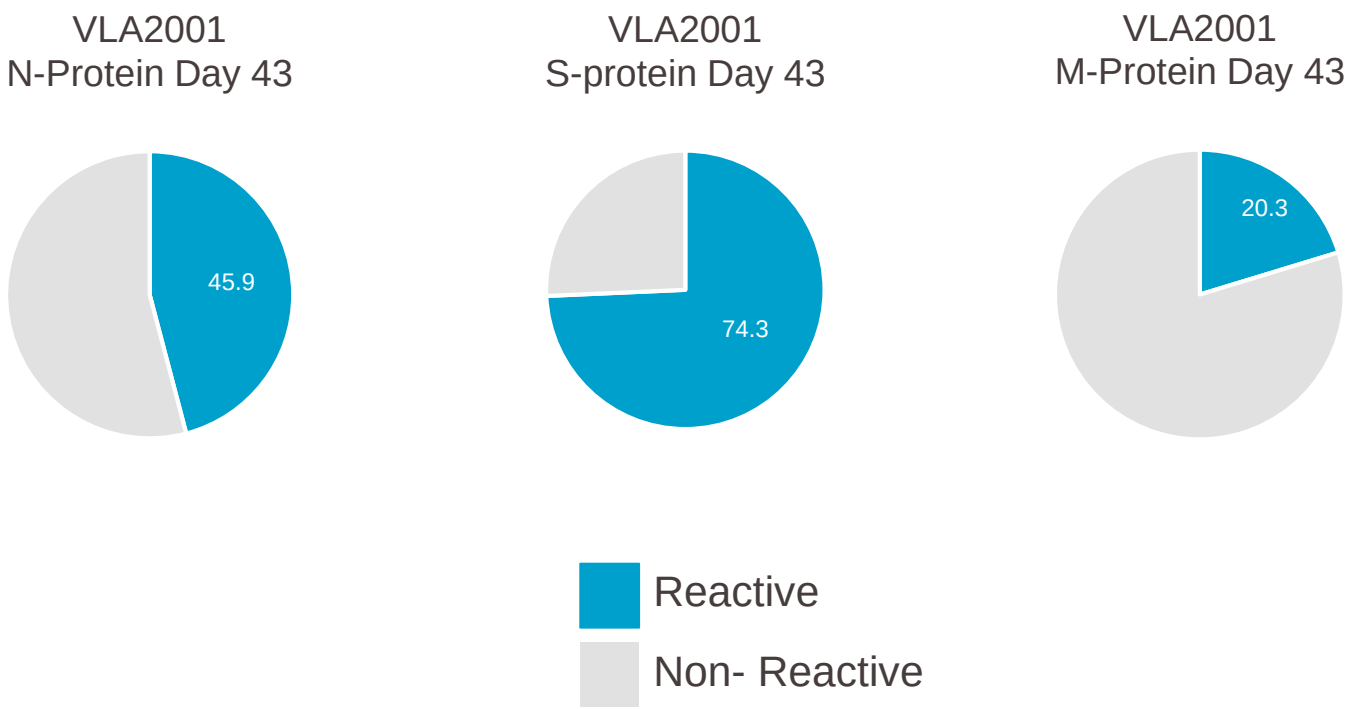


The trial met its co-primary immunogenicity endpoints at two weeks after the second vaccination (i.e. Day 43) in adults aged 30 years and above

- VLA2001 demonstrated superiority against AZD1222 (ChAdOx1-S) in terms of geometric mean titer for neutralizing antibodies as measured by live virus microneutralization assay. (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 above 95% in both treatment groups)

VLA2001-301 Immunogenicity Conclusions – Endpoints Met

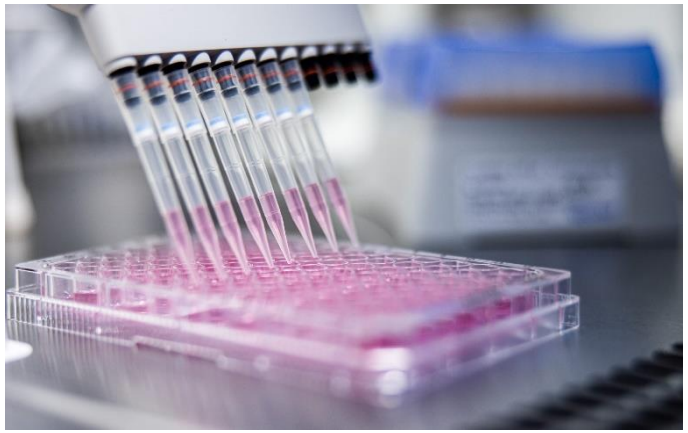
In addition, in the VLA2001 group, 45.9% had T-cells that were reactive against the N-protein, 74.3% against the S-protein and 20.3% against the M-protein.



Other Clinical Data Conclusions

- The **occurrence of COVID-19** cases (exploratory endpoint) was **similar between treatment groups** in the participants **30 years and above.**

- The **complete absence** of **any severe COVID-19 cases** may suggest that **both vaccines** used in the study **prevented severe COVID-19 caused by the circulating variant(s) (predominantly Delta).**



VLA2001 Clinical Development Plan

Plan will build further data and extend label

Ongoing

Ph1/2 VLA2001-201
- Extension for booster
- N= 77
- Age 18-55
- 6 Months follow-up

Ph3 VLA2001- 301a
- Adolescence
- Primary vaccination
- N= 660
- Age 12-17

Ph3 VLA2001-304
- Primary Elderly
- Single Arm Open Label
- N= 306
- Age 55+

Planned 2022

Ph3 VLA2001-301
- Primary Adults N=4012*
- **Extension for booster n=400**
- **Age 18-55+**

Ph3 VLA2001-321
- Pediatric
- N= 2200 Age 2-11
- Dose finding age 2-5
- Full dose age 5+

Ph3 VLA2001-3XX
- Booster study: N=200
- Age 12+
- Threshold based and min. 6 months after primary or infection

* Primary Adults VLA2001-301 ongoing

VLA2001: Route to Licensure

- **Valneva to submit Cov-Compare data to UK Medicines and Healthcare products Regulatory Agency (MHRA)**
  - Rolling submission with MHRA commenced in August 2021[1]
    - Final submission to MHRA anticipated for November
  - Potential initial approval by year-end
- **Valneva plans to submit data package to the European Medicines Agency (EMA)**
  - Pre-submission discussions with EMA ongoing
  - 306 elderly participants in the VLA2001-304 trial already enrolled[2] to collect additional data for the EMA data package
  - Cov-Compare endpoints aligned with EMA

1 Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine ; **2** Valneva Completes Recruitment of Elderly Participants in Phase 3 Trial of its Inactivated COVID-19 Vaccine

Chikungunya Vaccine – VLA1553

VLA1553: Only Chikungunya Vaccine Candidate in Phase 3 Today

1. **Positive Topline Results for Phase 3 trial VLA1553-301 reported[1]; Use of surrogate marker for Phase 3 endpoint confirmed by FDA[2]; Accelerated Approval Pathway confirmed[3]**
2. **Potentially eligible for Priority Review Voucher[4]; FDA Fast Track[5] and EMA PRIME[6] designation granted**
3. **Single shot, live attenuated[7] 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[8]**
5. **Excellent fit with existing commercial and manufacturing capabilities**

Note: Photo credit: James Gathany. **1** Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates **3** Valneva reports positive End-of-Phase 2 Chikungunya meeting with the U.S. FDA and sets stage for Phase 3 Study; **4** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program. **5** Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate. **6** Valneva's Chikungunya vaccine candidate awarded EMA prime designation. **7** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase). **8** Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-Income countries.

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[1]
- Lot-to-Lot consistency trial fully recruited (VLA1553-302), data expected late 2021[2]
- Antibody persistence follow-up trial (VLA1553-303) ongoing – up to 375 volunteers from VLA1553-301 will be followed up annually for five years after a single immunization[1]

Valneva is discussing with the FDA to bring VLA1553 to a potential licensure as soon as possible

The sponsor of the first chikungunya vaccine approved in the U.S. will be eligible to receive a PRV

1 Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate.

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 Cash Position of €329.8 million at End of June including Proceeds from US IPO

- **Cash / cash equivalents of €329.8 million at end of June (including proceeds from Global Offering)**
- **Successful Nasdaq listing (Q2); $107.6 million of gross proceeds**
  - Raised in an initial US public offering and a concurrent private placement in Europe

Key Upcoming Catalysts and Newsflow

Chikungunya vaccine candidate VLA1553

- Final Phase 3 trial results expected in Q1 2022 (topline results reported Aug 2021)
- Topline data of clinical lot-to-lot consistency Phase 3 trial expected late 2021

Lyme disease vaccine candidate VLA15

- Further Phase 2 read-outs expected in 2022
- Phase 3 trial initiation expected in 2022

COVID-19 vaccine candidate VLA2001

- Regulatory submissions and supply contracts
- Further clinical development plans to complement current clinical trials

Thank you
Merci
Danke
Tack

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