valneva

Advancing Vaccines for Better Lives

Company Presentation
June 2021

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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,** which help to fund our clinical development efforts
- **Highly experienced leadership team with expertise in the vaccine space**

Research & Development

Valneva Has Three Highly Differentiated Clinical Programs and Two Commercialized 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
Note: We are developing VLA1601, a highly purified inactivated vaccine candidate for Zika Virus and VLA84, a vaccine candidate against Clostridium difficile

Lyme Disease Vaccine – VLA15

Lyme Disease Is a Major Health Issue

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

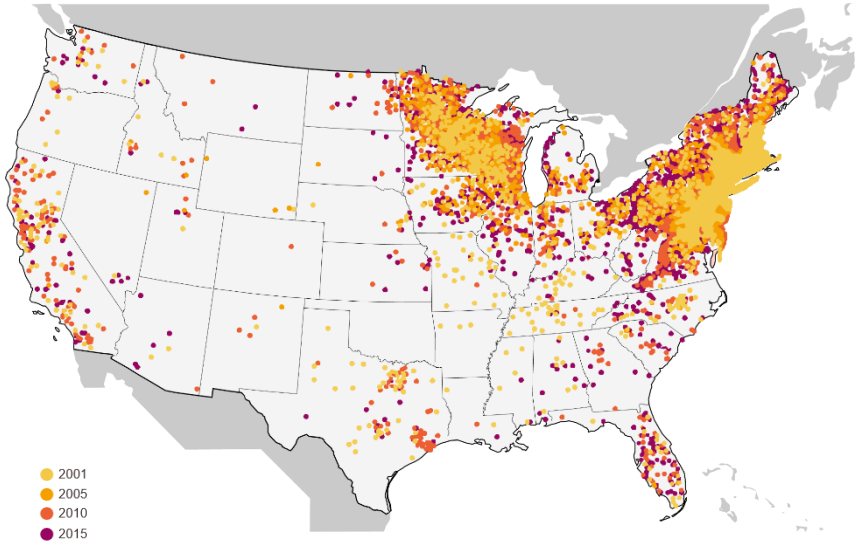
Early signs include **flu-like symptoms**[1] and **Erythema migrans rash**[2] which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

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 – 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 Program in Advanced Clinical Development Today

1. **FDA Fast Track Designation granted**
2. **Initial results reported from Phase 2 trials[1, 2]**
   Accelerated pediatric trial (VLA15-221) initiated in March 2021[3]
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; >$300m milestones ($140m already collected) plus tiered royalties starting at 19%**

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 announces acceleration of pediatric development for Lyme Disease vaccine candidate.

VLA15: Development Outlook

Phase 2 trial (VLA15-221) in adults and pediatric subjects initiated[1]

- Trial to include participants from 5-65 years of age and a reduced immunization schedule (Month 0-6 compared to Month 0-2-6)
- Initial pediatric population data expected in Q2 2022[1]
- VLA15-221 will also investigate a booster dose of VLA15, administered one year following the six Month dose[1]

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 end 2023

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.

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

Valneva's Response to the Global COVID-19 Crisis

Well-Known Inactivated Approach Based on Proven Technology

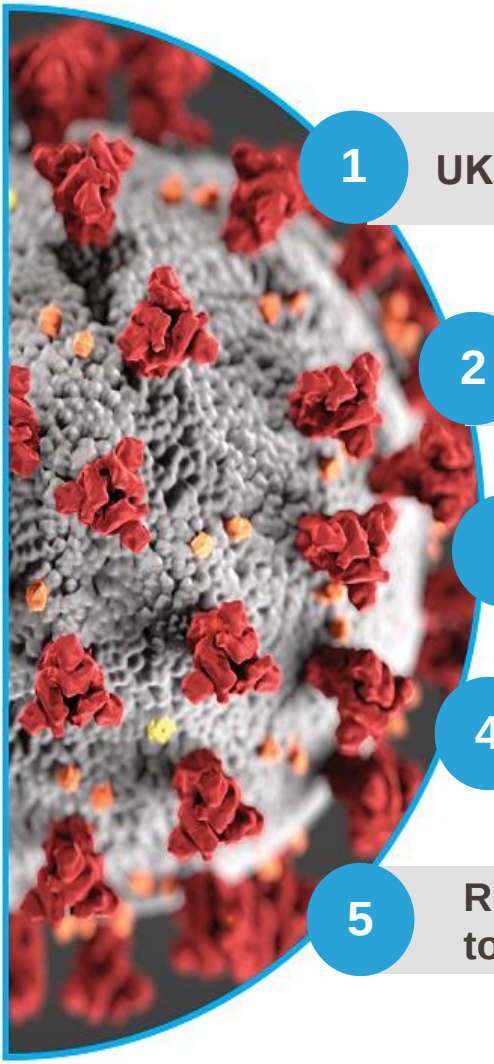
Intended for active immunization of **at-risk populations** to prevent carriage and symptomatic infection with COVID-19 during the **ongoing pandemic** and potentially **later for routine vaccination,** including addressing **new variants**

May be particularly well suited for boostering, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines

Inactivated vaccines are typically used in all groups, including the most vulnerable populations

Leverages the manufacturing platform used for Valneva's approved Japanese encephalitis vaccine, IXIARO®

VLA2001: The Only Inactivated Vaccine in Clinical Development in Europe; Adjuvanted with CpG 1018



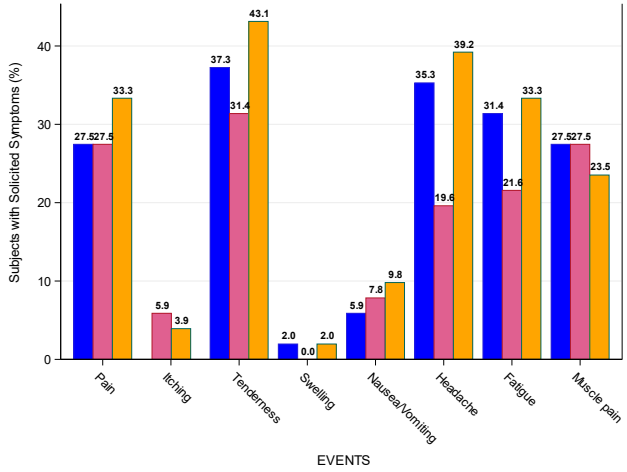
1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding
2. **Program acceleration enabled through use of Valneva's FDA-registered facility in UK; commercial manufacturing commenced Q1 2021**[2]
3. **Combines Valneva's proven approach of inactivated vaccines with Dynavax's advanced CpG 1018 adjuvant**[3]
4. **Phase 1/2 clinical trial results reported**[4]**; Phase 3 ongoing; Valneva participating in the world's first COVID-19 vaccine booster trial in the UK**[5]
5. **Regulatory submission to MHRA planned in autumn 2021, deliveries thereafter, subject to approval**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. **1** Valneva announces major COVID-19 vaccine partnership with U.K. Government. **2** Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment. **3** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine. **4** Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001; **5** Valneva to Participate in the World's First COVID-19 Vaccine Booster Trial in the UK

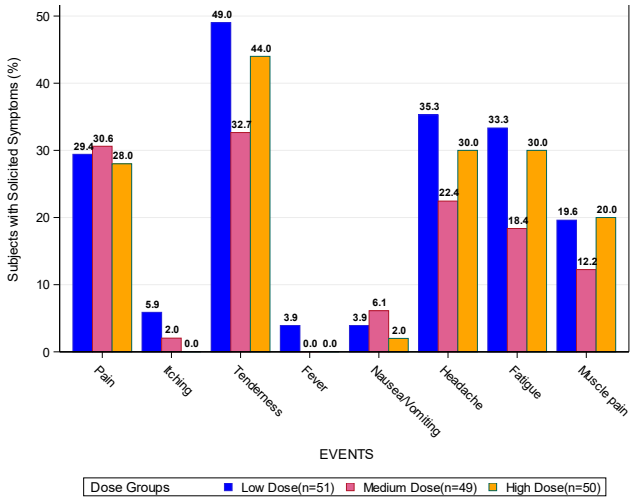
VLA2001 Was Well Tolerated in Phase 1/2

Safety Profile Within the Expected Range for an Inactivated Vaccine

First vaccination



Second vaccination



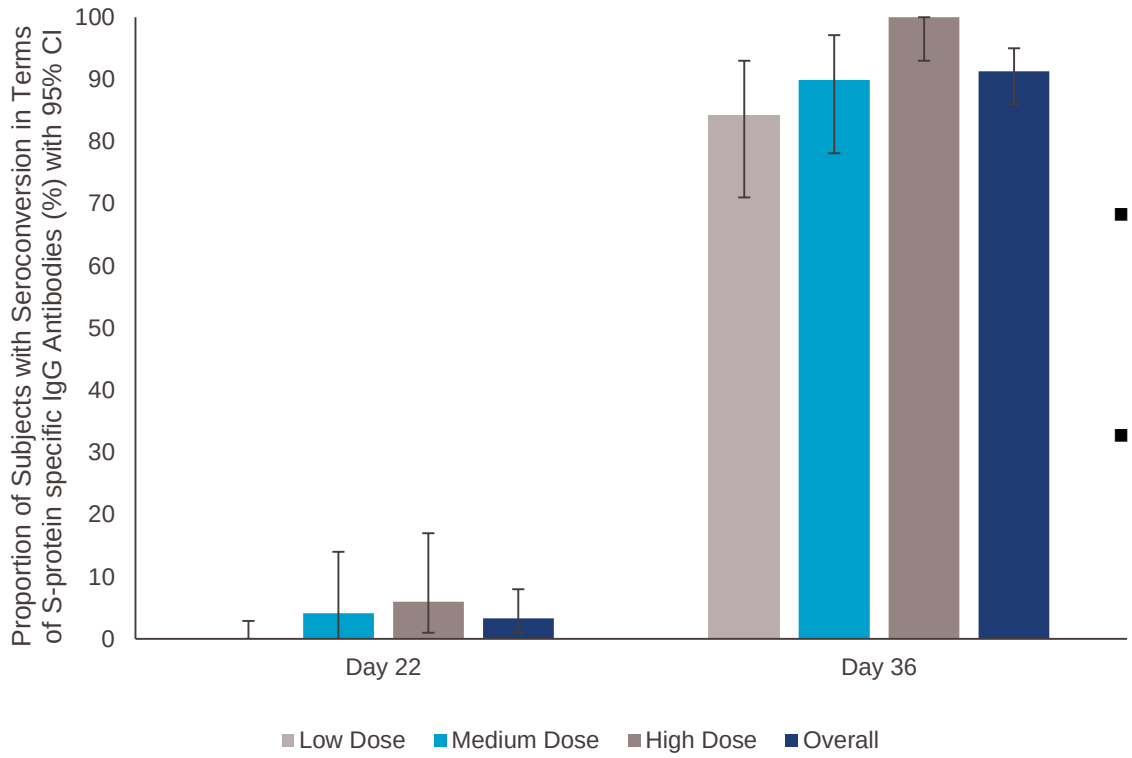
Safety Analysis Set, Figure 1.1.1 and 1.1.2, Table 14.2.1.2 and 14.2.1.3

- Generally well tolerated across all dose groups tested, no safety concerns identified by an independent Data Safety Monitoring Board.
- No statistically significant differences between dose groups and no differences between first and second vaccinations in terms of reactogenicity.
- Majority of Adverse Events (AEs) were mild or moderate and only two subjects reported severe solicited AEs (headache and fatigue).
- All solicited AEs were transient.
- Only 17.6% of unsolicited AEs up to day 36 were considered related to the vaccine and no severe unsolicited AEs were reported.
- No serious related AEs.

VLA2001 Was Highly Immunogenic in Phase 1/2

> 90% of Trial Participants Developed Significant Levels of Antibodies

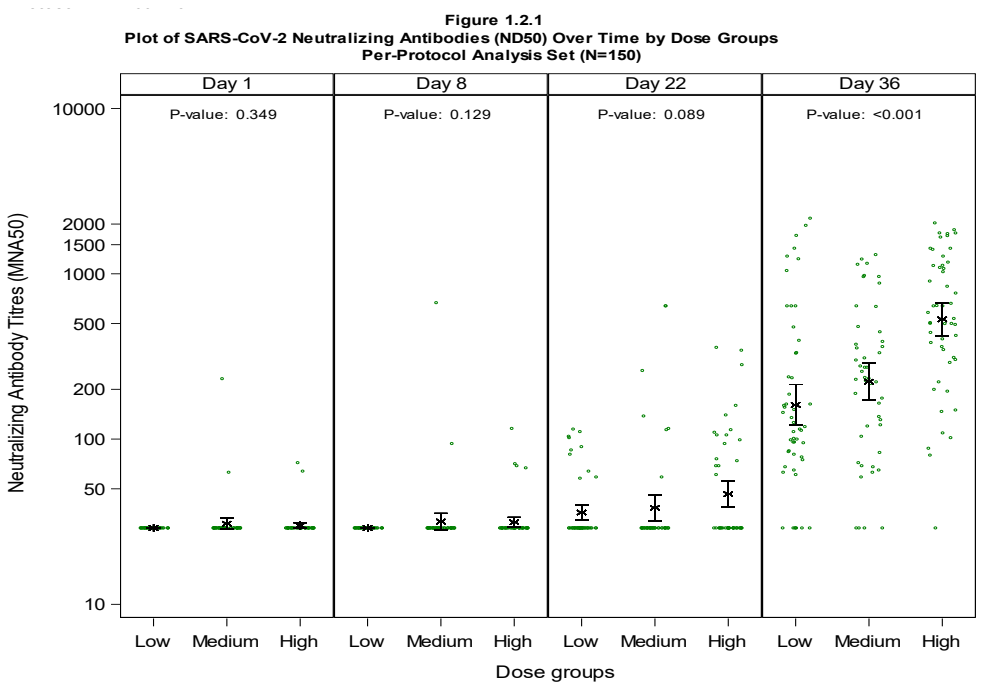
Seroconversion as Measured by IgG Against S-protein (ELISA)

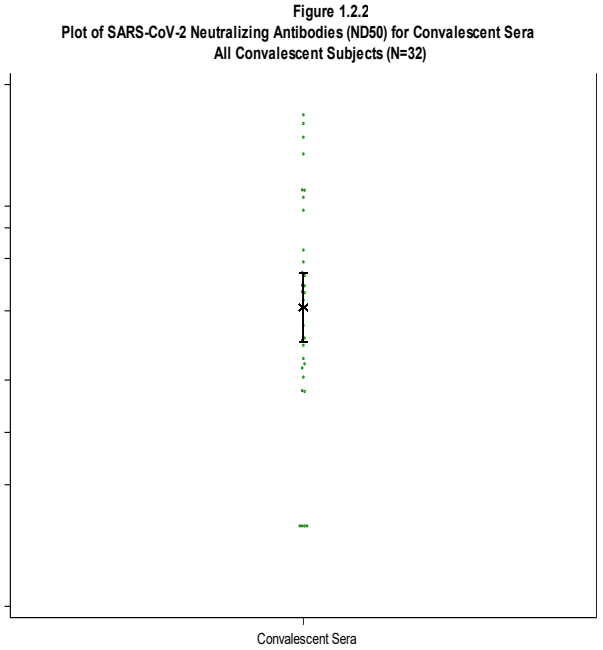


- More than 90% of all trial participants developed significant levels of antibodies to the SARS-CoV-2 virus spike protein across all dose groups tested.
- Seroconversion Rates (SCR) for S-protein binding IgG antibodies were 89.8% in the medium dose and 100% in the high dose group.
- Two weeks after completion of the two dose schedule, Geometric Mean Fold Rises (GMFRs) from baseline were 26 in the medium dose and 86 in the high dose group.

Per-Protocol Analysis Set, Table 14.3.5.1, Table 14.3.6.1

VLA2001 Generated Neutralizing Antibody Titers at or Above Levels Generally Seen in Convalescent Sera in Phase 1/2





SARS-CoV-2 Neutralizing Antibodies (MNA50)

- Dose dependent response, statistically significant higher Geometric Mean Titers (GMTs) in high dose group compared to low and medium dose groups.
- In high dose group, GMT of neutralizing antibody titers of 530.4 (95% CI: 421.49, 667.52).
- With a GMT ratio of vaccine vs. convalescent sera ≥ 1 vaccine efficacy has been reported above 80% for other vaccines.

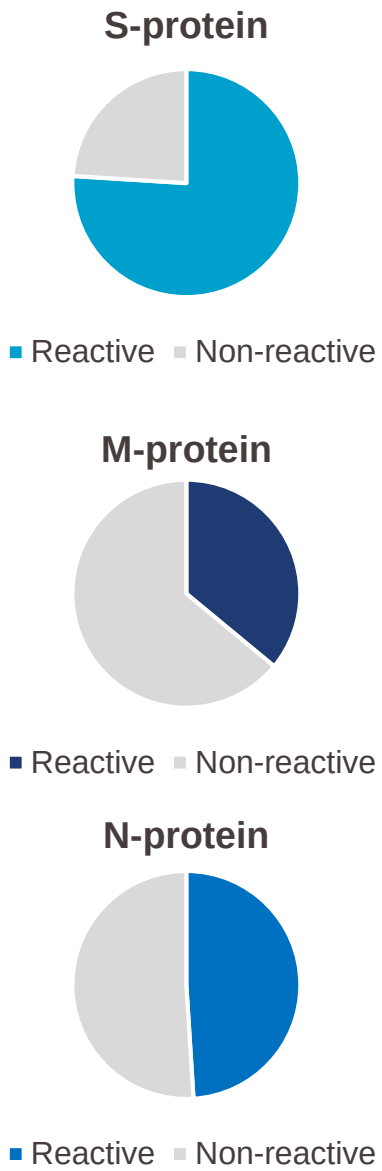
Per-Protocol Analysis Set, Figure 1.2.1; Convalescent Subjects, Figure 1.2.2
Earle et al. MedRxiv, March 2021, https://doi.org/10.1101/2021.03.17.20200246); Khoury et al. MedRxiv, March 2021, https://doi.org/10.1101/2021.03.09.21252641

Immunogenicity Summary – Cellular Response Induced

Exploratory endpoints evaluated T-cell responses by IFNgamma ELISpot analysis against **S**-protein, **M**embrane-protein and **N**ucleocapsid-protein.

At Day 36, in the high dose group:

- 76% of study participants (34/45) were reactive[1] against peptide pools spanning the full-length **S**-protein
- 36% (16/45) against the **M**-protein
- 49% (22/45) against the **N**-protein



[1]Sample is considered **reactive** against individual stimulation panel (peptide pools) if normalized spot counts (Nil control counts substracted) per 2.10 x 10^5 PBMCs ≥ 6

VLA2001: Development Outlook
Pivotal Phase 3 Trial Ongoing

Pivotal Phase 3 is a randomized, observer-blind, controlled, comparative immunogenicity trial in ~ 4,000 adults, recruitment complete

- Immunological comparison against a licensed vaccine to reasonably predict efficacy (superiority of VLA2001 in a two-dose immunization schedule four weeks apart - GMTs of neutralising antibodies, at two weeks after the second vaccination)
- Study conducted in UK supported by DHSC/NIHR, including funding
- Protocol agreed with MHRA; discussion with other regulatory bodies ongoing

Valneva participating in the world's first COVID-19 vaccine booster trial in the UK (including reduced booster dose)

Additional booster studies planned

Valneva has developed viral seed banks, including Alpha (UK) and Beta (South Africa) variants, to be in a position to manufacture variant-based vaccines

Chikungunya Vaccine – VLA1553

Chikungunya is a Significant Public Health Concern

A Mosquito-Borne Viral Disease in Tropical/Sub-Tropical Regions

Can cause **debilitating joint and muscle pain**, fever, headache, nausea and rash, **with potential serious, long-term health impairment[1]**

Currently there are no vaccines or effective treatments for chikungunya

Global market, including endemic regions (see below), estimated to exceed $500 million annually by 2032[2]

2020 outbreaks[3]: The Americas (incl. Brazil, the Caribbean, Colombia, Costa Rica, Mexico), Asia (India, Malaysia, Thailand) and Africa (Congo, Kenya, Sudan)

1 Valneva Chikungunya Factsheet. **2** VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020. **3** ECDC Geographical distribution of chikungunya virus disease cases reported worldwide, 2020.

VLA1553: Only Chikungunya Vaccine Candidate in Phase 3 Today

1. **Phase 3 trial VLA1553-301 fully enrolled[1]; Use of surrogate marker for Ph3 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 Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial. **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: Topline Read-out Expected Mid-2021

Phase 3 Clinical Development Program underway

- Pivotal Phase 3 safety and immunogenicity trial in 4,131 healthy volunteers fully recruited[1]
- Topline data read-out on Day 29 (based on surrogate of protection) mid-2021
- Lot-to-Lot consistency trial initiated (VLA1553-302) in ~400 volunteers[2]
- Antibody persistence follow-up trial initiated (VLA1553-303) – up to 375 volunteers from VLA1553-301 will be followed up annually for five years after a single immunization[1]
- Adolescents clinical trial in 750 volunteers in Brazil planned to commence in 2021[3]
- **Accelerated approval pathway agreed with FDA**[4]

VLA1553 may be eligible for Priority Review Voucher upon FDA approval[5]

1 Valneva Completes Recruitment for Pivotal Phase 3 Trial of Chikungunya Vaccine Candidate and Initiates Antibody Persistence Trial. **2** Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate. **3** In collaboration with development partner Instituto Butantan, under CEPI funding. **4** Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates.**5** 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)[1]

- **Direct sales channels in the US, Canada, UK, France, Nordics, and Austria**
- **Distributors in Germany, Australia/NZ 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 $135m if options are exercised**

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

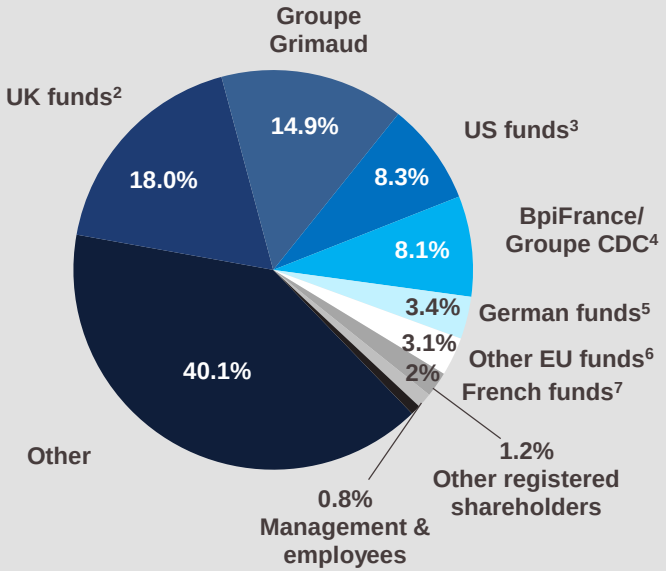
[1] Valneva reports record product sales and major pipeline progress in 2019, [2]Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership

Corporate Highlights and Newsflow

Valneva Completed its Nasdaq Listing in May 2021

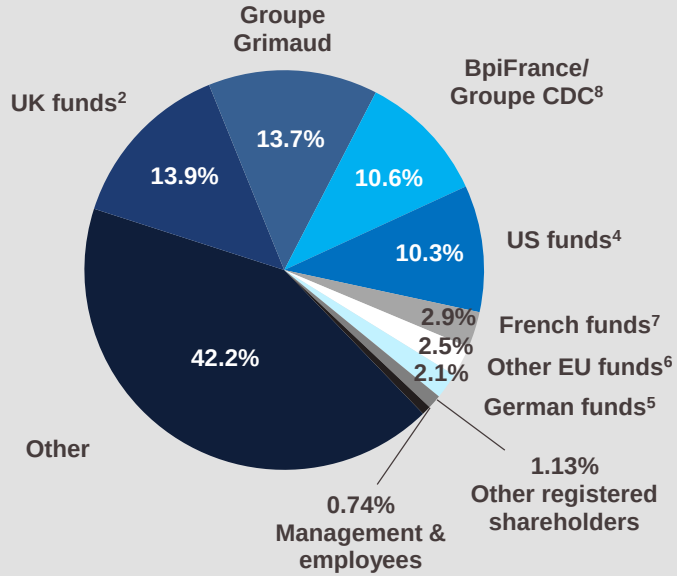
End February 2021

- Number of ordinary shares: 91.7m
- Shareholder structure[1]:



May 2021

- Number of ordinary shares: 99.9m
- Shareholder structure[1]:



1 Estimates based on ordinary share capital; **2** Combined positions of MVM Life Science Partners, Polar Capital LLP, Highclere, AXA Investment Managers Ltd. and Abingworth LLP; **3** Combined positions of U.S.-based funds managed by Armistice Capital, General American, Acadian AM, and others; **4** Groupe CDC is France's public financial institution and includes here the combined positions of BpiFrance and CDC Croissance; **5** Combined positions of Apus Capital, Medical Strategy GmbH, and others; **6** Combined positions of multiple funds based in Austria, Liechtenstein, Denmark and Luxembourg; **7** Combined positions of AXA Paris, Eiffel Investment Group, BFT IM and others.

Strong Cash Position of €235.9 million at End of March 2021, Plus Proceeds from US IPO

- **Cash / cash equivalents of €235.9 million at end of March (excluding proceeds from Global Offering)**
  - The increase in liquid funds compared to December 31, 2020 results from payments made by the UK government within the framework of the UK COVID-19 partnership

- **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 Potential Inflection Points

Lyme disease vaccine candidate VLA15

- Further Phase 2 milestones and read-outs during 2021; Phase 2 study VLA15-221, including pediatric development, initiated March 2021

COVID-19 vaccine candidate VLA2001

- Phase 1/2 initial data reported, Phase 3 data expected in Q3 2021
- Regulatory submissions planned autumn 2021 assuming clinical data positive
- Further trial initiations to strengthen the product candidate's differentiation
- Initial results for Cov-Boost trial expected in September 2021
- Further supply deals subject to negotiations and capacity

Chikungunya vaccine candidate VLA1553

- Initial Phase 3 data expected mid-2021; Phase 3 now fully recruited

Thank you
Merci
Danke
Tack

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