Advancing Vaccines for Better Lives

Company Presentation
November 2020

valneva

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Valneva's Value Proposition

Integrated business model with valuable R&D and commercial assets

R&D provides upside for shareholders

Lyme vaccine in Phase 2

US/EU market opportunity of ~$1bn per annum

- Only program known to be in clinical development
- Strategic collaboration with Pfizer[1]

Chikungunya Phase 3 initiated Sept. 2020

Global market opportunity of ~$0.5bn per annum

- Synergy with existing infrastructure
- Possible Priority Review Voucher upside

COVID-19 vaccine candidate

Phase 1 to be initiated before the end of 2020

- Only inactivated vaccine candidate currently in development in the US & EU
- UK Government agreement worth up to €1.4 billion

Commercial Business

Total sales revenues of €129.5m in 2019; Guidance for 2020 ~ €70m

- Pandemic impact on travel industry
- Commercial infrastructure - important strategic asset capable of launching future brands
- Marketing & Distribution partnership with Bavarian Nordic announced June 2020[2]

IXIARO®

- Only licensed Japanese encephalitis vaccine for travelers in US, CAN and EU; mandatory for US military
- New US DoD supply contract worth up to $166 million[3]

DUKORAL®

- Cholera (LT-ETEC[4]) vaccine, licensed in CAN, EU, ROW

1 Valneva PR: Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15; **2** : Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership; **3** Valneva Announces New IXIARO® Supply Contract with the US Government worth up to $166 million; **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

Valneva's R&D Pipeline
Active Programs

Product Candidate	Pre-clinical	Phase 1	Phase 2	Phase 3	Partner	PRV* Eligible
VLA1553 Chikungunya					**proprietary**	✓
VLA15 Lyme disease					**Pfizer**	
VLA2001 COVID-19					**proprietary**	

*PRV = U.S. Priority Review Voucher: *https://priorityreviewvoucher.org/*

Lyme Disease Vaccine – VLA15

Lyme Disease is a Massively Important Health Issue

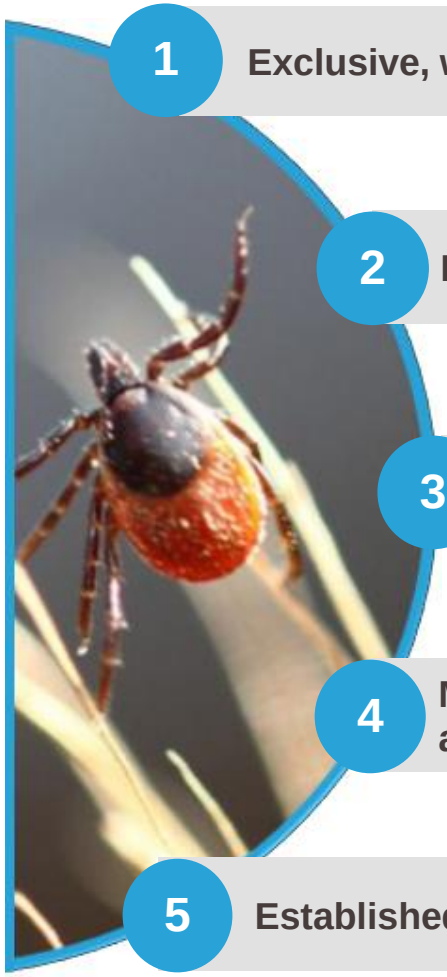
No available treatment to protect against Lyme disease

Major unmet medical need in North America and Europe

Lyme disease cases may rise 92% in the US due to climate change (New Scientist)[1]

1 https://www.newscientist.com/article/2232705-lyme-disease-cases-may-rise-92-per-cent-in-us-due-to-climate-change/

VLA15: Only Lyme disease vaccine in clinical development today



1. Exclusive, worldwide partnering deal with Pfizer
2. Positive initial results from Phase 2 studies (VLA15-201 and VLA-202) reported[1,2]
3. FDA Fast Track Designation granted
4. Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe
5. Established and proven Mode 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

VLA15: Exclusive, Worldwide Partnering Deal with Pfizer and Positive Initial Phase 2 Results

Partnered with Pfizer for late stage development and future commercialization[1]

- Valneva and Pfizer will work closely together throughout development
- Pfizer will fund 70% of all development costs through program completion
- Valneva is eligible to receive a total of $308 million upfront and milestone payments ($130 million already received[2])
- Pfizer will pay Valneva tiered royalties starting at 19%

Positive initial results from two Phase 2 studies (VLA15-201 and VLA-202) reported[3,4]

- Phase 2 studies VLA15-201 and VLA15-202 top line data positive
  - Compared to Phase 1, the higher doses used in this trial elicited higher antibody responses across all serotypes
- Encouraging immunogenicity profile confirmed, including older adults (50-65 years)
- VLA15 generally safe across all dose and age groups tested
- VLA15-202 Day 208 safety and immunogenicity data support advancing the program with the Month 0-2-6 schedule and 180 µg dose

Valneva and Pfizer working on next development steps.

1 Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15, **2** Valneva Reports H1 Results Marked by Major Corporate Achievements and Strong Cash Position; **3** Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate; **4** Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15

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

Responding to the COVID-19 Crisis

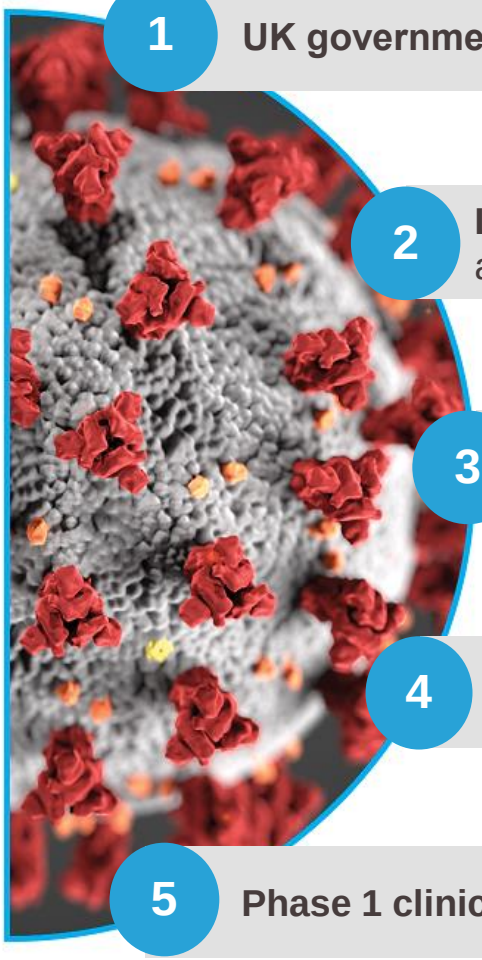
There is currently no approved vaccine and no specific treatment available for the novel coronavirus, SARS-CoV-2

Physical distancing has been effective[1], but nationwide lockdowns are not a long-term solution

Numbers of confirmed COVID-19 cases and deaths continue to increase worldwide[2]

1 Flaxman, S., Mishra, S., Gandy, A. *et al.* Estimating the effects of non-pharmaceutical interventions on COVID-19 in Europe. *Nature* (2020). https://doi.org/10.1038/s41586-020-2405-7**;**
2 John's Hopkins University COVID-19 Dashboard

VLA2001: Only inactivated COVID-19 vaccine candidate in US & EU



1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding
2. **Leveraging Valneva's existing capabilities:** BSL3 labs recommissioned for pre-clinical activities**;** Plug-and-play at Valneva's FDA-approved Livingston manufacturing facility
3. **Facilitated program acceleration through use of Valneva's FDA-approved platform**
4. **Combines Valneva's proven approach with Dynavax's advanced CpG 1018 adjuvant**[2]
5. **Phase 1 clinical trials to commence in December 2020**

1 Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government; **2** Valneva and Dynavax Announce Commercial Supply Agreement for Inactivated, Adjuvanted COVID-19 Vaccine; **Photo credit**: CDC/Alissa Eckert, MSMI; Dan Higgins, MAMS

VLA2001: Agreement to Provide up to 190 Million Doses of Inactivated, Adjuvanted Vaccine to the UK

UK Government Agreement Worth up to €1.4 Billion

- Valneva to supply up to 190 million doses in a deal worth up to €1.4 billion[1]
- Including 60 million doses worth approximately €470 million for 2021
  - › Options to purchase up to 130 million doses worth up to €900 million between 2022 and 2025

Agreement includes funding for expansion of Valneva's UK-based manufacturing facility and Phase 1/2 clinical trials in the UK

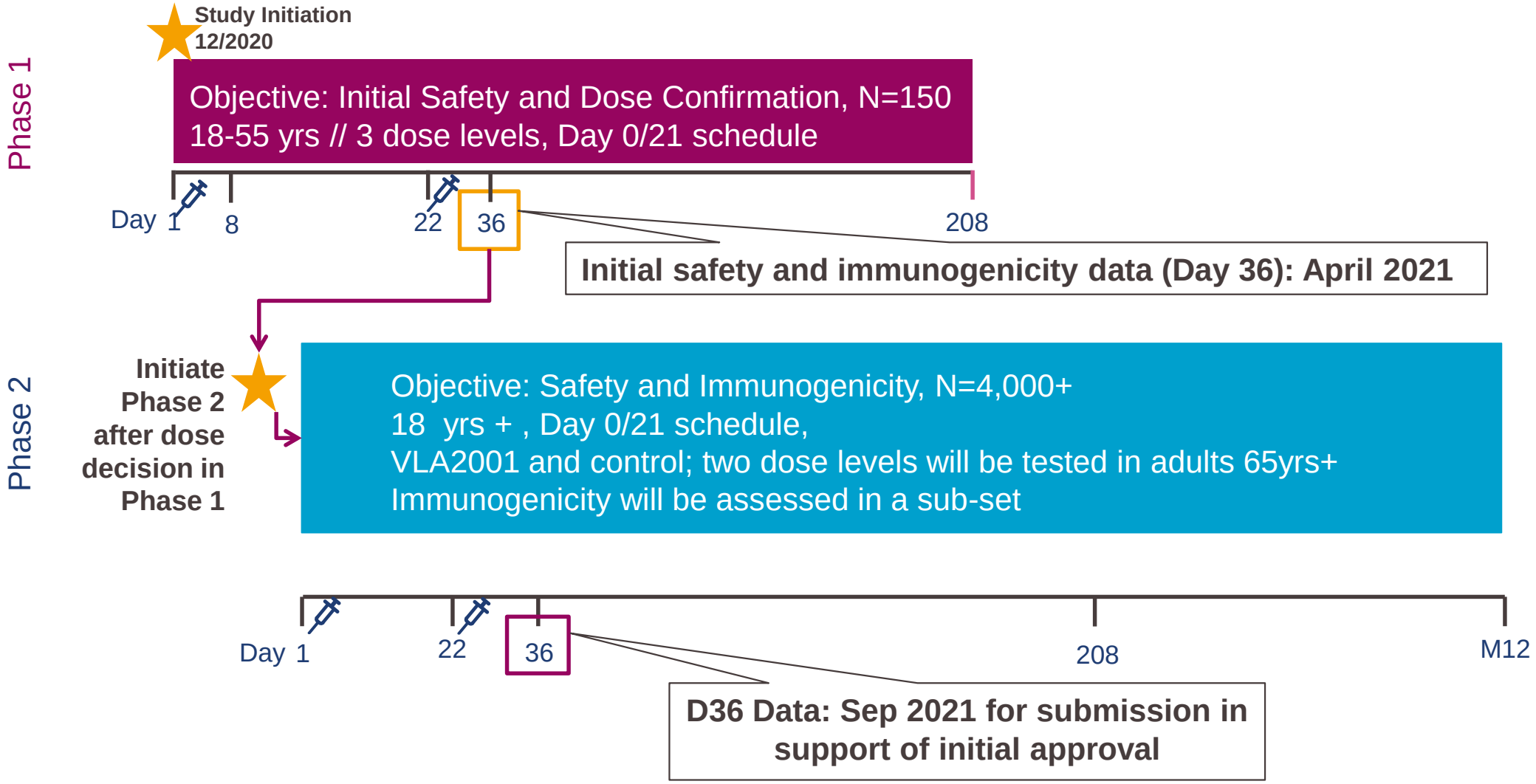
- Vaccine to be manufactured at Valneva's facilities in Livingston, Scotland[2]
- Valneva plans further investments in both its Scottish and Swedish facilities

Pre-clinical and industrialization activities on track

1 Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government ; **2** Valneva Confirms Participation in UK Government COVID-19 Vaccine Response Program

VLA2001: Inactivated SARS-CoV-2 Vaccine

Clinical entry December 2020, initial data April 2021



Chikungunya Vaccine – VLA1553

Chikungunya is a Growing and Enduring Problem

Representing a major public health threat

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[1]

2019 - 2020: outbreaks[2] in Africa (Chad, Djibouti, Ethiopia, Kenya, Sudan), Asia (Cambodia, Philippines, Thailand), and South America (Brazil, Colombia)

1 VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020, **2** *Chad*, *Djibouti*, *Ethiopia*, *Kenya*, *Sudan*; *Cambodia*, *Philippines*, *Thailand*; *Brazil*, *Colombia*

VLA1553: Most advanced single-shot chikungunya vaccine candidate

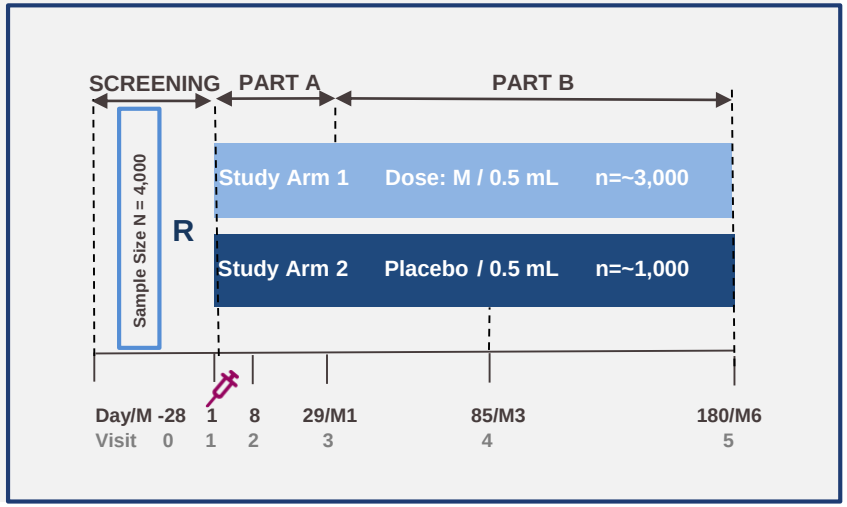
1. Phase 3 initiated in September 2020[1]; Positive EoP2 meeting with the FDA; Accelerated Approval Pathway confirmed[2]
2. Priority Review Voucher eligible; FDA Fast Track[3] and EMA PRIME[4] designations granted
3. Up to $23.4 million (€20.3 million) awarded to Valneva for R&D by CEPI
4. Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset; Partnership with Instituto Butantan for LMICs[5]
5. Monovalent live attenuated[6] prophylactic vaccine targeting chikungunya virus neutralization

1 Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553 ; **2** Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study; **3** Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate; **4** Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation; **5** Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; **6** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; **Photo credit**: James Gathany

VLA1553-301: Pivotal Phase 3 Study

Double-Blinded, Controlled, Randomized Study

1. **Objectives:** pivotal safety and immunogenicity; Seroprotection rate at D29 based on an immunological surrogate (defined in NHPs for baseline negative subjects). [1]
2. **Population:** Healthy subjects aged 18 years and above, randomized 3:1 to VLA1553 or control
3. **Sample Size:** approx. N=4,060; Safety: VLA 1553 (n=3,000) vs. control (n=1,000); IMM subset (n=500)
4. **Trial Sites:** Multicenter study in non-endemic regions of the U.S.
5. **Prim. Endpoint:** Seroprotection rate at D29
6. **Schedule:** Single-shot i.m. immunization at Day 1
7. **Expected Duration:** 9 - 12 months**)



1 Seroprotection threshold subject to final approval by regulators
2 Duration may be impacted by different parameters, including adverse clinical operations implications due to ongoing COVID-19 pandemic

Commercial Products

Valneva has a niche commercial travel vaccine business and is a vaccine provider to the US Military

- **Direct sales channels in US, Canada, UK, France, Nordics, Austria**

- Distributors in Germany, Australia, Southern Europe

- Business sector reshaped given COVID-19 pandemic impact on travel industry
- Key asset for the future, including chikungunya route to market

IXIARO®/JESPECT®

Only vaccine against Japanese encephalitis (JE) in US, Canada and Europe

IXIARO®/JESPECT®

- **Designed to protect travelers and military against JE, the leading cause of viral neurological disease and disability in Asia**
- Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older[1]

Commercial position

- Currently, **no effective treatment for the disease**
- **The only approved vaccine available for US, EU and Canadian travelers**
- Supply agreement in place with US military and strong history of repeat contracts
- Limited competition - local producers exist in endemic regions and mainly serve public markets

New US DoD supply contract worth up to $166 million[2]

- Spans a total of **three years**:
  - **Base year value of $61 million**
  - **DoD option to purchase a total of $76 million – $105 million worth of IXIARO® across two option years**
- Base year deliveries to commence Q4 2020

1 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. The currently available presentation for IXIARO® can be used in children from 3 years of age. Prior to availability of the new presentation, no attempt should be made to adjust the syringe volume or to administer a 0.25mL/3µg dose in children less than 3 years of age; **2** Valneva Announces New IXIARO® Supply Contract with the US Government worth up to $166 million

DUKORAL®

Only cholera (ETEC[1]) vaccine approved in EU, Canada and Australia

DUKORAL®

- **For the prevention of diarrhea caused by *Vibrio cholera* and/or heat-labile toxin producing enterotoxigenic *Escherichia coli* (ETEC)**[1]
- **Designed to protect adults and children** traveling to endemic areas

Commercial position

- In several markets, incl. EU, indicated for cholera only
- **Only approved cholera vaccine available for Canadian, European and Australian travelers**
  - ~3-5 million cholera cases, 100,000-120,000 deaths/year[2]
  - ~5-18 million reported ETEC cases/year[3] (ETEC is the most frequent form of traveler's diarrhea)
  - WHO pre-qualification widely used in other countries
  - Asian manufacturers predominantly serve local markets

1 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; **2** https://www.who.int/bulletin/volumes/90/3/11-093427/en/; **3** Lundkvist J, Steffen R, Jonsson B. Cost-benefit of WC/rBS oral cholera vaccine for vaccination against ETEC-caused travelers' diarrhea. J Travel Med 2009; 16(1):28-34

Corporate Highlights and Newsflow

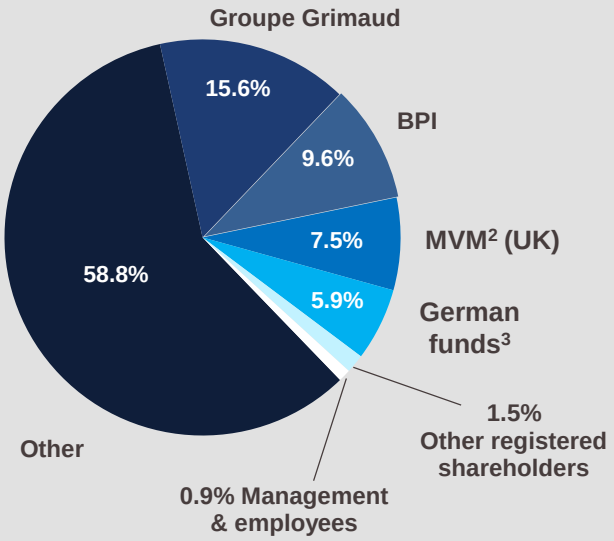
Company well positioned for next stage of growth

- Strong balance sheet (year end cash expected to be €180m - €200m)
  - UK COVID-19 deal does not rely on Valneva capital
- US IPO intention announced, EGM planned December 2020
- Sales revenue €130m in 2019, expected to be c€70m in 2020, is expected to recover and grow post-COVID alongside travel industry

VLA has strengthened its institutional shareholder base with blue-chip healthcare investors including US-based investors

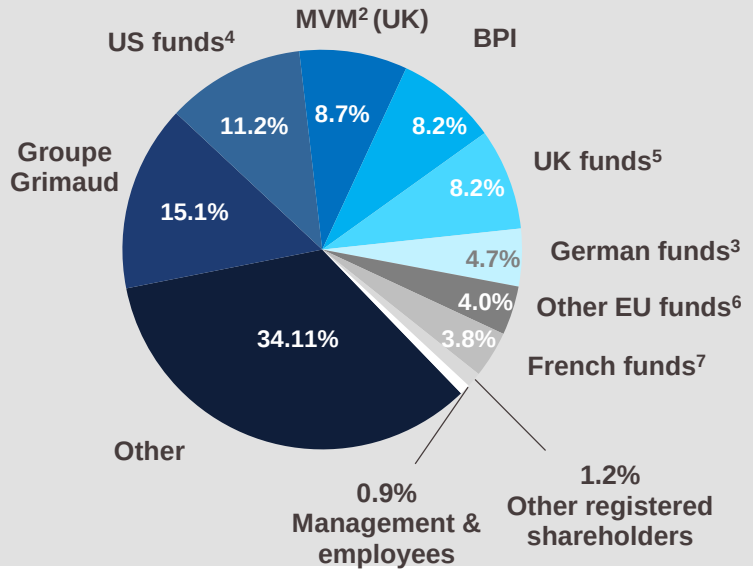
January 2018

- Number of ordinary shares: 77.6m
- Shareholder structure[1]:



October 2020

- Number of ordinary shares: 90.9m
- Shareholder structure[1]:



1 Estimates based on ordinary share capital; **2** Funds managed by MVM Life Science Partners; **3** Combined positions of Apus Capital, Apo AM, Lupus alpha, and others; **4** Combined positions of U.S.-based funds managed by Deerfield Partners, Armistice Capital, Acadian AM, General American, and others; **5** Combined positions of Polar Capital LLP, Highclere, AXA Investment Managers Ltd. and Abingworth LLP; **6** Combined positions of multiple funds based in Liechtenstein, the Netherlands, Austria, and Luxembourg; **7** Combined positions of CDC Entreprises Valeurs Moyennes, AXA Paris and others.

Key Upcoming Newsflow

Lyme disease vaccine candidate VLA15

- Valneva and Pfizer will prepare for next development steps in the coming months

Chikungunya vaccine candidate VLA1553

- Phase 3 recruitment completion expected in Q4 2020

Initiation of Phase 1 COVID-19 vaccine clinical trial expected at the end of 2020

- Top line data early Q2 2021

Thank you
Merci
Danke
Tack

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