Advancing Vaccines for Better Lives

Company Presentation
October 2020

valneva

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As a specialty vaccine company, Valneva currently focuses its development activities on three unique vaccine candidates:

Lyme disease

COVID-19

Chikungunya

Valneva's Pipeline

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

Media attention spiked again this year

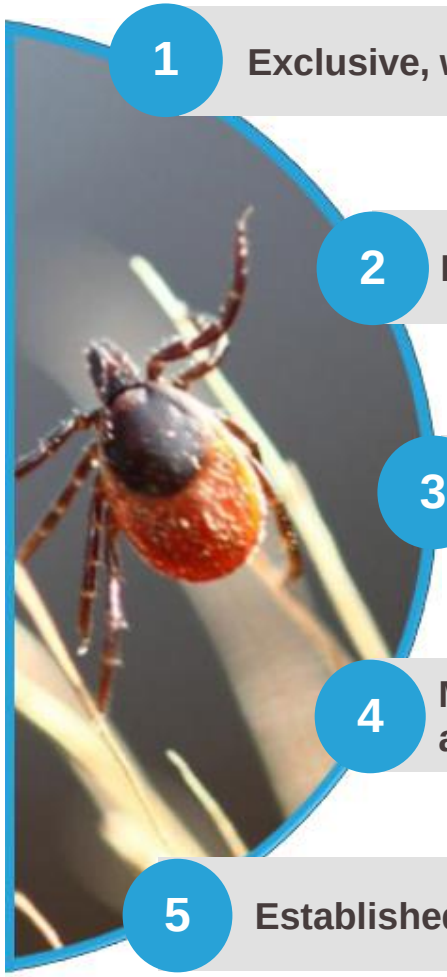
No available treatment to protect against Lyme disease

Major unmet medical need in North America and Europe

Lyme disease cases may rise 92 per cent in 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 for first Phase 2 study (primary endpoint) released July 2020[1]
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

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 for first Phase 2 study (VLA15-201)[3]

- Phase 2 study VLA15-201 met its endpoints
- 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

Initial results for the second Phase 2 study, VLA15-202, expected in Q4 2020

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

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

Responding to the COVID-19 Crisis

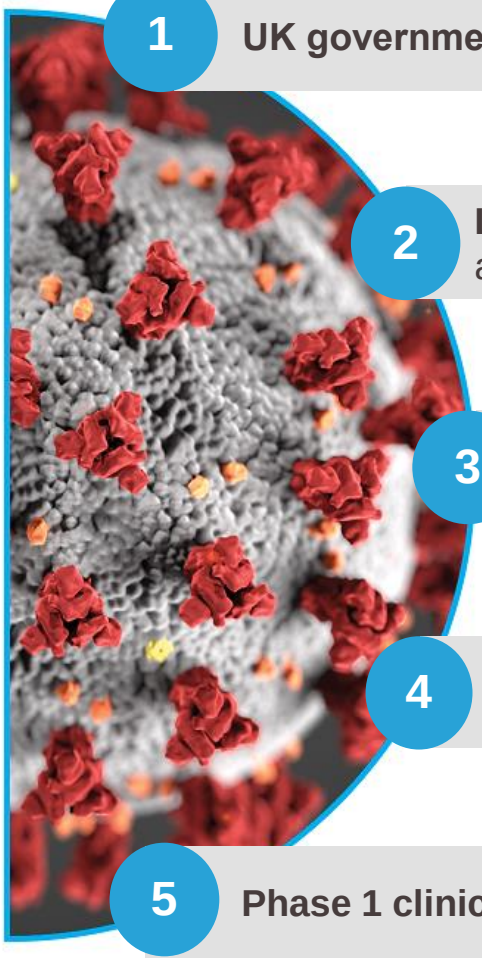
There is currently no vaccine and no specific treatment available for the novel coronavirus, SARS-CoV-2

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

There have been over 33 million confirmed cases and over 1 million deaths from COVID-19 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 Data retrieved from the John's Hopkins University COVID-19 Dashboard on September 30, 2020

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 by end of 2020 (subject to successful preclinical work)**

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 60-190 Million Doses of Inactivated 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]
- UK gov has purchased 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
- Vaccine to be manufactured at Valneva's facilities in Livingston, Scotland[2]
  - Agreement includes funding for expansion of Valneva's UK-based manufacturing facility and Ph1/2 clinical trials
- Valneva plans further investments in both its Scottish and Swedish facilities

Benefits of an Inactivated Vaccine Approach

- Inactivated vaccines are well studied and widely used
- Can be used in at risk groups (i.e., pregnant women, older and certain immunocompromised patients)
- Some other SARS-CoV-2 approaches (e.g., RNA- and DNA-based) have never been approved in humans
- Expected to be stable therefore VLA2001 likely requires standard cold chain storage (2 to 8°)

VLA2001 to commence Phase 1 clinical trials before the end of 2020

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

Chikungunya Vaccine – VLA1553

Chikungunya is a Growing and Enduring Problem

Representing a major public health threat

Currently there are no vaccines or any therapeutics for chikungunya

Global market including endemic regions (see below); Traveler vaccine market estimated at up to €250m[1]

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

1 Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market., 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 Designation granted[3]
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[4]
5. Monovalent live attenuated[5] prophylactic vaccine targeting chikungunya virus neutralization
6. Currently no preventive vaccines or effective antiviral treatments exist for chikungunya

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 to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; **5** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; **Photo credit**: James Gathany

VLA1553: First Phase 3 Chikungunya Program in the World

VLA1553-301 Initiated: Study Details

- Double-blinded, placebo-controlled, multi-center study
  - › Conducted in the U.S.
- ~4,000 healthy adults aged 18 or above
  - › Followed for a total of six months
- Randomized into two groups (receiving VLA1553 or placebo)
- **Primary endpoint**: Demonstrate safety and immunogenicity 28 days after a single-shot vaccination
- Subset of participants to be tested for sero-protection based on an immunological surrogate (under the Accelerated Approval pathway)

Study expected to take nine months. BLA process thereafter.

1 Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553

Commercial Products

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 track record 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

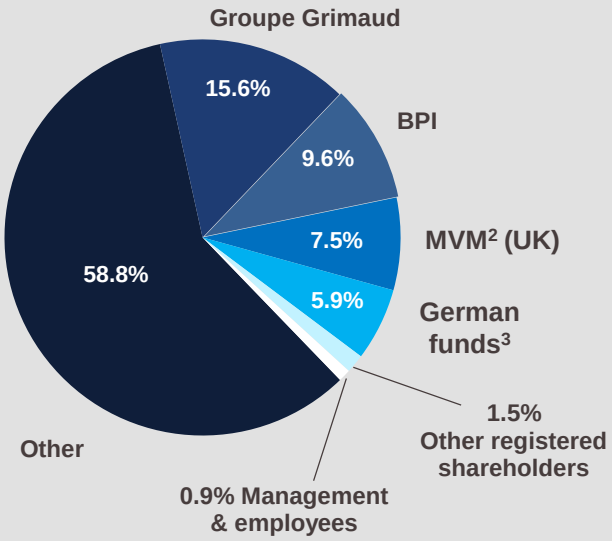
- In several markets, incl. EU, indicated for cholera only
- **Only approved cholera vaccine available for Canadian, European and Australian travelers**
  - ~3-5 million cholera cases, 100,000-120,000 deaths/year[2]
  - ~5-18 million reported ETEC cases/year[3] (ETEC is the most frequent form of traveler's 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** WHO cholera factsheet February 2014; **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;

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

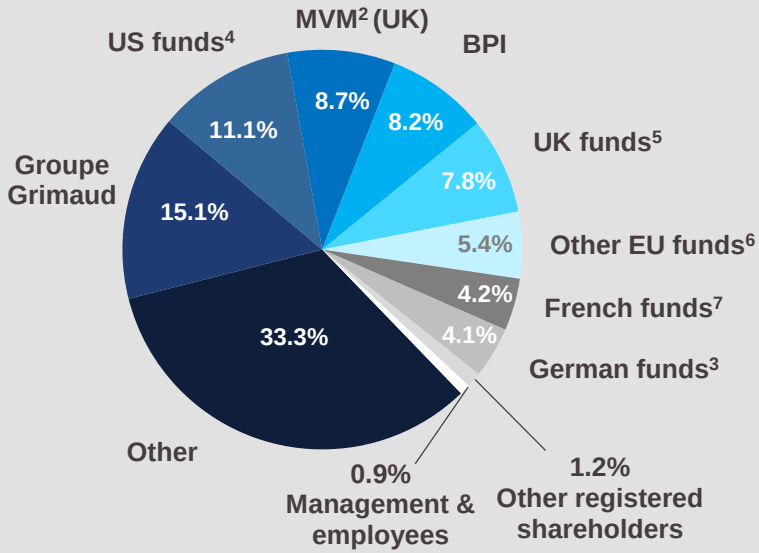
January 2018

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



August 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, Luxembourg, and Switzerland; **7** Combined positions of CDC Entreprises Valeurs Moyennes, AXA Paris and others.

Key Upcoming Newsflow

Lyme disease vaccine candidate VLA15

- **Further Phase 2 data expected Q4 2020**

Chikungunya vaccine candidate VLA1553

- **Phase 3 recruitment completion expected in Q4 2020**
- **Top line data end of Q1 2021**

Initiation of Ph1 COVID-19 vaccine clinical trial

- **Top line data end of Q1 2021**

Thank you
Merci
Danke
Tack

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Appendix

Chikungunya: Vector Prevalence and Disease Outbreaks

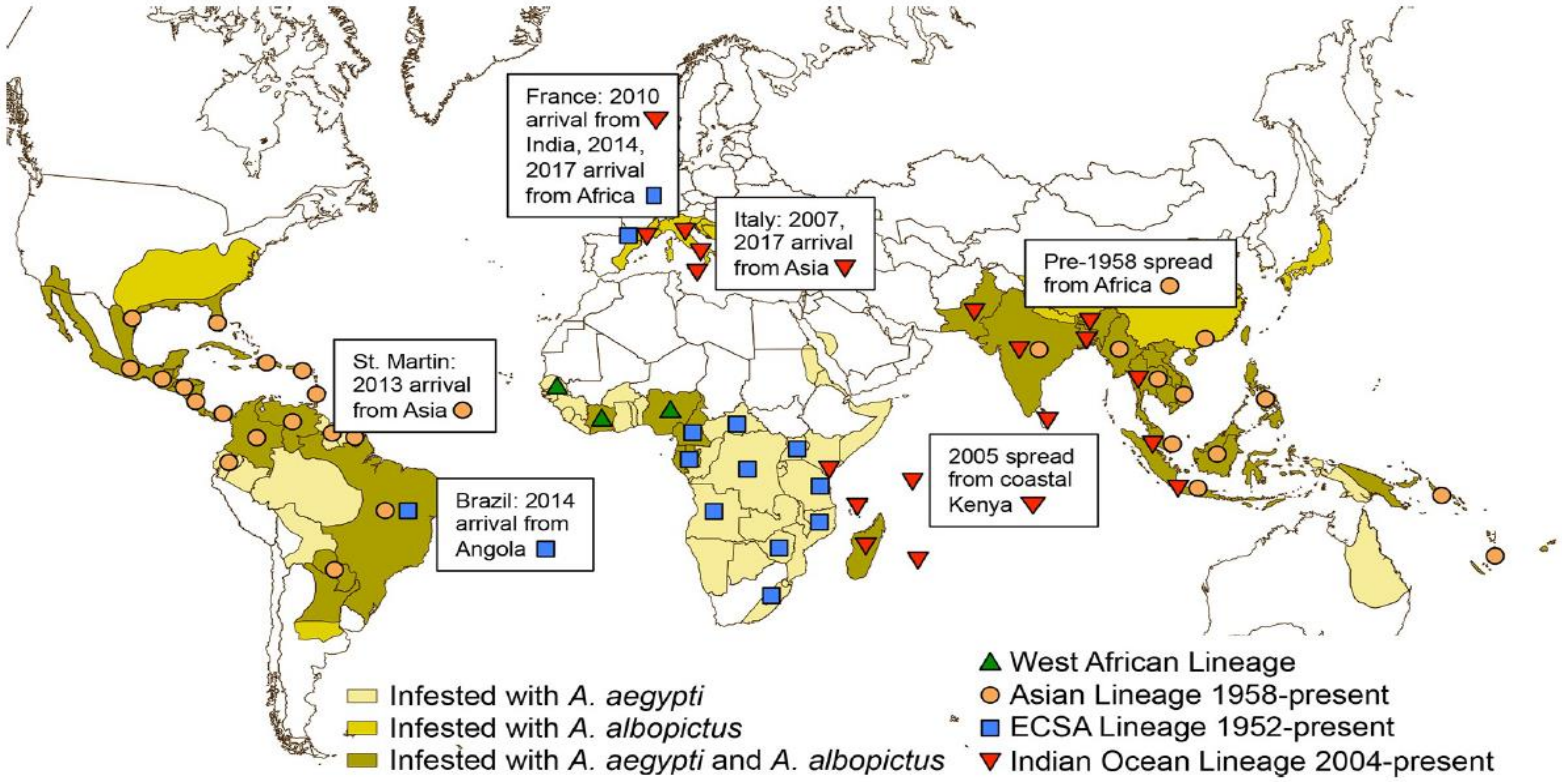

Fig 1. World map with countries where autochthonous (locally initiated) chains of CHIKV transmission have been identified. Data from World Health Organization (http://www.who.int/emergencies/diseases/chikungunya/en/) and Pan American Health Organization (https://www.paho.org/hq/index.php?option=com_topics&view=article&id=343&Itemid=40931&lang=en). CHIKV, chikungunya virus.

https://doi.org/10.1371/journal.pntd.0006919.g001

Rezza & Weaver 2019

VLA1553 Key Differentiators

The most advanced single-shot vaccine candidate for chikungunya today

Rapid onset of long-lasting protection

- Single vaccination is sufficient to induce sustaining, high titer, neutralizing antibodies

Cross-protection potential against globally circulating strains

“Intrinsic human viral challenge” provided first indication of efficacy

Full-scale drug substance manufacturing process established at existing FDA licensed facility in Livingston, Scotland

- Product is lyophilized, providing optimized storage conditions

Regulatory approval will be based on an immunological surrogate[1] (Accelerated Approval Pathway)[2]

Manufacturing and commercial infrastructure to produce and commercialize VLA1553 already in place

1 Immune marker reasonably likely to predict clinical benefit, as an immunogenicity endpoint in lieu of a clinical endpoint to infer vaccine effectiveness; **2** Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study

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