



# Advancing Vaccines for Better Lives

Company Presentation  
September 2020



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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)<sup>1</sup>**



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



# Lyme Disease Vaccine Candidate VLA15: Exclusive, Worldwide Partnering Deal with Pfizer and Initial Positive Phase 2 Results

## Exclusive, worldwide partnering deal with Pfizer for late stage development and future commercialization<sup>1</sup>.

- Valneva and Pfizer will work closely together throughout the development of VLA15
- Pfizer will fund 70% of all development costs through completion of the development program
- Valneva is eligible to receive a total of \$308 million upfront and milestone payments (\$130 million already received<sup>2</sup>)
- Pfizer will pay Valneva tiered royalties starting at 19%



## Positive initial results for first Phase 2 study (VLA15-201)<sup>3</sup>.

- 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, are expected in Q4

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



# VLA15: Key Value Driver in 2020 and Beyond

The only Lyme disease vaccine candidate in clinical development today



- 1** Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe
- 2** Positive initial results for first Phase 2 study (primary endpoint) released July 2020<sup>1</sup>
- 3** FDA Fast Track Designation granted
- 4** Established and proven Mode of Action for a Lyme disease vaccine
- 5** Favorable safety profile and no associated safety concerns in Phase 1 studies<sup>2</sup>  
First Phase 2 study results confirmed favorable safety profile of VLA15

<sup>1</sup> [Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate](#); <sup>2</sup> [Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate](#)

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



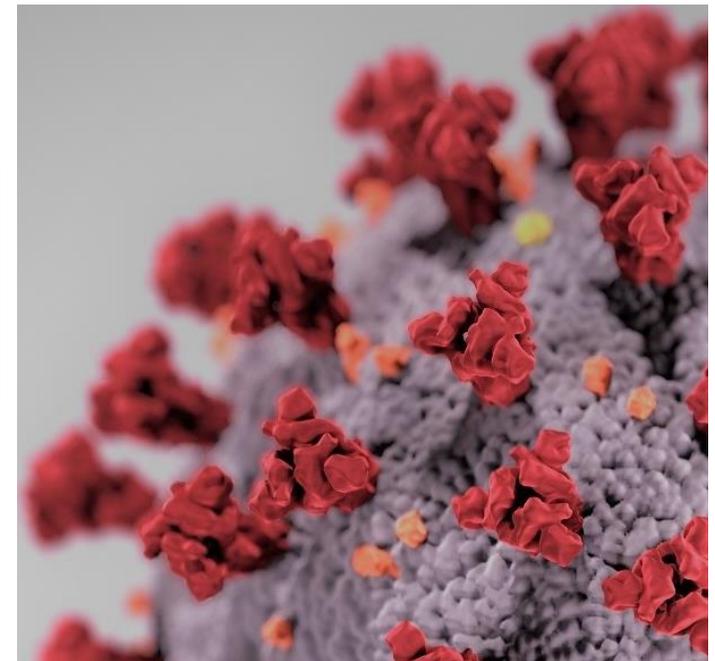


# Responding to the COVID-19 Crisis

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

**Physical distancing has been effective<sup>1</sup>, but nationwide lockdowns are not a long-term solution**

**There have been over 29 million confirmed cases and over 930,000 deaths from COVID-19 worldwide<sup>2</sup>**



<sup>1</sup> 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>;  
<sup>2</sup> Data retrieved from the [John's Hopkins University COVID-19 Dashboard](#) on September 16, 2020

# VLA2001: SARS-CoV-2 Vaccine Program for COVID-19<sup>1</sup>



## Leveraging Valneva's existing capabilities to develop an inactivated, adjuvanted whole-virus vaccine candidate

- BSL3 labs recommissioned for pre-clinical activities ; grant funding sought to support project
- Valneva to align clinical strategy with regulatory authorities
- Ph1 clinical trials will commence by end of 2020 (subject to successful preclinical work)
- Plug-and-play at Valneva's FDA-approved Livingston manufacturing facility with ability for rapid scale-up; facilitated program acceleration through use of a previously FDA-approved platform
- Combines Valneva's proven approach with Dynavax's advanced CpG 1018 adjuvant<sup>2</sup>

## 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° C)



<sup>1</sup> Valneva and Dynavax Announce Collaboration to Advance Vaccine Development for COVID-19; <sup>2</sup> Valneva and Dynavax Announce Commercial Supply Agreement for Inactivated, Adjuvanted COVID-19 Vaccine



## SARS-CoV-2 Vaccine Candidate VLA2001: Agreement to Provide 60-190 Million Doses to the UK

**Valneva will supply the UK government up to 190 million doses of its SARS-CoV-2 vaccine candidate in a deal worth up to €1.4 billion<sup>1</sup>**

- UK has purchased 60m doses worth approximately €470m for 2021
  - Options to purchase up to 130m doses worth up to €900m between 2022 and 2025
- To be manufactured at Valneva's facilities in Livingston, Scotland<sup>2</sup>



**Agreement with UK government to provide funding for expansion of Valneva's UK-based manufacturing facility and Ph1/2 clinical trials**

**This agreement is a recognition of the strong track record and capabilities that the Company has built over the past fifteen years, both in the UK and beyond**

- Valneva plans further investments in both its Scottish and Swedish facilities

**VLA2001 will commence Phase 1 clinical trials before the end of 2020**

<sup>1</sup> [Valneva Announces Major COVID-19 Vaccine Partnership with U.K. Government](#); <sup>2</sup> [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<sup>1</sup>**

**2019 - 2020: outbreaks<sup>2</sup> in Africa** (Chad, Djibouti, Ethiopia, Kenya, Sudan), **Asia** (Cambodia, Philippines, Thailand), **and South America** (Brazil, Colombia)



<sup>1</sup> Chikungunya. L.E.K. interviews, research and analysis for traveler vaccine market., <sup>2</sup> *Chad, Djibouti, Ethiopia, Kenya, Sudan; Cambodia, Philippines, Thailand; Brazil, Colombia*

# Chikungunya Vaccine Candidate VLA1553: First Phase 3 Clinical 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 is expected to take nine months. BLA process thereafter.**

<sup>1</sup> [Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553](#)



# VLA1553: Key Growth Driver for Future Valneva Sales

Most advanced single-shot vaccine candidate against chikungunya today



- 1** VLA1553 is a monovalent live attenuated<sup>1</sup> prophylactic vaccine targeting chikungunya virus neutralization
- 2** Currently no preventive vaccines or effective antiviral treatments exist for chikungunya
- 3** FDA Fast Track Designation granted. Priority Review Voucher eligible
- 4** Positive EoP2 meeting with the FDA; Accelerated Approval Pathway confirmed<sup>2</sup>; Phase 3 initiated in September 2020<sup>3</sup>
- 5** Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset; Partnership with Instituto Butantan for LMICs<sup>4</sup>
- 6** Up to \$23.4 million (€20.3 million) awarded to Valneva for R&D by CEPI

<sup>1</sup> CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; <sup>2</sup> Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study; <sup>3</sup> Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553; <sup>4</sup> Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; Photo credit: James Gathany (source)

# 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<sup>1</sup>

### 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<sup>2</sup>

- 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



<sup>1</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. 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; <sup>2</sup> [Valneva Announces New Ixiaro® Supply Contract with the US Government worth up to \\$166 million](#)

Only cholera (ETEC<sup>1</sup>) 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)<sup>1</sup>
- 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<sup>2</sup>
  - ~5-18 million reported ETEC cases/year<sup>3</sup> (ETEC is the most frequent form of traveler's diarrhea)
  - WHO pre-qualification widely used in other countries
  - Asian manufacturers predominantly serve local markets



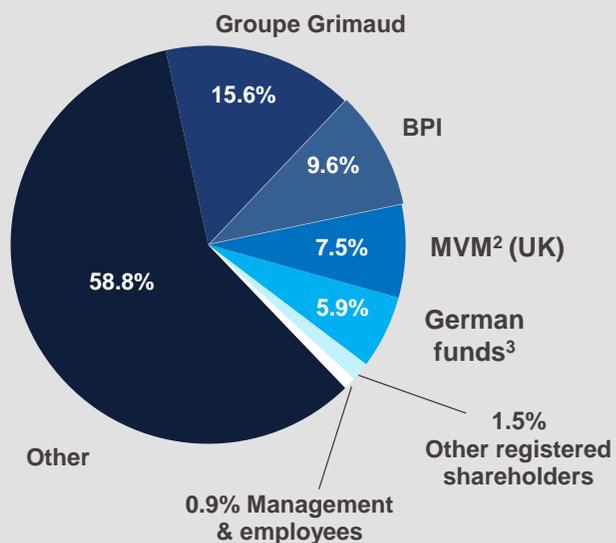
<sup>1</sup> Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium; <sup>2</sup> WHO cholera factsheet February 2014; <sup>3</sup> 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

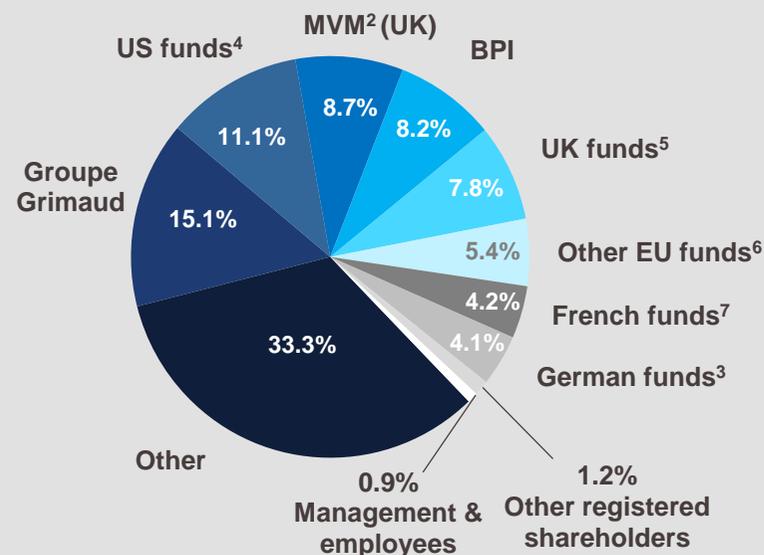
## January 2018

- Number of ordinary shares: 77.6m
- Shareholder structure<sup>1</sup>:



## August 2020

- Number of ordinary shares: 90.9m
- Shareholder structure<sup>1</sup>:



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



## 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



# Appendix



# Chikungunya: Vector Prevalence and Disease Outbreaks

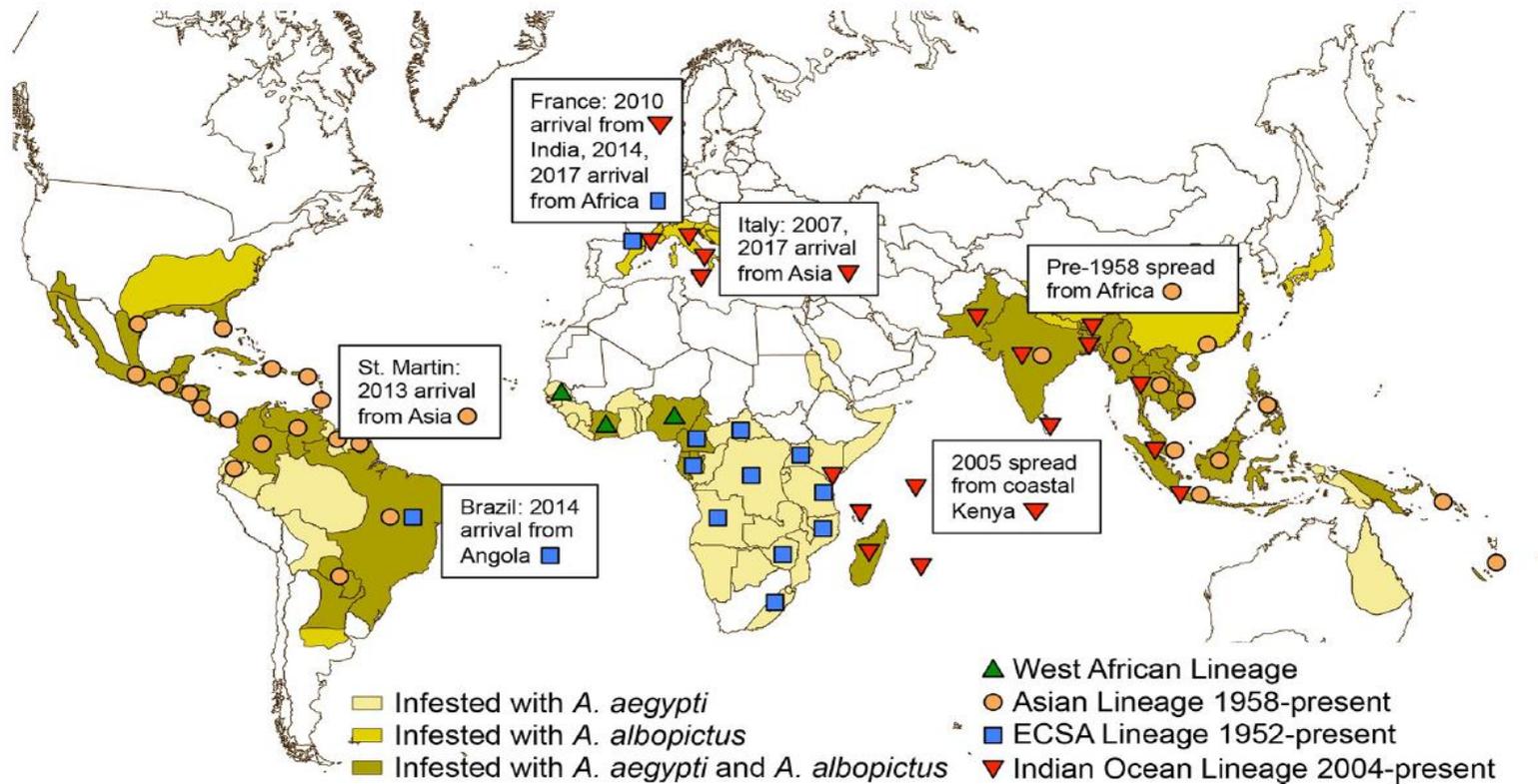


Fig 1. World map with countries where autochthonous (locally initiated) chains of CHIKV transmission have been identified. Data from World Health Organization (<http://www.who.int/emergencies/diseases/chikungunya/en/>) and Pan American Health Organization ([https://www.paho.org/hq/index.php?option=com\\_topics&view=article&id=343&Itemid=40931&lang=en](https://www.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<sup>1</sup> (Accelerated Approval Pathway)<sup>2</sup>**

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

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

