# Advancing Vaccines for Better Lives

Company Presentation
July 2020

valneva

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# Valneva's Value Proposition

## Integrated business model with valuable commercial and R&D assets

### R&D

**Lyme vaccine in Phase 2; data read out from July; strategic collaboration with Pfizer announced April 2020[1]**

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

- Only program in clinical development
- Pfizer to lead late-stage development and drive commercialization

**Chikungunya Phase 3 to commence Q4 2020**

Global market opportunity of ~$0.5bn per annum

- Huge synergy with existing infrastructure
- Possible Priority Review Voucher upside

**R&D provides upside for shareholders**
Two unique vaccines with low R&D risk profile

### Commercial Business

**Total sales revenues €129.5m in 2019, +25% vs. 2018; Marketing & Distribution partnership with Bavarian Nordic announced June 2020[2]**

IXIARO®

- Only licensed JE vaccine for travelers in US CAN, EU; mandatory for US Military
- Sales > €90m in 2019

DUKORAL®

- Cholera (LT-ETEC) vaccine, licensed in CAN, EU, ROW
- Sales > €30m in 2019

**Recent transactions underline major valuation disconnect**
BN product acquisition from GSK @ 4.5x revenue

**1** Valneva PR: Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15; **2** Valneva PR: Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership

# Valneva: A specialty vaccine company focused on prevention against diseases with major unmet needs

**> 500 people**

Four main sites
Six in-market commercial teams

# 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/

# Valneva and Pfizer Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

**This partnership provides the opportunity for the rapid development and launch of a vaccine that has the potential to address a major unmet medical need.**

**The collaboration with Pfizer validates Valneva's strong vaccine R&D capabilities.**

**As an established global leader in the pharmaceutical industry with a strong commitment to vaccines and infectious diseases, Pfizer is the best partner for VLA15.**

# Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15

**Valneva and Pfizer will work closely together throughout the development of VLA15**

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- Valneva is eligible to receive a total of $308 million cash payments consisting of a $130 million upfront payment, $35 million in development milestones and $143 million in early commercialization milestones
- Valneva will fund 30% of all development costs through completion of the development program
- Pfizer will pay Valneva tiered royalties starting at 19%

Pfizer

- Pfizer will fund 70% of all development costs through completion of the development program
- Pfizer will lead late-stage development and have sole control over commercialization

# 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. Phase 2 interim data (primary endpoint) expected mid-2020
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[1]
   Phase 2 run-in (higher dosages than Phase 1) confirmed favorable safety profile of VLA15

1 Valneva PR: Valneva Reports Positive Initial Booster Data and Final Phase 1 Data for its Lyme Disease Vaccine Candidate

# Chikungunya Vaccine – VLA1553

# Chikungunya is a Growing and Enduring Problem

## Representing a major public health threat

**Currently there is no vaccine or any treatment options for chikungunya**

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

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

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

# VLA1553: Key Growth Driver for Future Valneva Sales

## The only single-shot vaccine candidate against chikungunya today

1. VLA1553 is a monovalent live attenuated[1] 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. Phase 1 complete. Potential Phase 3 start as soon as the COVID-19 situation permits (currently planned for Q4 2020)
5. Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset; Partnership with Instituto Butantan for LMICs[2]
6. Up to $23.4 million (€20.3 million) awarded to Valneva for R&D by CEPI

**1** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; **2** Valneva PR: Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; Photo credit: James Gathany (source)

# VLA1553: Excellent Data and Progressing Rapidly

## Status and clinical development overview

**End of Phase 2 (EoP2) FDA meeting held**

- Detailed Phase 3 design confirmation expected delayed due to COVID-19 situation
- Accelerated Approval Pathway already confirmed
- Excellent Phase 1 previously reported

**Additional non-clinical studies requested by FDA fully completed**

- Mosquito transmission studies
- NHP study addressing biodistribution
- Passive transfer study in NHPs to develop surrogate of protection using human sera from VLA1553-101

**Phase 3 initiation preparation proceeding**

*Subject to FDA approval

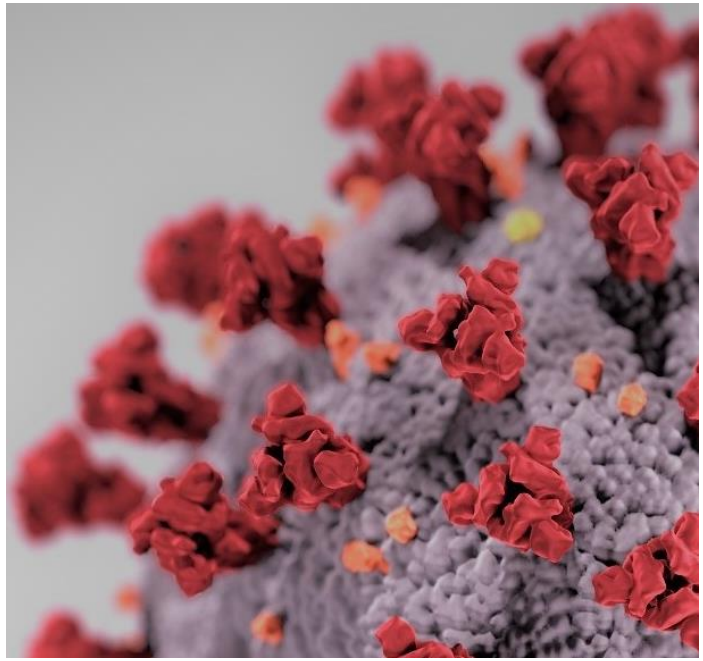
# SARS-CoV-2 (COVID-19) – VLA2001

# 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 10 million confirmed cases and over 500,000 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 June 30, 2020

# VLA2001: SARS-CoV-2 Vaccine Program for COVID-19

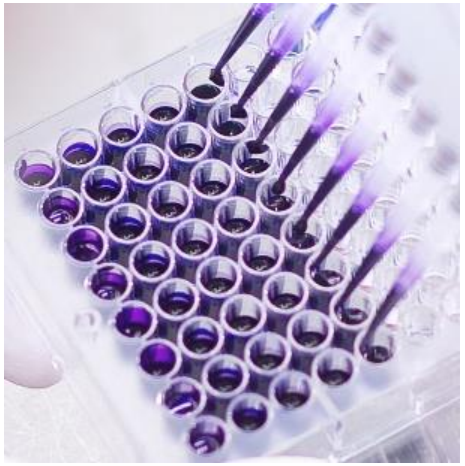
## Collaboration with Dynavax

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

- BSL3 labs recommissioned for pre-clinical activities
- Resources from other early stage programs reallocated; grant funding also sought for clinical development and manufacturing
- Valneva and Dynavax to align with regulatory authorities on optimal strategy to expedite clinical development
- Goal to initiate clinical trials before end of 2020 (subject to successful preclinical work and receipt of appropriate funding)
- 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

**Benefits of an Inactivated Vaccine Approach**

- Inactivated vaccines are well studied and widely used
- They can be used in vulnerable populations (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



# 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]

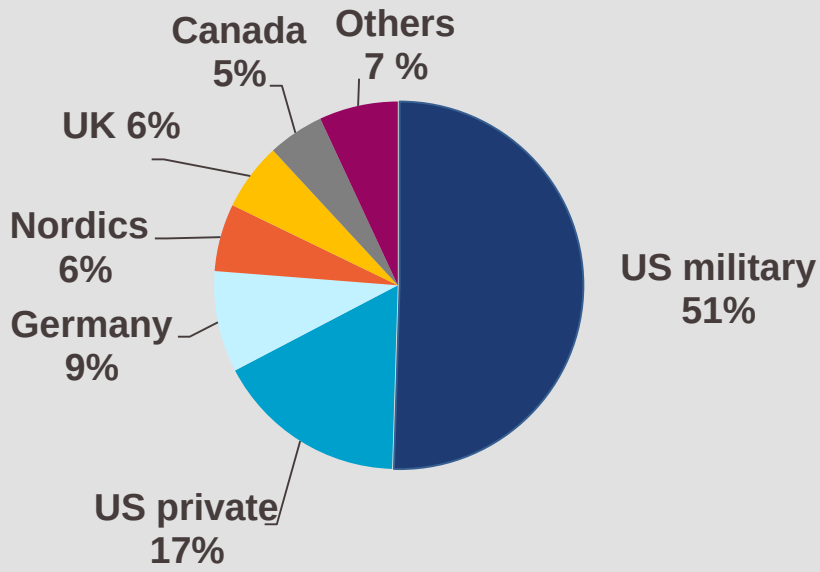
**Commercial position**

- 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

### North America driving growth

*FY '19 product sales analysis*

**€94.1m**




**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.

# 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

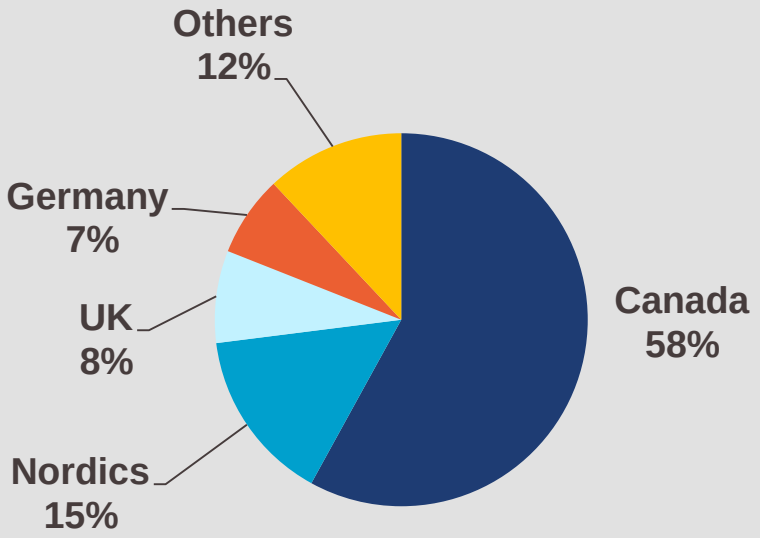
**Commercial position**

- 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

### Canada remains our key market

*FY '19 product sales analysis*

**€31.5m**




**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;

# Valneva's Management and Advisory Team – Dedicated to Deliver VLA's Vision

Experienced international team

## Management Board

- **Thomas Lingelbach –** President & CEO (center)
- **Franck Grimaud –** President & CBO (2nd from left)
- **David Lawrence** – CFO (2nd from right)
- **Wolfgang Bender, MD, PhD** – CMO (left)
- **Frédéric Jacotot** – General Counsel & Corporate Secretary (right)

## Supervisory Board

- **Frédéric Grimaud** (France), *Chairman*
- **James Sulat** (US), *Chair – Audit Committee*
- **Anne-Marie Graffin** (France)
- **Thomas Casdagli** (UK)
- **Sharon Tetlow** (US)
- **Johanna Pattenier** (CH)

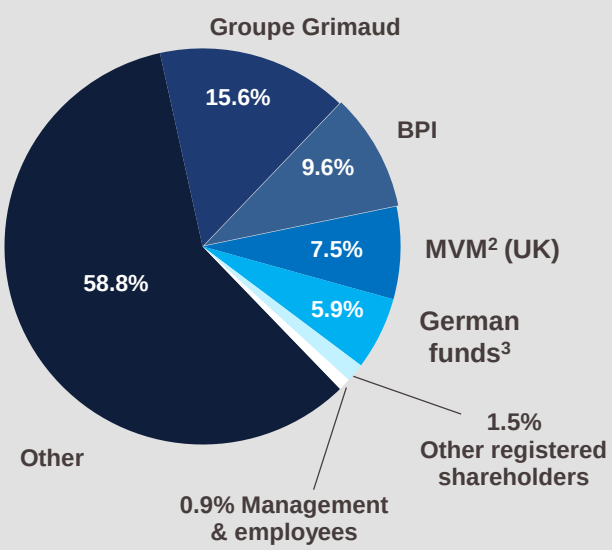
## Scientific Advisory Board

- **Ralf Clemens, MD, Ph.D.,** *Chair*
- **Norman W. Baylor, Ph.D.**
- **Anna Durbin, MD**
- **Alain Munoz, MD, Ph.D.**
- **George R. Siber**
- **Stanley Plotkin, MD**

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

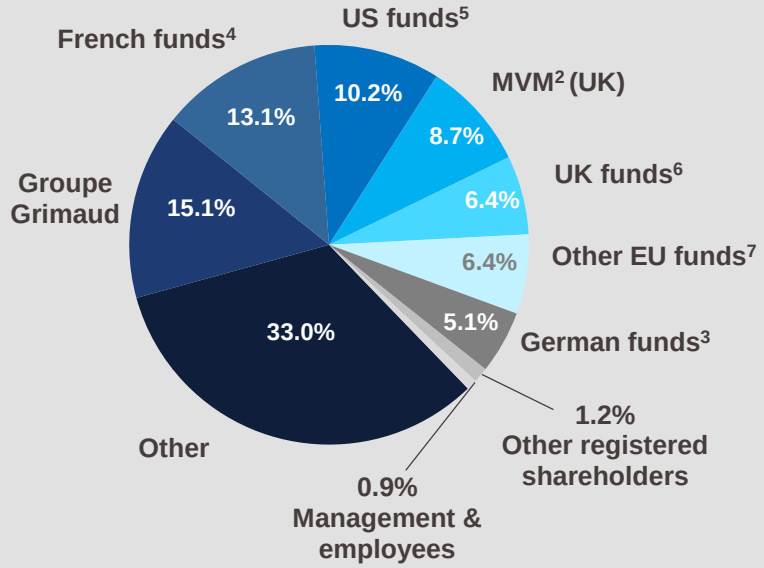
## January 2018

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




## May 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 BPI, AXA Paris and others; **5** Combined positions of U.S.-based funds managed by Deerfield Partners, Armistice Capital, New Leaf, General American, Granite Point and others; **6** Combined positions of Highclere, AXA Investment Managers Ltd. and Abingworth LLP; **7** Combined positions of multiple funds based in Liechtenstein, the Netherlands, Austria, Luxembourg, and Switzerland.

# Key Upcoming Newsflow

**Lyme disease vaccine candidate VLA15**
- **First Phase 2 data expected July 2020**

**Chikungunya vaccine candidate VLA1553**
- **Phase 3 initiation (pending FDA confirmation)**

**New IXIARO® contract with the U.S. Department of Defense expected mid-2020**

**COVID-19 vaccine candidate expected to enter clinical trials before the end of 2020**

Thank you
Merci
Danke
Tack

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# Appendix

# Chikungunya: Vector Prevalence and Disease Outbreaks

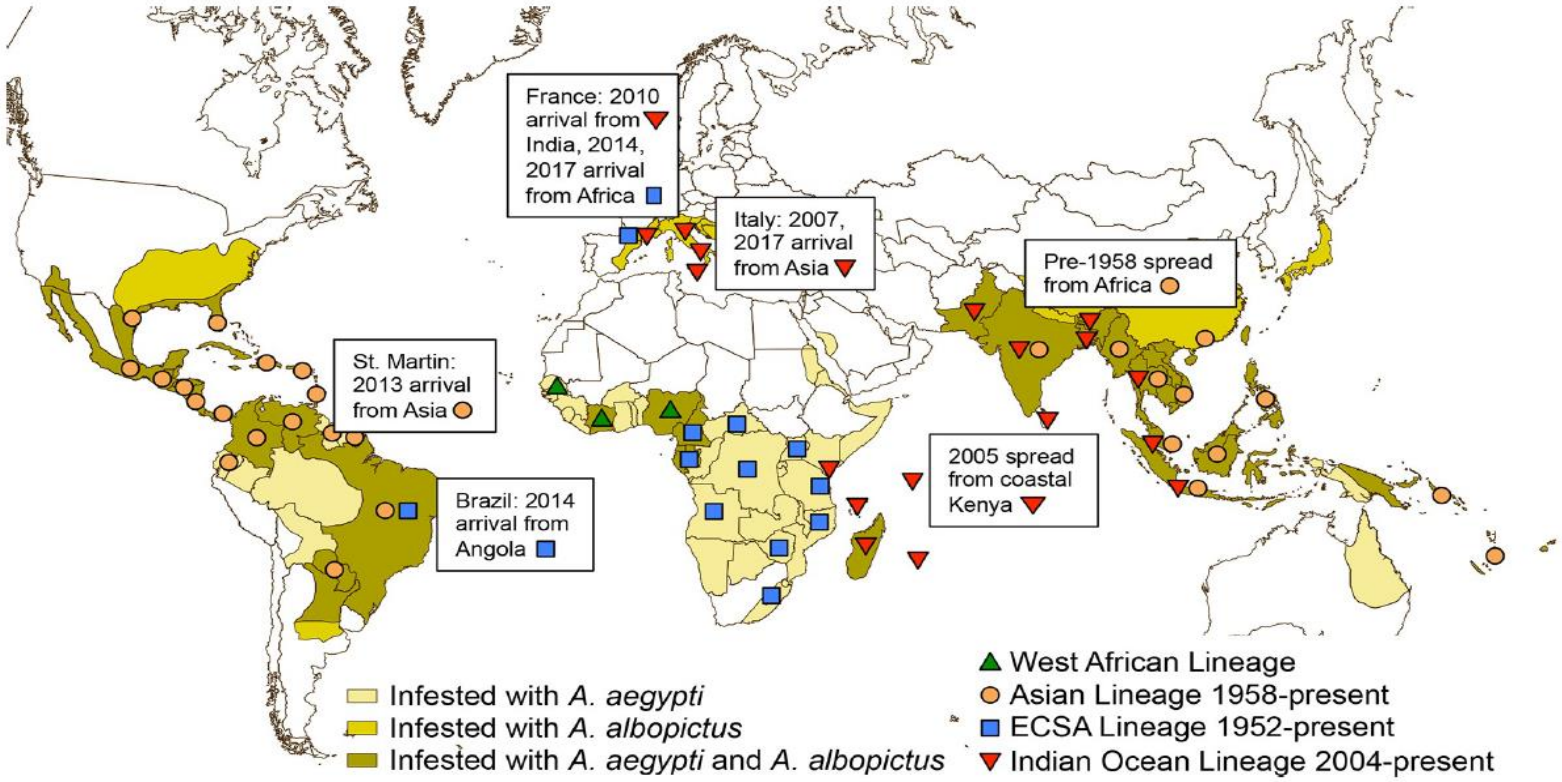


**Fig 1. World map with countries where autochthonous (locally initiated) chains of CHIKV transmission have been identified.** Data from World Health Organization (http://www.who.int/emergencies/diseases/chikungunya/en/) and Pan American Health Organization (https://www.paho.org/hq/index.php?option=com_topics&view=article&id=343&Itemid=40931&lang=en).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

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

*Rezza & Weaver 2019*

# VLA1553 is Expected to be Highly Differentiated

## Competition overview

| | Valneva | Emergent (Paxvax) | Themis |
|---|---|---|---|
| *Vaccine candidate* | Monovalent, single dose, live-attenuated vaccine candidate | Virus-like particle (VLP) vaccine | Measles-vectored Chikungunya vaccine (MV-CHIK), Live-recombinant vaccine |
| *Schedule* | Single-shot - Day 0 | 2 shots - Day 0 & 28 | 2 shots - Day 0 & 28 |
| *Development stage* | Phase 1 in US complete (data published)<br><br>No Phase 2 trial needed (single shot efficacy) | Phase 2 completed | Multiple Phase 2 studies<br>- 2x completed (in EU/PR)<br>- 1 recruiting<br>- 1 active, not recruiting |
| *Duration of protection* | 100% seroconversion at **13 months** following single-dose administration | 6 months | 6 months |
| *Phase 3 Guidance* | **Pivotal trial (Phase 3) initiation planned Q4 2020[4]** | 2020 | 2020 |

**1** PR Emergent BioSolutions Announces Interim Results From Phase 2 Study Evaluating CHIKV-VLP, Chikungunya Virus Vaccine Candidate (Link) + Detailed study results Emergent/Paxvax' Phase 2 clinical trial results (Link), **2** PR Themis Bioscience Publishes Compelling Phase 2 Results for Lead Vaccine Candidate against Chikungunya Fever in The Lancet (Link) + Themis' Phase 2 clinical trial results: (Link), **3** PR Valneva reports further positive results for its chikungunya vaccine candidate (Link); 4 Potential Phase 3 start as soon as the COVID-19 situation permits

# VLA1553 Key Differentiators

## The only 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 in-house FDA licensed facility**

- Product is lyophilized, 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 PR: Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study

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