Advancing Vaccines for Better Lives

Company Presentation
April 2020

valneva

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Valneva's Value Proposition

Integrated business model with valuable commercial and R&D assets

Commercial Business

Total sales revenues €129.5m in 2019; +25% vs. 2018

IXIARO®
- Only licensed JE vaccine for travelers, Military in North America, CAN, EU
- Sales approaching €100m

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

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

R&D

Lyme vaccine in Phase 2 with data reading out from mid-2020

US/EU market opportunity of ~$1bn per annum
- Only program in clinical development
- Commercial/development partner tbc (expected by year end)

Chikungunya vaccine entering Phase 3 in 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 to be launched in the next 3-4 years

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

€85m–€115m product sales expected in 2020[1]
(incl. COVID-19 impact)

€64.4m cash in 2019
$85m debt facility secured early 2020

~ 65% gross margin in 2019
~ 80% direct sales

~ 500 people
Four main sites
Six in-market commercial teams

1 2020 Guidance from Valneva PR: Valneva Provides Business Update on COVID-19 Situation;

Lyme Disease Vaccine – VLA15

Lyme Disease is a Massively Important Health Issue – Media Attention Spiked Again in January 2020

No approved options that can protect humans against Lyme disease

Analysis suggests a Lyme vaccine in the US and EU could have peak revenue potential of more than ~$1b[1]

Lyme disease cases may rise 92 per cent in US due to climate change (New Scientist)[2]

1 Lyme Disease. L.E.K. interviews, research and analysis, 2 https://www.newscientist.com/article/2232705-lyme-disease-cases-may-rise-92-per-cent-in-us-due-to-climate-change/

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

VLA15: Phase 2 – Optimizing Dose and Schedule

Observer-blind, randomized, placebo-controlled, Phase 2 studies conducted in the US and EU[1]

Phase 2
819 subjects in two studies
Primary objective: Safety and immunogenicity data four weeks after completed schedule
Secondary objectives: Long-term immunogenicity and safety data

Study **VLA15-201** with run-in phase

Study **VLA15-202**

Enrollment completed for both studies

VLA15-201 Run-in phase (completed June 2019[2])

- Conventional schedule, higher dose
- **3 adjuvanted dose levels, placebo**
- **120 healthy volunteers** (18 to 40 years)

90 µg w/ alum	30 subjects
135 µg w/ alum	30 subjects
180 µg w/ alum	30 subjects
Placebo	30 subjects

VLA15-201 (initiated June 2019[2]): Schedule 0, 1, 2 months

- **2 adjuvanted dose levels** (135 µg and 180 µg) chosen after run-in phase, placebo
- **453 healthy volunteers** (18 to 65 years)
- **9 sites in the US and Europe**

VLA15-202 (initiated July 2019[3]): Schedule 0, 2, 6 months

- **2 adjuvanted dose levels** (135 µg and 180 µg) chosen after run-in phase, placebo
- **246 healthy volunteers** (18 to 65 years)
- **5 sites in the US**

1 VLA15-201 only (ClinicalTrials.gov Identifier: NCT03769194); Phase 2 subjects are baseline seropositive (10%) or seronegative (90%); **2** Valneva PR: Valneva Reports Successful Outcome of Phase 2 Run-In for its Lyme Disease Vaccine Candidate; **3** Valneva PR: Valneva Initiates Second Phase 2 Study for its Lyme Disease Vaccine Candidate VLA15 ; VLA15-202 ClinicalTrials.gov Identifier: NCT03970733

VLA15 Phase 2 Progressing Extremely Well
– Clinical development overview

Patient recruitment for both Phase 2 studies completed September 2019

Phase 2 first data due mid-2020

- Initial data: Day 85 after base immunization schedule expected mid-2020

Phase 3 initiation planned in 2021/2022

- Two placebo-controlled Phase 3 efficacy studies
  - 8,000 subjects in each of US and Europe
  - Based on current estimates of Lyme disease incidence rates in order to demonstrate efficacy of the vaccine in Lyme endemic regions in the U.S. and Europe
- Detailed plans for Phase 3 entry to be discussed with FDA based on Phase 2 data
- Timing depends on schedule, tick season(s), Phase 2 data and other factors

*Subject to development progress, regulatory approvals and company funding

Chikungunya Vaccine – VLA1553

Chikungunya is a Growing and Enduring Problem

Currently there is no vaccine or any treatment options for chikungunya

Global market including endemic regions (see below)
Traveller 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. Accelerated Approval Pathway confirmed with potential Phase 3 start in Q4 2020[2]
5. Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset
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 Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study; Photo credit: James Gathany (source)

Chikungunya Phase 1 Study (VLA1553-101) – Final Results

Sustained immunogenicity with single shot for over one year

Immunogenicity

100% Seroconversion Rate (SCR)[1] achieved at Day 14 after a single vaccination in all dose groups[2]

SCR sustained at 100% after 13 months with no decline in neutralizing antibody titers in the groups after a single vaccination[2]

Excellent immunogenicity profile after single vaccination

Safety[2]

Generally safe in all dose groups

Well-tolerated at the low and medium doses

- Superior safety profile, including viremia, in low and medium doses compared to highest dose

Excellent local tolerability

No adverse events of special interest (e.g. chikungunya infection related) and no vaccine related Serious Adverse Events (SAEs) up to Month 13

Excellent safety profile in low and medium doses[2]

1 SCR defined as proportion of subjects achieving a CHIKV-specific neutralizing antibody titre as $NT_{50} \geq 20$; **2** Valneva Reports Excellent Final Phase 1 Results for its Chikungunya Vaccine Candidate, Confirms Plans

VLA1553 – Excellent Data and Progressing Rapidly

Status and clinical development overview

Positive End of Phase 2 FDA meeting (EoP2)

- Detailed Phase 3 design confirmation expected
- Confirmation for the Accelerated Approval Pathway already received
- 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

Awaiting detailed protocol review with FDA before initiating Phase 3 in Q4 2020

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]

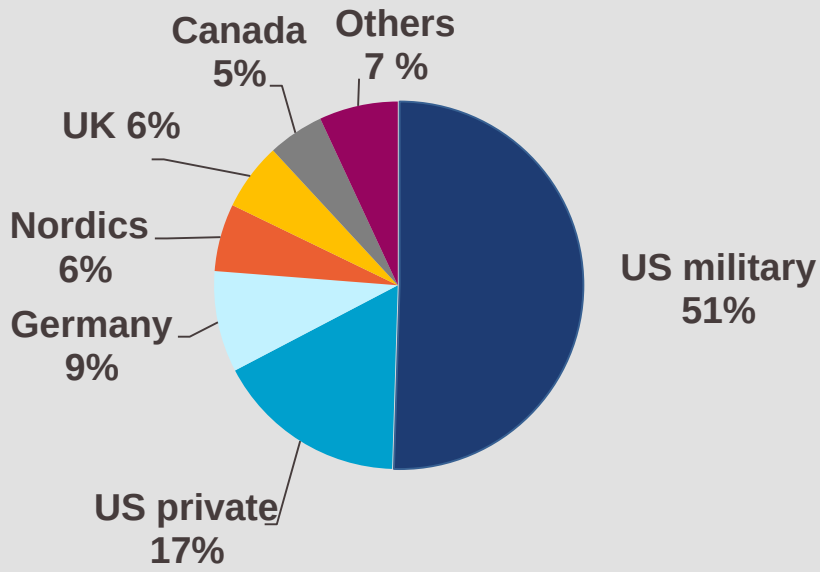
Commercial position

- 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

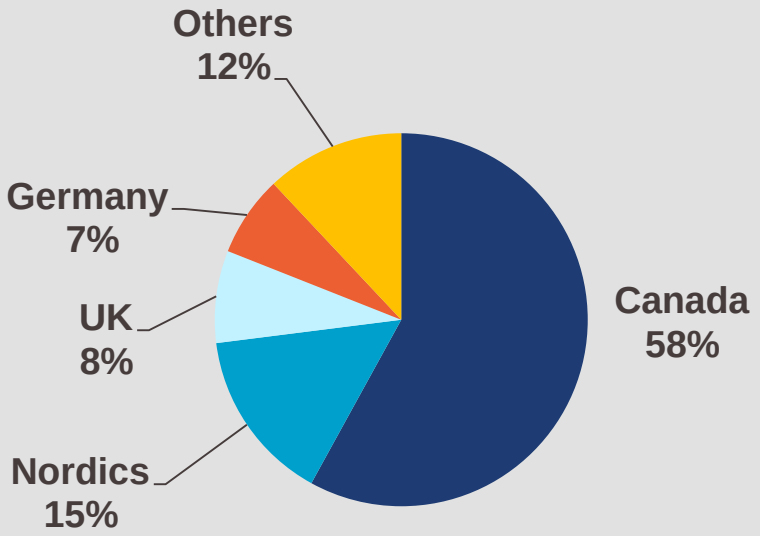
Commercial position

- 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*
- **Lisa Shaw-Marotto** (US), *Vice Chairperson, Chair – Nomination & Compensation Committee*
- **James Sulat** (US), *Chair – Audit Committee*
- **Anne-Marie Graffin** (France)
- **Alexander von Gabain, Prof., PhD** (Austria)
- **Thomas Casdagli** (UK)
- **Sandra E. Poole** (US)

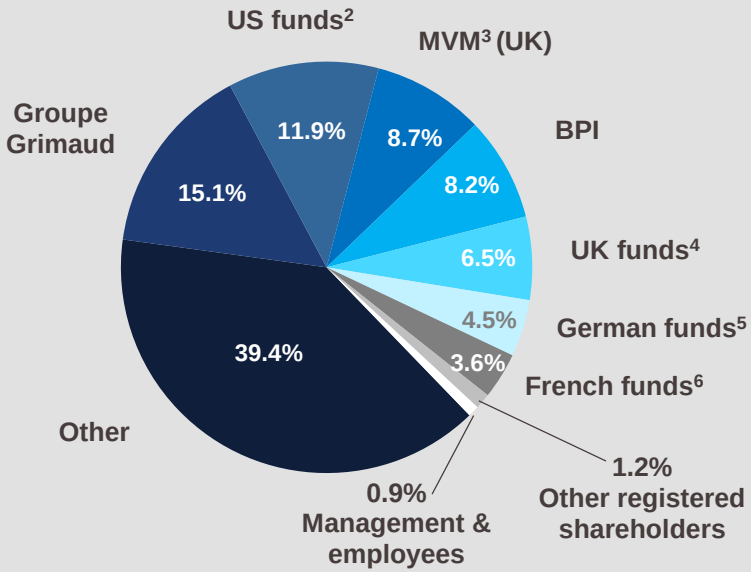
Scientific Advisory Board

- **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

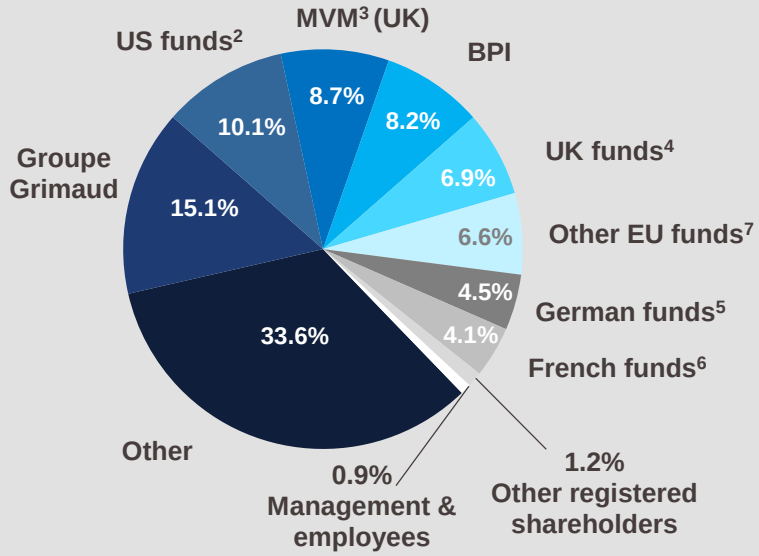
November 2019

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



January 2020

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



Capital strategy

- Leveraging commercial business for non-dilutive funding to complement equity capital
- Intended Nasdaq listing to co-fund late-stage Lyme disease program development

1 Estimates based on ordinary share capital; **2** Combined positions of U.S.-based funds managed by Deerfield Partners, Armistice Capital, New Leaf, General American, Granite Point and others; **3** Funds managed by MVM Life Science Partners; **4** Combined positions of Highclere, AXA Investment Managers Ltd. and Abingworth LLP; **5** Combined positions of Apus Capital, Apo AM, Lupus alpha, and others; **6** Combined positions of AXA Paris, CDC Entreprises Valeurs Moyennes and others; **7** Combined positions of 10 funds based in Liechtenstein, the Netherlands, Austria, Luxembourg, and Switzerland.

2020 Key Newsflow

Lyme disease vaccine candidate VLA15

- **First Phase 2 data expected mid-2020**

Chikungunya vaccine candidate VLA1553

- **Phase 3 initiation (Detailed design and timing pending FDA confirmation)**

New IXIARO® contract with the U.S. Department of Defense expected H1 2020

US IPO update during H2 2020

Thank you
Merci
Danke
Tack

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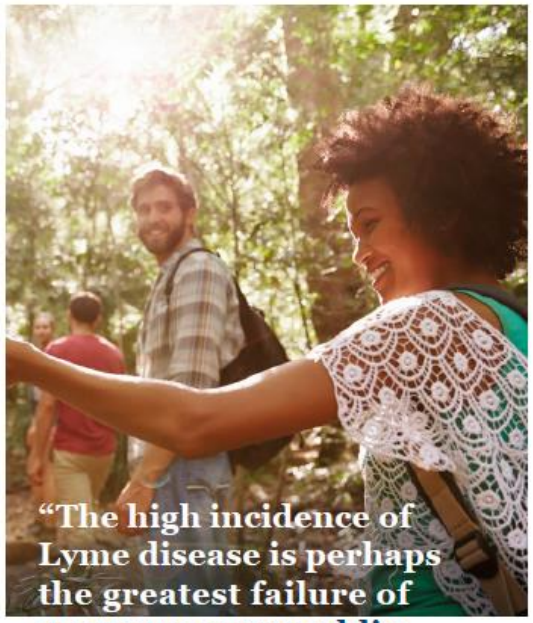
Appendix

Vaccination against Lyme Disease

Justification for a Lyme vaccine



— STANLEY A. PLOTKIN
Emeritus Professor of the Wistar Institute at the University of Pennsylvania and inventor of the Rubella vaccine

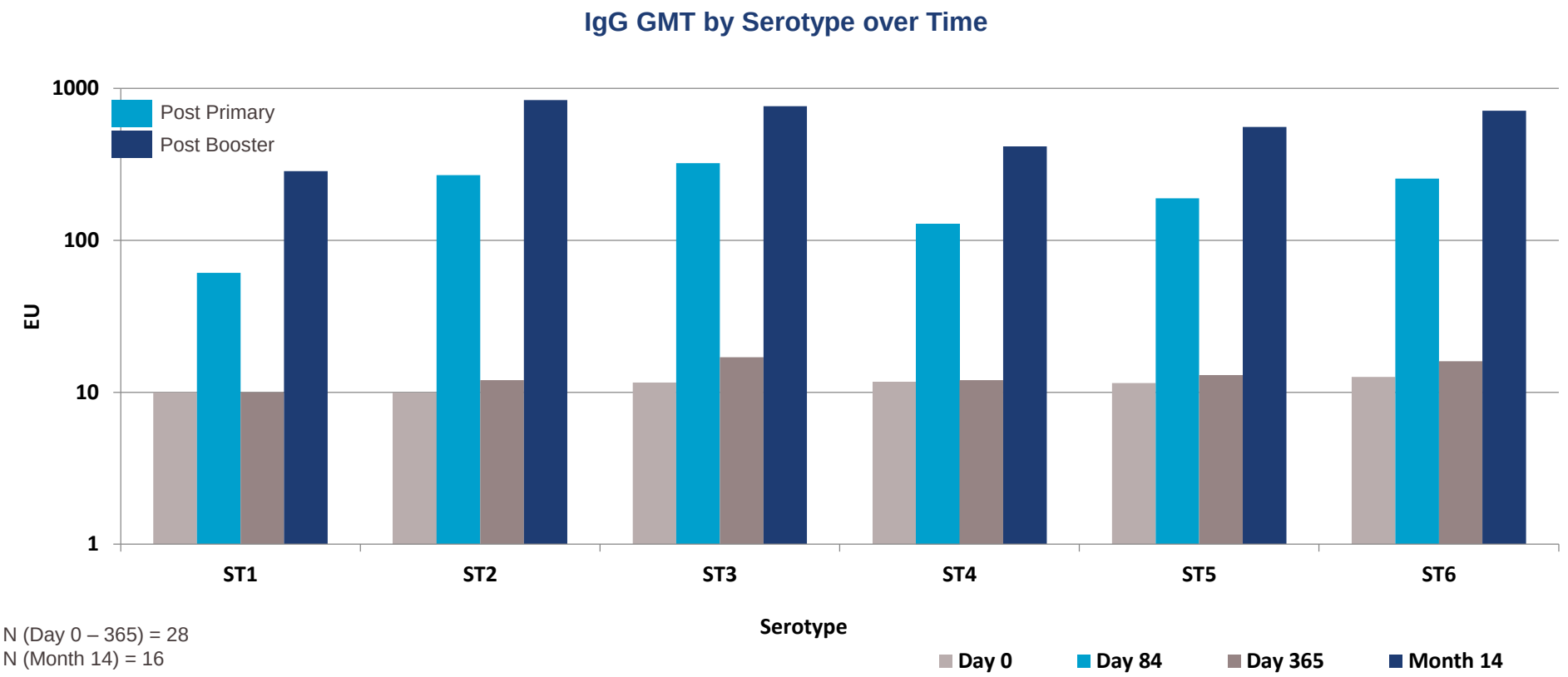
- Vaccination with OspA has been proven to work in the past (Lymerix®, ImuLyme®)
- **Disproven postulate[1], restrictive recommendations and corporate decisions resulted in there being no Lyme vaccine available for humans since 2002**
- **Delayed or inadequate treatment can lead to disabling sequelae**
- **Disease footprint widens[2]**
- **Direct medical costs in the US estimated up to $1.3 billion[3] – indicating an attractive health economical benefit**
- **Other preventive measures have not been shown to work on a public health scale**

1 Steere et al. CID 2011: 52 (Suppl3) S259; **2** New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017 https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-yourself/ ; **3** Adrion, E. et al PLOS ONE Feb 2015

Lyme Phase 1 Study (VLA15-101) – Immunogenicity

GMT for highest adjuvanted dose group between 61 (ST1) and 269 (ST2), substantial booster effect

IgG GMT of Highest Adjuvanted Group (90µg + Alum) Before and After Primary Series and Booster Dose



N (Day 0 – 365) = 28
N (Month 14) = 16

Chikungunya: Vector Prevalence and Disease Outbreaks

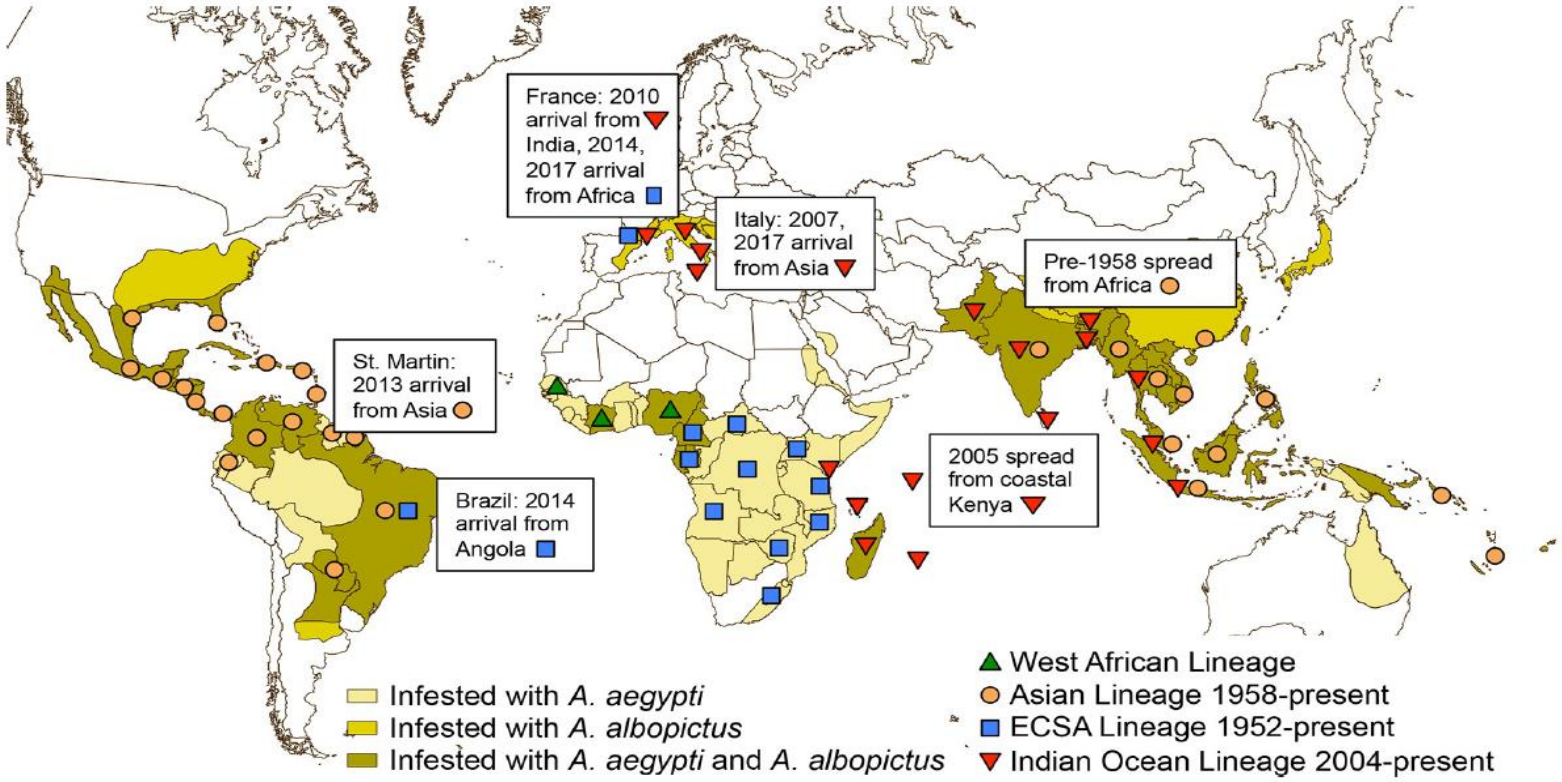


Fig 1. World map with countries where autochthonous (locally initiated) chains of CHIKV transmission have been identified. Data from World Health Organization (http://www.who.int/emergencies/diseases/chikungunya/en/) and Pan American Health Organization (https://www.paho.org/hq/index.php?option=com_topics&view=article&id=343&Itemid=40931&lang=en). 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 (manuscript in preparation) No Phase 2 trial needed (single shot efficacy)	Phase 2 completed	Multiple Phase 2 studies - 2x completed (in EU/PR) - 1 recruiting - 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**	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),

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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