valneva

Advancing Vaccines for Better Lives

Company Presentation – August 2019

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Valneva – Highlights and key information

+ **Valneva is a biotech company** developing and commercializing vaccines for infectious diseases with major unmet needs
  - › > €100m product sales revenues[1]
  - › Cash flow positive[1]

+ **Specializes in important, high value niches**
  - › Travel vaccines
  - › Technological competence on vector-transmitted diseases

+ **Focused R&D programs in development including**
  - › the only Lyme disease vaccine in clinical development today
  - › a unique, differentiated chikungunya vaccine candidate

+ **International footprint** with approximately 480 employees
  - › Locations in EU and North America for Manufacturing, R&D, and Sales & Marketing

2018 Revenues: €113.0m
2019 Rev. Guidance: €125-135m

Cash: €81.7m (as of Dec. 31, 2018)

Ticker: EPA – VLA

1 In 2018: https://valneva.com/press-release/valneva-reports-strong-2018-results-expects-further-growth-and-major-pipeline-progression-in-2019/

Valneva's mid-term strategy

To become the leading commercial stage vaccine biotech

Commercial Products

Growing product sales revenues to €200m and beyond

R&D

Investing in innovative R&D programs to address major unmet needs

Financial

Use proceeds from commercial business to fund R&D; raise capital for major R&D programs as required

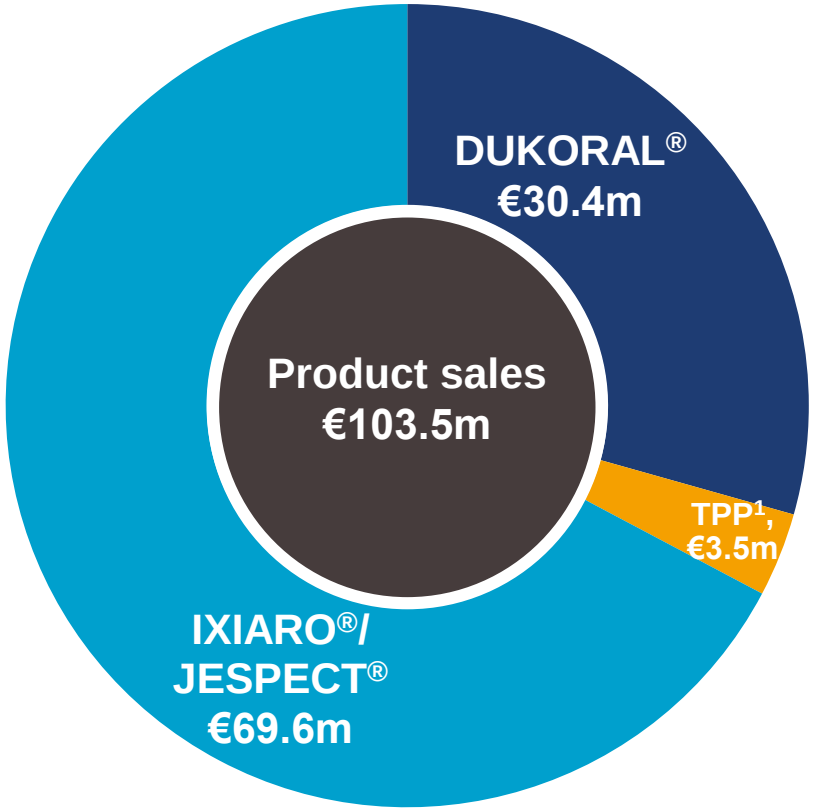
Strategic Growth

Organic growth complemented by targeted acquisition and licensing strategies

Valneva's profitable commercial business funds R&D programs

Product sales growth 2017-2018 16% (CER);
Repeated double-digit sales growth expected 2018-2019

2018 Full-year results



Direct sales
81.2%

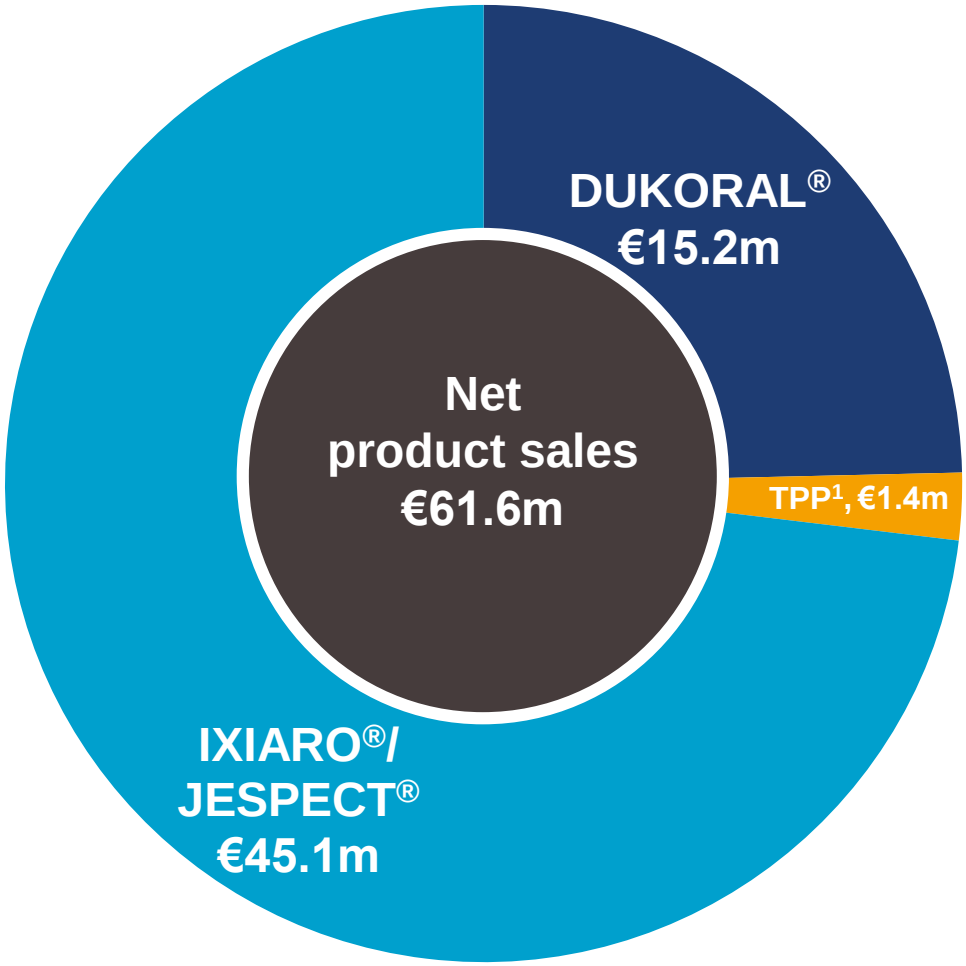
Gross
margin
60.7%

Cash
generated
€16.3m

Innovative R&D pipeline in areas of major unmet need

CER: *at constant exchange rates;* ***1*** *Third party products sold by Valneva's commercial organization;* ***2*** *Gross margin on product sales*

Strong product sales and gross margin in H1 2019



Product sales growth (CER)
12%

Direct sales
88.4%

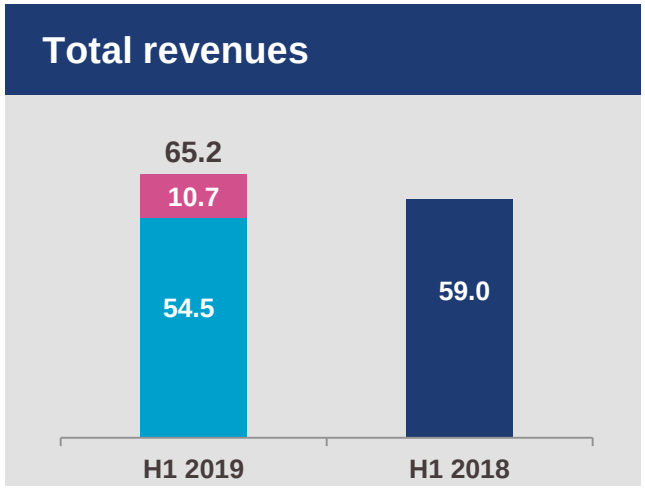
Gross margin[2]
66.1%

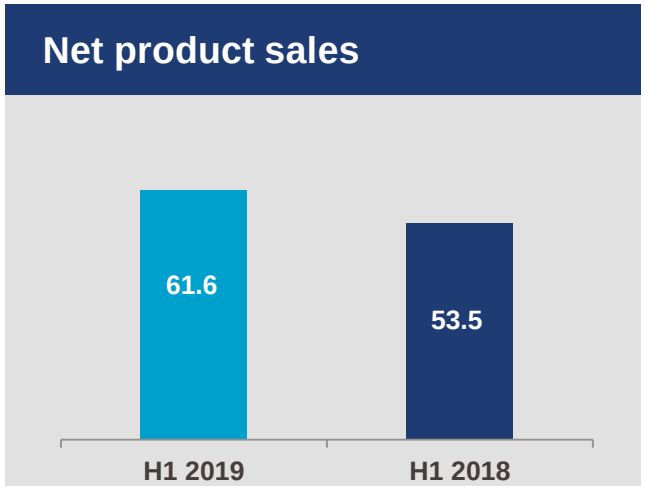
*CER: at constant exchange rates; **1** Third party products sold by Valneva's commercial organization; **2** Gross margin on product sales*

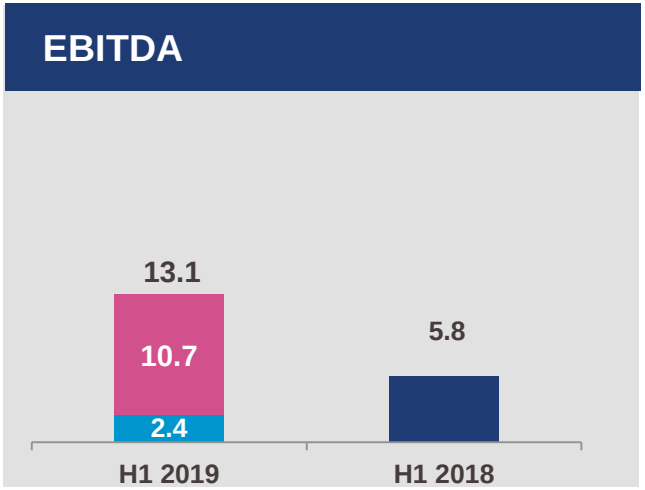
Strong year on year financial performance

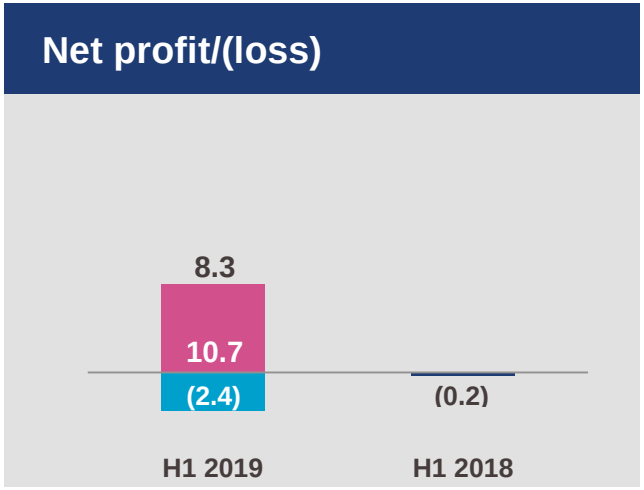
Financial results highlights (IFRS, € million) incl. GSK SAA termination effects

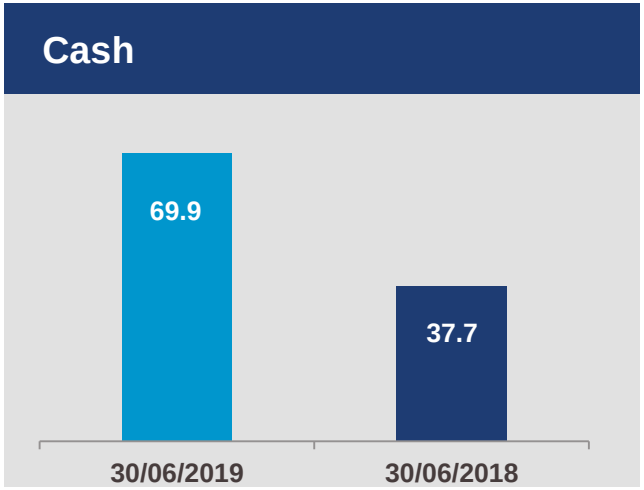
GSK SAA termination effects





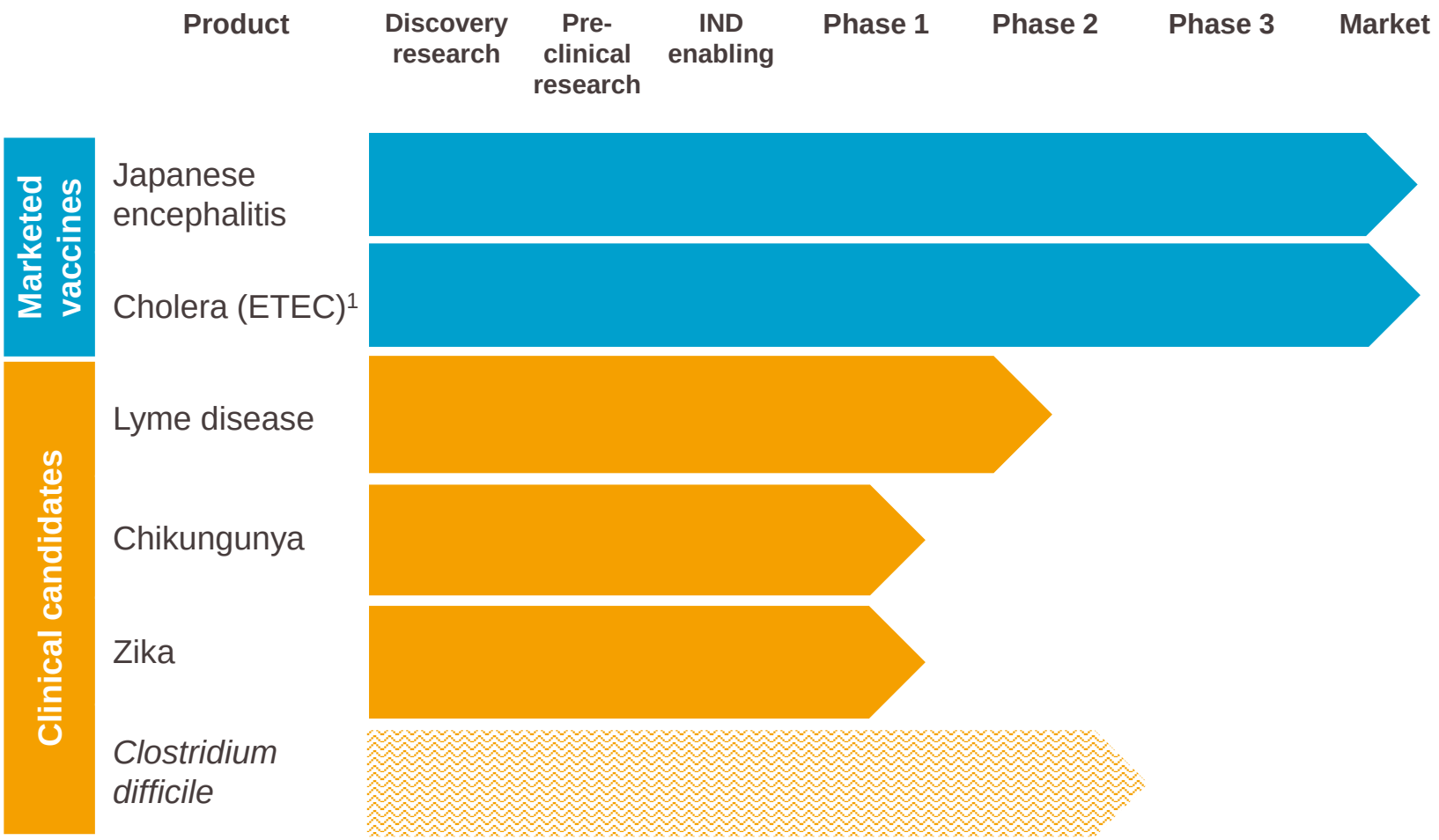






Valneva's R&D pipeline

Focusing on vaccines with major unmet need



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*

IXIARO®/JESPECT®

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

IXIARO®/JESPECT®

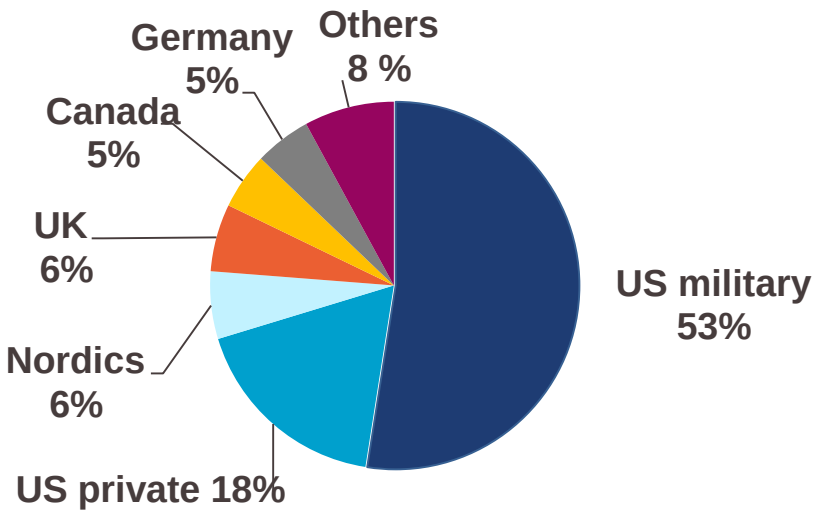
+ **Designed to protect travelers and military against JE, the leading cause of viral neurological disease & disability in Asia**
+ Indicated for active immunization against JE in **adults, adolescents, children and infants** aged two months and older[1]

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

IXIARO®/JESPECT®: US accounts for >70% of sales

H1 '19 product sales analysis



Growth expected to be 15% CER[2] or more in 2019

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*** *CER: at constant exchange rates*

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]

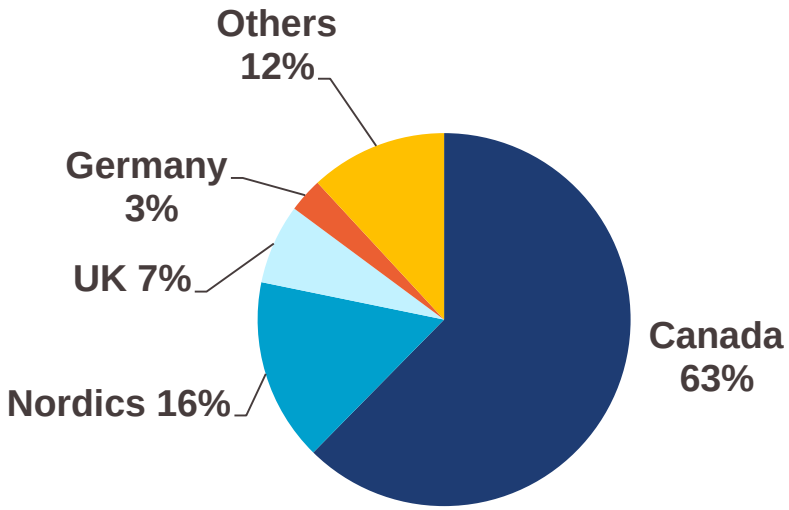
+ **Designed to protect adults and children** from two years of age who will be visiting endemic areas

Commercial position

+ In several markets, including EU, currently indicated to protect against 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 and primarily for cholera only

DUKORAL®: Canada accounts for >60% of sales

H1 '19 product sales analysis



Revenues to grow by up to 5% CER[4] in 2019

__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; 4 CER: at constant exchange rates

Lyme disease is a serious unmet medical issue

VLA15 is the only vaccine candidate in clinical development today

1. **Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe**
2. **Targets OspA of Lyme borrelia, preventing spirochetes from migrating through the tick's mid-gut – an established and proven Mode of Action for a Lyme disease vaccine**
3. **Safe and immunogenic with excellent boosterability in Phase 1 studies[1]**
4. **Currently in Phase 2 with clear development path for US and EU licensure; FDA Fast Track Designation granted**
5. **Semi-generic manufacturing process with three fusion proteins expressed in *e. coli* – Final industrialization for Phase 3 already anticipated**
6. **Addressing a very significant market opportunity**

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

Overview of Lyme disease

Severe tick-transmitted infection with high prevalence in N. America & Europe

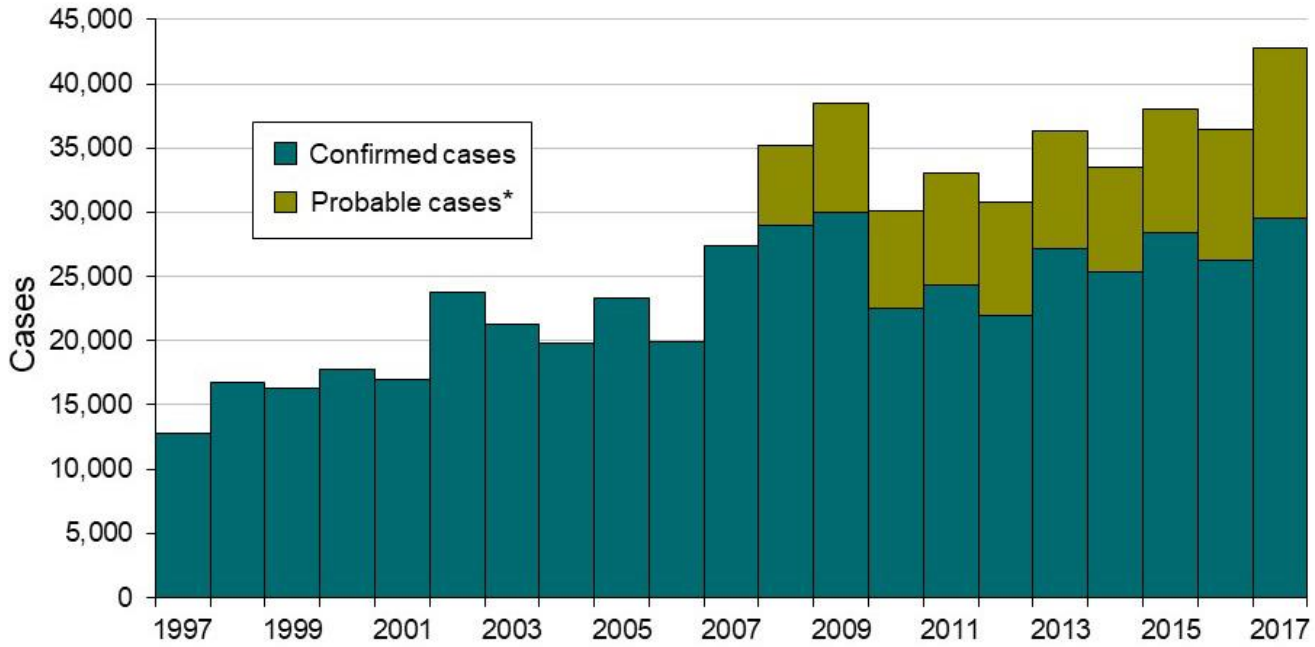
- Tickborne disease (Vector-Ixodes ticks)
- Caused by *Borrelia burgdorferi* spirochete (resides in gut of tick – migrates to salivary gland – enters host during feeding)
- Early signs and symptoms (3-30 days after tick bite) include flu-like sympthoms[1] and Erythema migrans rash[2]
- Left untreated, can spread to joints (arthritis), heart (carditis) and cause neurological problems
- Diagnosed by clinical symptoms, exposure to known endemic area, and lab tests
  - › Treatment: antibiotics (doxycycline, amoxicillin, or cefuroxime axetil)

1 *Fever, chills, headache, fatigue, muscle and joint aches, swollen lymph nodes;* ***2*** *Occurs in approx. 70-80% of infected persons.*

Lyme disease epidemiology

The most common vector-borne illness in the Northern hemisphere

Annual Reported Cases of Lyme Disease in the US[1]



- **Lyme disease has seen a marked increase in reported cases, driven by:**
  - Climate change contributing to increased tick and host populations
  - Longer tick breeding seasons
  - Increasing awareness and healthcare follow-ups

Estimated Cases

- **~ 300,000 cases in US (p.a.)[2]**
- **~ 200,000 cases in EU (p.a.)[3]**
- Most-affected US regions:
  - 95% of US cases in 2016 occurred in Northern US states
- Key age Groups:
  - 17.3% of cases occur in 5-14 years
  - 36.6% of cases occur in 40-64 years

1 https://www.cdc.gov/lyme/why-is-cdc-concerned-about-lyme-disease.html; 2 https://wwwnc.cdc.gov/eid/artickle/21/9/15-0417_article; 3 Estimated from available national data. Number largely underestimated based on WHO Europe Lyme Report as case reporting is highly inconsistent in Europe and many LB infections go undiagnosed; ECDC tick-borne-diseases-meeting-report; 4 Climate change influences on the annual onset of Lyme disease in the United States; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4631020/;

VLA15: Phase 2 – Optimizing dose and schedule

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

Phase 2
820 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**

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 Primary phase (initiated June 2019[2])

+ 2 selected dose levels (adjuvanted) chosen after run-in phase, placebo
+ 450 healthy volunteers (18 to 65 years)
+ Schedule: 0, 1, 2 months

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

VLA15-202 Secondary phase (initiated July 2019[3])

+ 2 selected dose levels (adjuvanted) chosen after run-in phase, placebo
+ 250 healthy volunteers (18 to 65 years)
+ Alternative schedule: 0, 2, 6 months

135 µg w/ alum	100 subjects
180 µg w/ alum	100 subjects
Placebo	50 subjects

__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

Lyme disease vaccine candidate VLA15: progression on track

Status update

Final Phase 1 data and first booster data for Lyme vaccine candidate reported ✓

Successful outcome of Phase 2 Run-In (June) and initiation of second Phase 2 study VLA15-202

+ Based on DSMB clearance, two lead dosage levels have been selected for ongoing Phase 2 clinical development ✓
+ VLA15-202 evaluates an alternative immunization schedule for two lead dosage levels ✓
+ Patient recruitment ongoing and on track

Phase 2 expected to provide first data by mid-2020

+ Initial Data: Day 85 after short schedule: dose determination
+ Alternative schedule data expected late 2020
+ Booster studies with additional 12 months follow-up

ON TRACK

Phase 3 could be initiated 2021/2022

**Subject to development progress, regulatory concurrence and company funding*

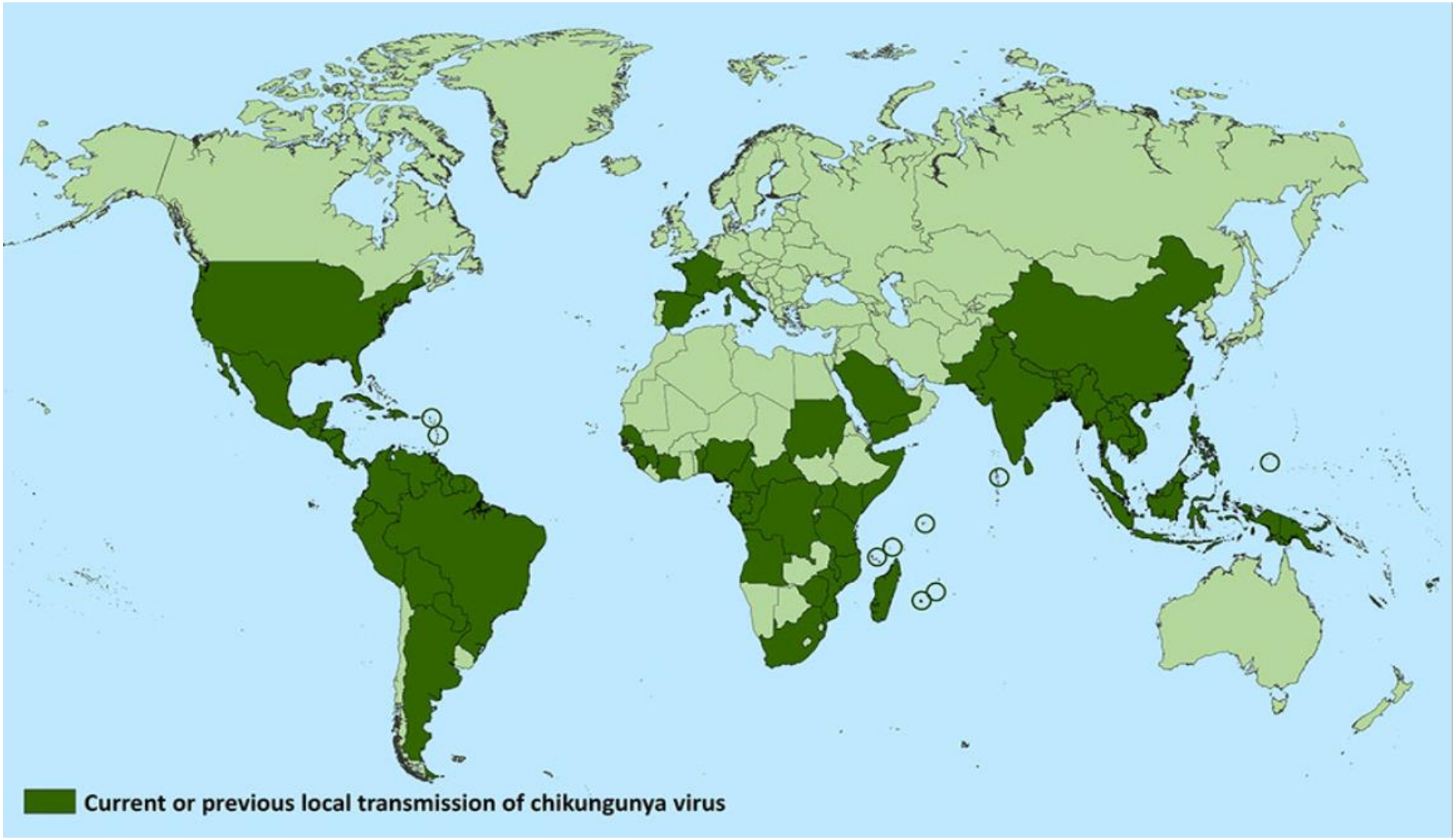
Chikungunya is a major public health threat
VLA1553 is a unique, differentiated single-shot vaccine candidate

1. **Currently no preventive vaccines or effective antiviral treatments exist for chikungunya**
2. **VLA1553 is a monovalent, single dose, live attenuated[1] prophylactic vaccine targeting chikungunya virus neutralization**
3. **Excellent immunogenicity and safety in Phase 1 with first hints on efficacy[2]**
4. **Currently in Phase 1 (follow-up) – Acceleration directly into pivotal trial under evaluation; FDA Fast Track Designation granted**
5. **Full-scale drug substance manufacturing process established at in-house FDA licensed facility**
6. **Addressing a very significant market opportunity**

__1__ CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; __2__ Valneva Reports further Positive Results for its Chikungunya Vaccine Candidate; Photo credit: James Gathany (source)

Chikungunya epidemiology

Countries and territories where chikungunya cases have been reported (as of May 29, 2018)[1]



1 https://www.cdc.gov/chikungunya/geo/index.html

Chikungunya Phase 1 study (VLA1553-101) – Interim results

Excellent immunogenicity and safety profile up to Month 7[1]

Immunogenicity

- 100% Seroconversion Rate (SCR)[2] achieved at Day 14 after a single vaccination in all dose groups[1]
  - SCR fully sustained at 100% after six months[1]
- Single vaccination of VLA1553 is sufficient to induce sustaining, high titer, neutralizing antibodies[1]

Excellent immunogenicity profile after single vaccination

Safety

- Generally safe in all dose groups
- Well-tolerated in 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 (AESIs) up to Month 7[1]

Excellent safety profile in low and medium doses

1 Valneva Reports further Positive Results for its Chikungunya Vaccine Candidate; 2 SCR defined as proportion of subjects achieving a CHIKV-specific neutralizing antibody titre as NT_{50} ≥ 20; 3 As occurs with other live-attenuated vaccines

Chikungunya vaccine candidate VLA1553: progression on track

Status update

Further Phase 1 results for single-shot chikungunya vaccine candidate reported ✓

+ Day 28 safety and immunogenicity after single dose
+ Viremia data at Days 3, 7 and 14 post-vaccination
+ Month 6 safety and immunogenicity data providing information on antibody persistence
+ Month 7 re-vaccination safety, immunogenicity and viremia data as early indicator of efficacy

CEPI awarded up to $23.4m for late-stage development of our single-dose vaccine ✓

+ Accelerate regulatory approval for use in regions where outbreaks occur, support WHO prequalification to facilitate broader access in lower/middle income countries

Supporting non-clinical experiments in preparation/process

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

ON TRACK

Aiming for accelerated approval procedure at FDA*

** Subject to development progress, regulatory concurrence and company funding*

2019 financial guidance confirmed irrespective of GSK SAA termination effects

	2018	2019
Product sales revenues	€103.5m	€115m - €125m
Total revenues	€113.0m	€125m - €135m
R&D investments	€25.3m	€35m - €40m
Gross margin	60.7%	> 60%
Net operating margin[1]	24.1%	25% - 35%
EBITDA	€13.1m	€5m - €10m

1 *Net operating margin is based on the P&L for the Commercial Products segment including an allocation (56%) of G&A costs from Corporate Overheads and Amortisation of Intangibles related to IXIARO®*

Corporate Governance and Shareholder Structure

Management Board

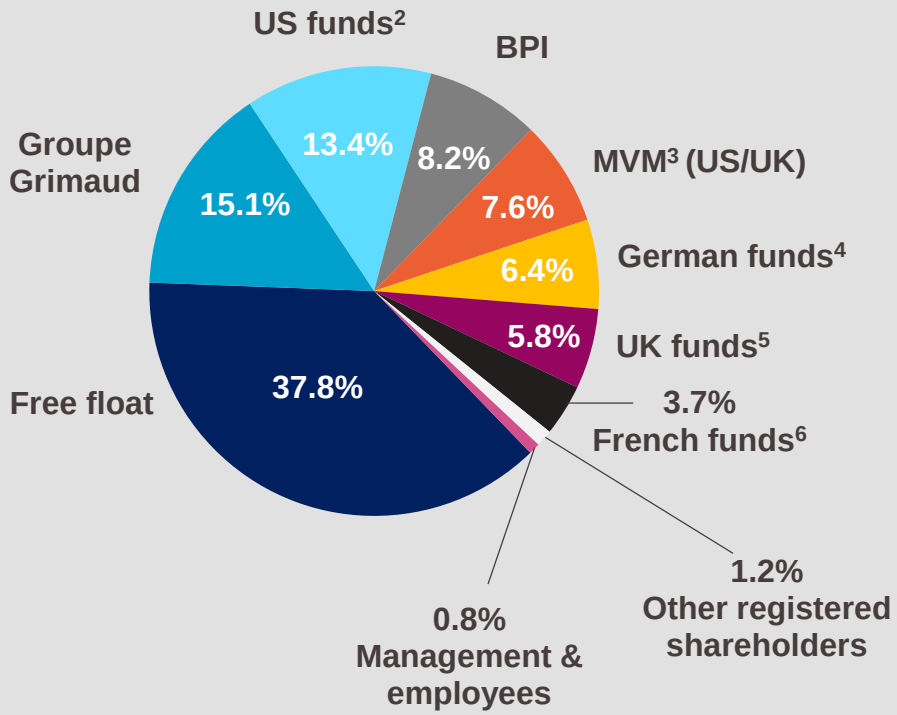
+ **Thomas Lingelbach**, *President & CEO*
+ **Franck Grimaud**, *President & CBO*
+ **David Lawrence**, *CFO*
+ **Wolfgang Bender, MD, PhD**, *CMO*
+ **Frédéric Jacotot**, *General Counsel & Corporate Secretary*

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)
+ **Balaji Muralidhar, MD, PhD** (UK)
+ **Sandra E. Poole** (US)

Stock Information

+ Primary listing = Euronext (Paris)
+ Number of ordinary shares: 90.9m
+ Shareholder structure[1]:



1 Estimates as of May 2019, based on ordinary share capital; 2 Combined positions of 11 U.S.-based funds managed by Deerfield Partners, Armistice Capital, Artisan Partners L.P., New Leaf, General American, Granite Point and others; 3 Funds managed by MVM Life Science Partners; 4 Combined positions of DWS Investment, Apus Capital, Apo Asset Management, Lupus alpha, Medical Strategy, Hauck & Aufhäuser, CD-Ventures, and Deutsche Apotheker; 5 Combined positions of Highclere, AXA Investment Managers Ltd., and Abingworth LLP; 6 Combined positions of CDC Entreprises Valeurs Moyennes, AXA Paris, La Banque Postale AM, AG2R, PRO BTP, Chaussier Gestion, and Mandarine Gestion.

Recent and expected upcoming newsflow

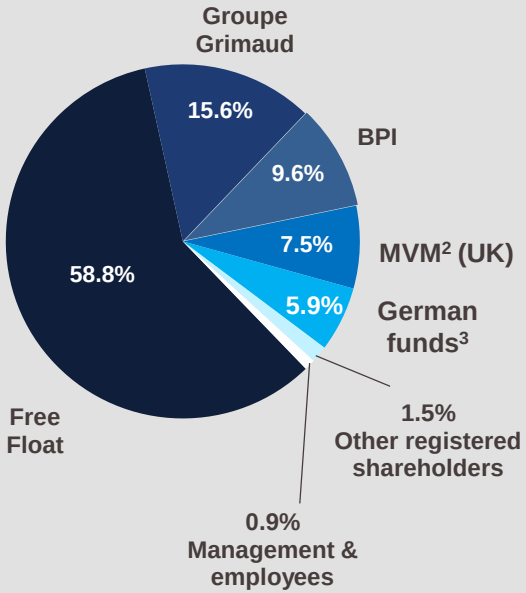
- Valneva held its R&D Investor Day in New York
- CEPI agreement, award of up to $23.4 million for late-stage development of a single-dose chikungunya vaccine
- Establishment of a Scientific Advisory Board announced
- On track to deliver 15-20% CER product sales growth expected in 2019
- Lyme disease vaccine candidate VLA15: Phase 2 execution on track for initial data mid-2020
- Chikungunya vaccine candidate VLA1553: progressing towards potential accelerated development strategy

Appendices

VLA continuously strengthening its institutional shareholder base with blue-chip healthcare investors

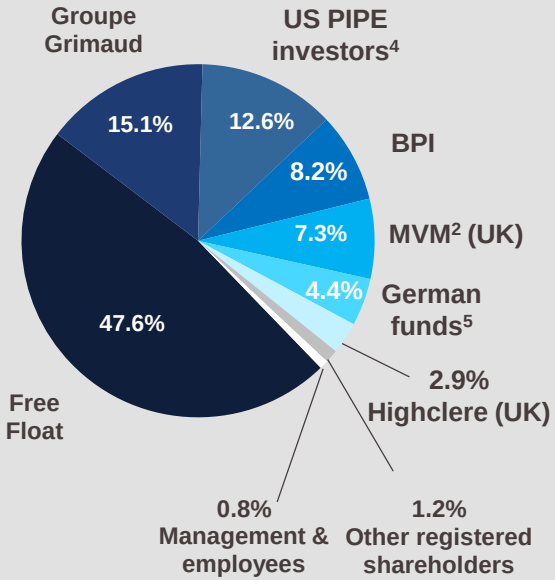
January 2018

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



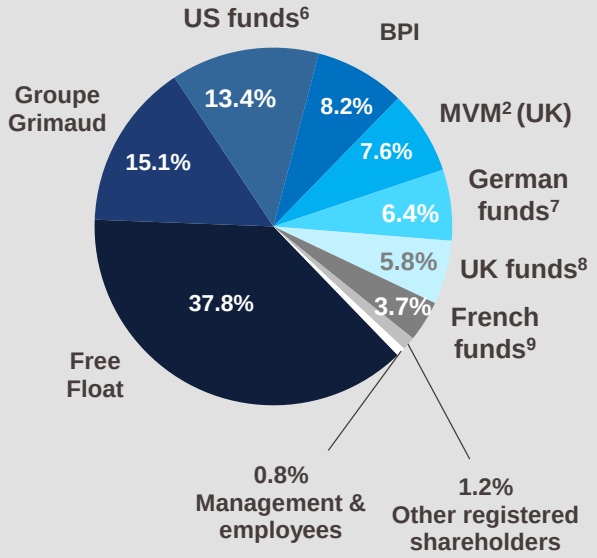
October 2018

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



May 2019

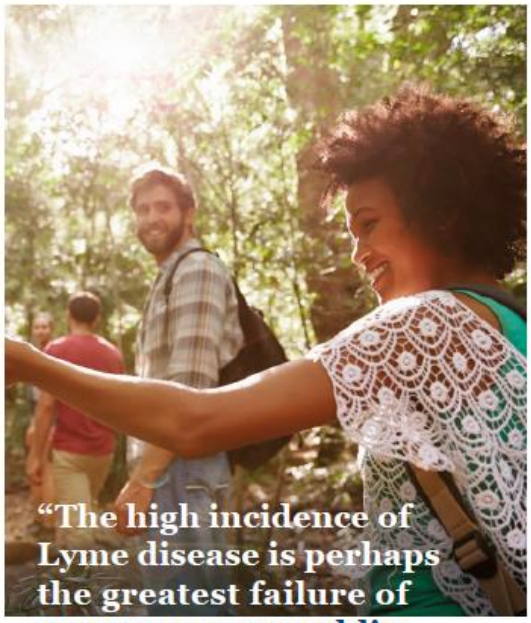
+ Number of ordinary shares: 90.9m
+ Shareholder structure[1]:



1 Estimates based on ordinary share capital; 2 Funds managed by MVM Life Science Partners; 3 Combined positions of 10 Germany-based funds managed by Apus Capitral, Apo Asset Management, Lupus alpha, CD-Ventures, SK Vermögensverwaltung, Hauck & Aufhäuser, and others; 4 Combined positions of U.S.-based participants in Valneva's September 2018 private placement; 5 Combined positions of Apus Capital, Lupus Alpha, Apo Asset Management, CD-Ventures, and Medical Strategy; 6 Combined positions of 11 U.S.-based funds managed by Deerfield Partners, Armistice Capital, Artisan Partners L.P., New Leaf, General American, Granite Point and others; 7 Combined positions of DWS Investment, Apus Capital, Apo Asset Management, Lupus alpha, Medical Strategy, Hauck & Aufhäuser, CD-Ventures, and Deutsche Apotheker; 8 Combined positions of Highclere, AXA Investment Managers Ltd., and Abingworth LLP; 9 Combined positions of CDC Entreprises Valeurs Moyennes, AXA Paris, La Banque Postale AM, AG2R, PRO BTP, Chaussier Gestion, and Mandarine Gestion.

Vaccination against Lyme disease

Justification for a Lyme 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**

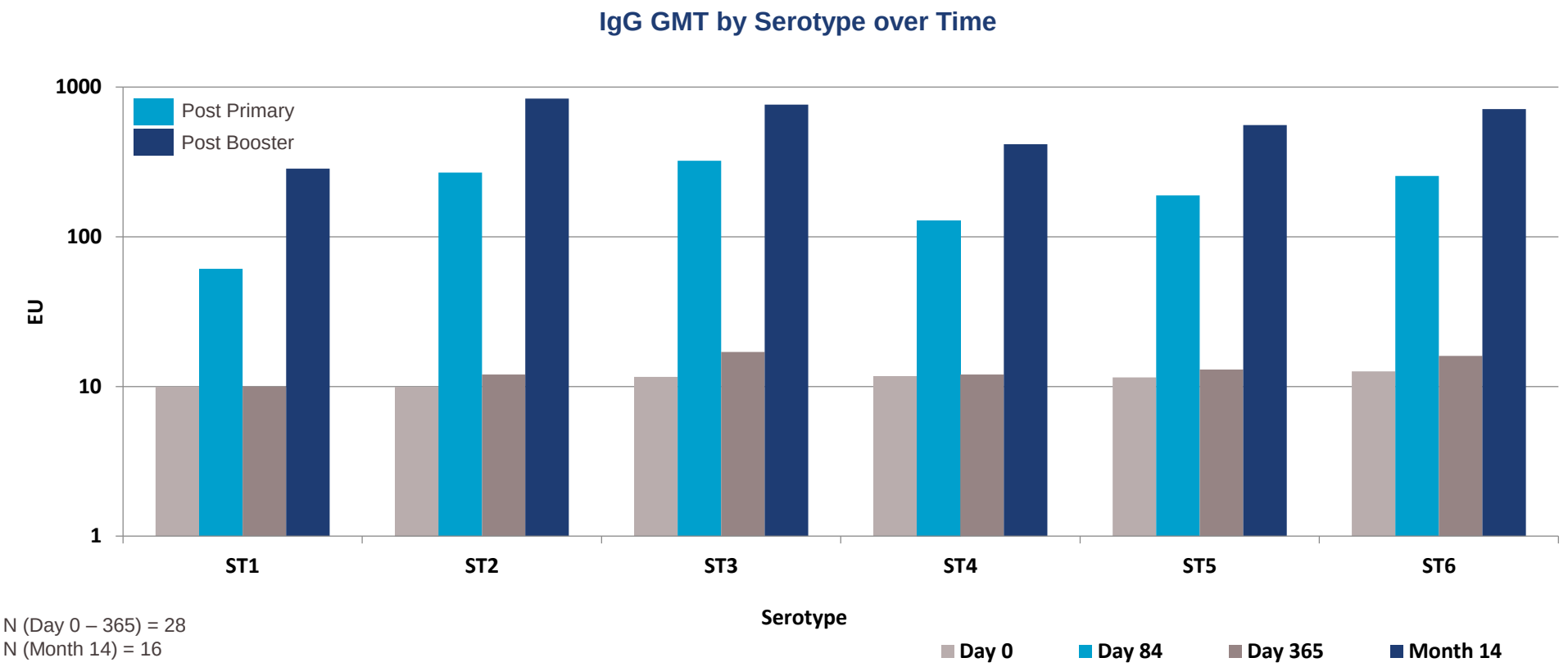
- **Other preventive measures have not been shown to work on a public health scale**

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

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

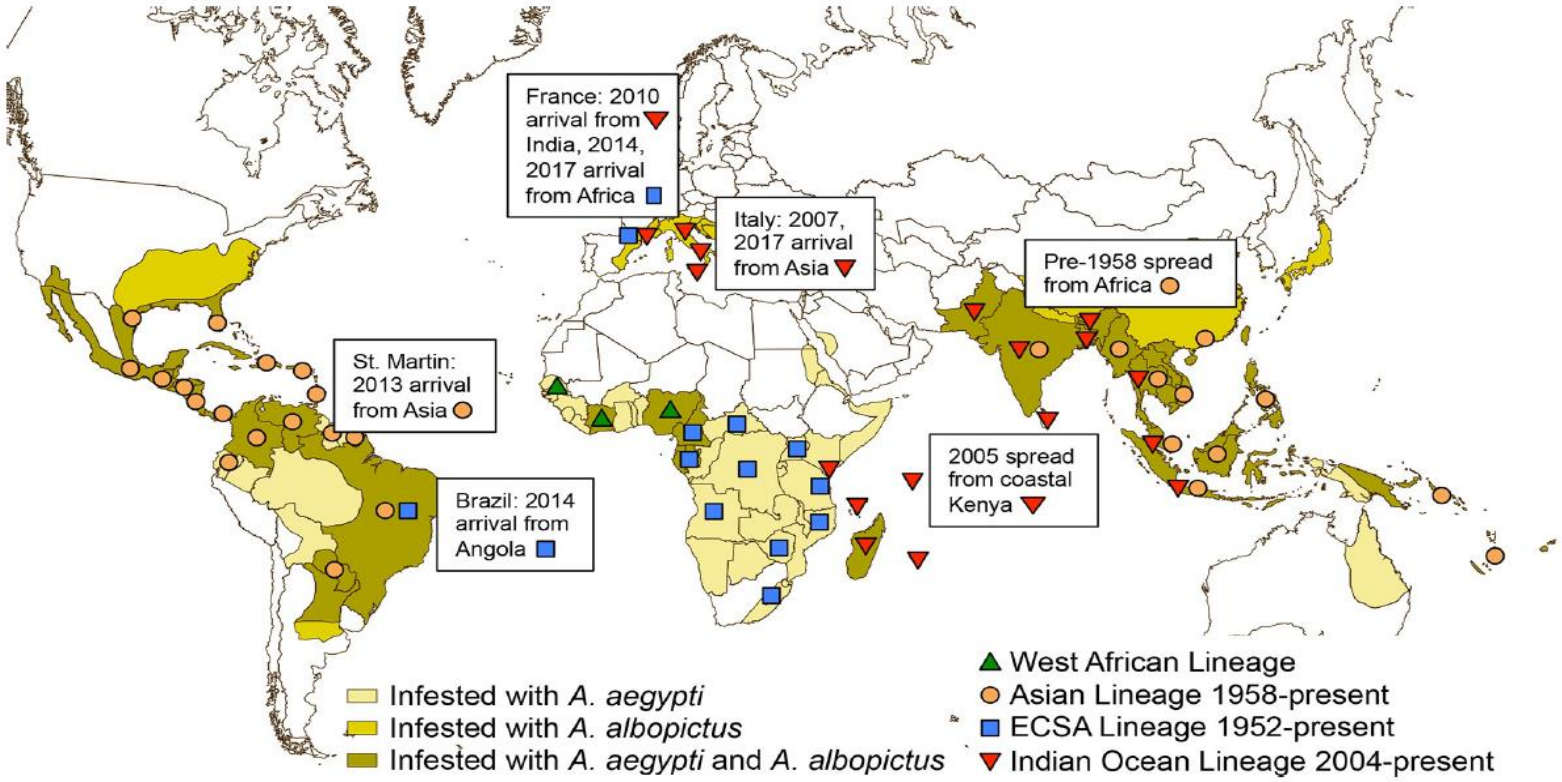


Fig 1. World map with countries where autochthonous (locally initiated) chains of CHIKV transmission have been identified. Data from World Health Organization (http://www.who.int/emergencies/diseases/chikungunya/en/) and Pan American Health Organization (https://www.paho.org/hq/index.php?option=com_topics&view=article&id=343&Itemid=40931&lang=en).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

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

Rezza & Weaver 2019

VLA84: Unpartnered *Clostridium difficile* vaccine candidate

Vaccine targeting healthcare-associated diarrhea, an increasing threat to the elderly in a $1 billion market[1]

Clostridium difficile (C. diff)

- **Single most common pathogen of acute healthcare-associated infections in the US[2] (~ 450,000 cases of annually and ~ 30,000 deaths[3])**
- **~ 172,000 cases in EU member states per year[4]**
- **Targeting primary prevention of *C. difficile***
  - Current antibiotic treatments have significant limitations with recurrence in ~20% of cases[5]

Valneva's vaccine candidate VLA84

- **One of two late stage vaccine candidates**
- **Modern, recombinant single subunit-toxin antigen (CTAB) expressed in e. coli w/o adjuvants**
- **Potential distinct competitive advantages on industrialization/future manufacturing**

Phase 2 completed

- **Phase 3 ready**
- **Highly immunogenic in all age groups tested (strong immune responses to both C. diff toxins A & B)**
- **Good safety and tolerability profile confirmed**
- **Comparable immunological profile to other CDI clinical programs targeting primary prevention of CDI**

New development & partnering approach

- **Potential partners hesitant about level of Phase III investment required and investment-risk proposition**
- **VLA to use first CDI vaccine approval and consider "Head to Head" non-inferiority Phase 3 on immunological correlate**
- **New approval expected to substantially improve investment-risk proposition for own or partnered development to market**

Source picture: www.123rf.com; ***1*** *VacZine Analytics Clostridium difficile prophylactic vaccines Market View, January;* ***2*** *Magill S, Edwards J R, Bamberg W et al. Multistate Point-Prevalence Survey of Health Care–Associated Infections. New England Journal of Medicine 2014;370:1198-208;* ***3*** *Lessa et al, Burden of Clostridium difficile Infection in the United States. N Engl J Med 2015;372:825-34.* ***4*** *Clostridium difficile infection in Europe. A CDI Europe Report.;* ***5*** *Leffler et al, Clostridium difficile infection. N Engl J Med 2015;372:1539-48;*

Thank you
Merci
Danke
Tack

valneva