valneva

Advancing Vaccines for Better Lives

Company Presentation
January 2021

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Valneva in Summary

We are **a specialty biotech company** developing & commercializing **novel prophylactic vaccines** with high unmet need

- **A highly specialized, targeted approach** to vaccine development
- **An advanced pipeline of clinical-stage assets** designed to address large target populations
- **Product development and regulatory expertise** with a demonstrated ability to move new vaccines through the clinic to commercialization
- **A nimble and sophisticated manufacturing infrastructure** designed to support growth through rapid, efficient vaccine development and commercialization
- **Validating collaborations across the portfolio**
- **Two commercial vaccines, specialist sales infrastructure and distribution rights for third-party vaccines**
- **A highly experienced leadership team with a track record of success in the vaccine space**

Research & Development

Our Approach to Vaccine Selection

We target diseases that lack preventative or effective therapeutic solutions

Disease-first approach

- **We identify diseases that lack preventative or therapeutic solutions and apply our understanding and experience,** rather than looking at opportunities where effective modes of action already exist
- This allows us to develop **differentiated vaccine candidates by applying the most suitable technology**

We consider industrial and commercial synergy

We consider potential future partnering value

Valneva Has Three Highly Differentiated Clinical Programs

Asset Indication	Phase 1	Phase 2	Phase 3	Development Partner	PRV* Eligible
VLA15 Lyme disease				**Pfizer**	
VLA1553 Chikungunya				**proprietary**	✓
VLA2001 COVID-19				**UK Govt**	

*PRV = U.S. Priority Review Voucher: *https://priorityreviewvoucher.org/*

Lyme Disease Vaccine – VLA15

Lyme Disease is a Major Health Issue

No available treatment to protect against Lyme disease

Major unmet medical need in North America and Europe

Lyme disease cases may rise 92% by 2100 in the 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: The Only Lyme Disease Vaccine in Clinical Development Today

1. Exclusive, worldwide partnering deal with Pfizer
2. FDA Fast Track Designation granted
3. Positive initial results reported from Phase 2 studies[1, 2]
   Initiation of accelerated pediatric study (VLA15-221) planned for Q1 2021[3]
4. Multivalent vaccine (six serotypes) to protect against Lyme disease in North America and Europe
5. Follows proven Mechanism of Action for a Lyme disease vaccine

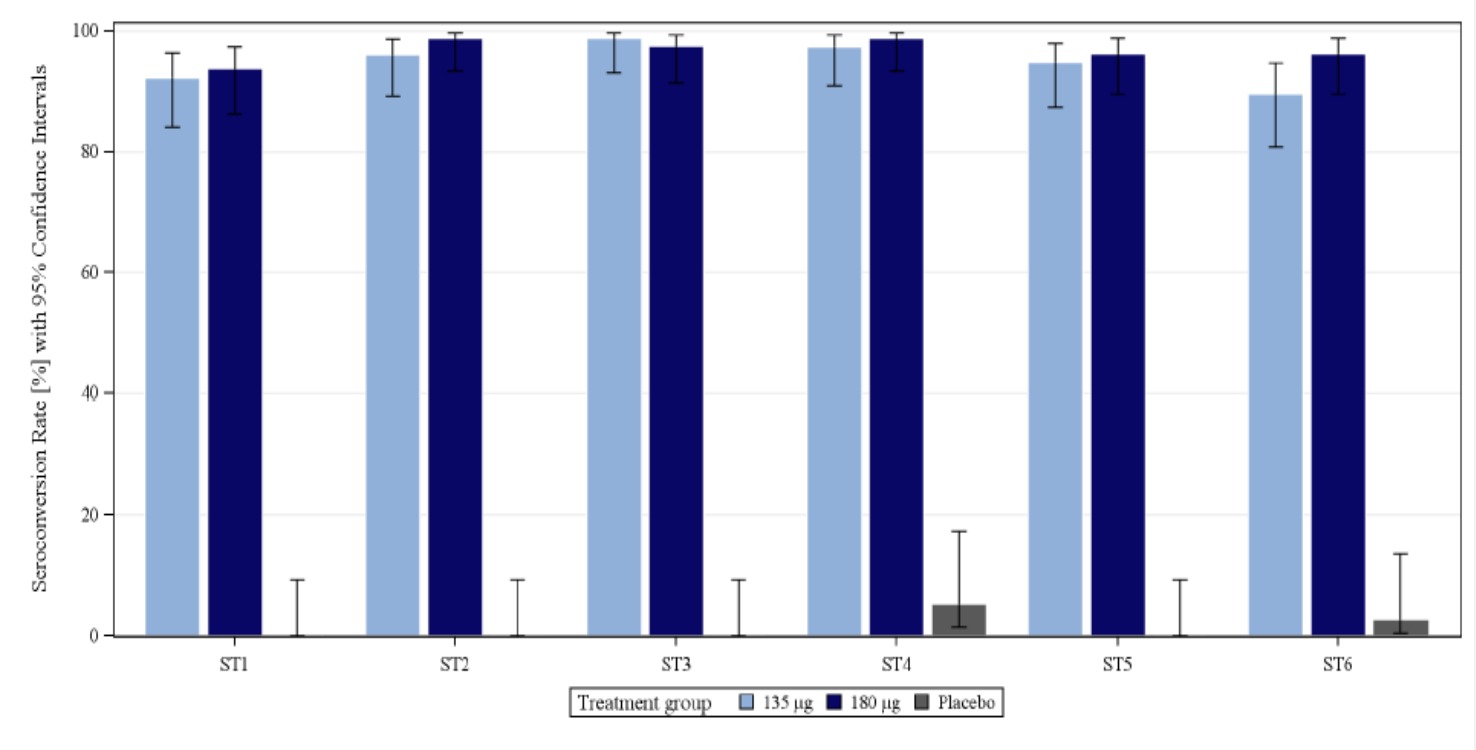
1 Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate; **2** Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15; **3** Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate

VLA15: In Phase 2 Clinical Studies, Positive Phase 1 and Interim Phase 2 Data Reported

VLA15 is a multivalent protein subunit vaccine targeting the outer surface protein A (OspA) of *Borrelia*

✓ **Immunogenicity further enhanced using a Month 0-2-6 schedule[1]**

- Seroconversion Rates (SCRs) ranged from 93.8% [serotype 1] to 98.8% [serotypes 2 and 4]



✓ **A Serum Bactericidal Assay (SBA)[2], assessing the functional immune response against Lyme disease after VLA15 vaccination, demonstrated functionality of antibodies against <u>all</u> OspA serotypes**

1 Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15; **2** Assays, such as SBAs, are commonly used to enable a potential prediction of vaccine efficacy via the measurement of vaccine-induced functional immune responses.

VLA15: Exclusive, Worldwide Partnering Deal with Pfizer

Collaboration with Pfizer for late stage development and future commercialization[1]

- Pfizer funding 70% of development costs through program completion
- Valneva eligible to receive a total of $308 million upfront and milestone payments ($130 million already received in May 2020[2])
- Valneva to receive tiered royalties starting at 19%

Positive initial Phase 2 results reported[3,4]

- Positive seroconversion data, dose and schedule agreed

Initiation of pediatric study VLA15-221 (aged 5-17 years), planned for Q1 2021[5]

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; **4** Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15; **5** Valneva Announces Acceleration of Pediatric Development for Lyme Disease Vaccine Candidate

Chikungunya Vaccine – VLA1553

Chikungunya is a Growing Problem

A **mosquito-borne** viral disease that can cause **debilitating joint and muscle pain**, fever, headache, nausea and rash, **with potential serious, long-term health impairment**[1]

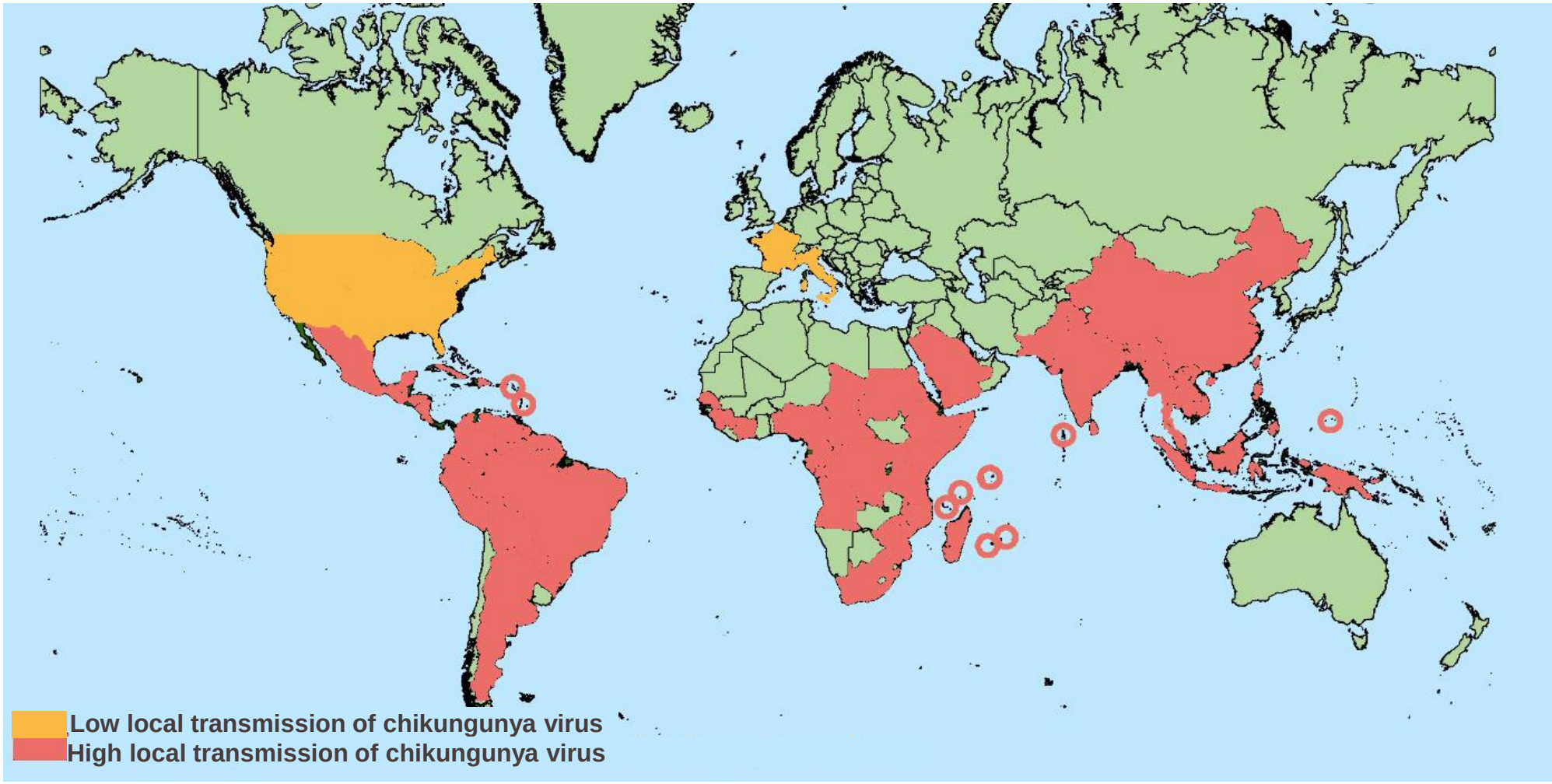
Currently there are no vaccines or effective treatments for chikungunya

Global market, including endemic regions (see below), estimated to exceed $500 million annually by 2032[2]

2020 outbreaks[3]**: The Americas (incl. Brazil, the Caribbean, Colombia, Costa Rica, Mexico), Asia (India, Malaysia, Thailand) and Africa (Congo, Kenya, Sudan)**

1 Valneva Chikungunya Factsheet**; 2** VacZine Analytics Chikungunya virus vaccines Global demand analysis. February 2020; **3** *ECDC chikungunya worldwide overview*

Chikungunya: Previously Reported in the US and EU, Widespread in the Southern Hemisphere



Countries and territories where chikungunya cases have been reported (as of Oct 30, 2020), Adapted from *cdc.gov*
https://www.cdc.gov/chikungunya/pdfs/Chik_World_Map_10-30-20-P.pdf

VLA1553: Single-Shot Chikungunya Vaccine Candidate in Phase 3 Clinical Studies; Most Advanced in the World

1. Phase 3 initiated in September 2020[1], recruitment on track; Positive EoP2 meeting with the FDA; Accelerated Approval Pathway confirmed[2]
2. Priority Review Voucher eligible; FDA Fast Track[3] and EMA PRIME[4] designation granted
3. Up to $23.4 million awarded to Valneva for R&D by CEPI
4. Compatible with existing commercial and manufacturing capabilities; Partnership with Instituto Butantan for LMICs[5]
5. Monovalent live attenuated[6] prophylactic vaccine targeting chikungunya virus neutralization

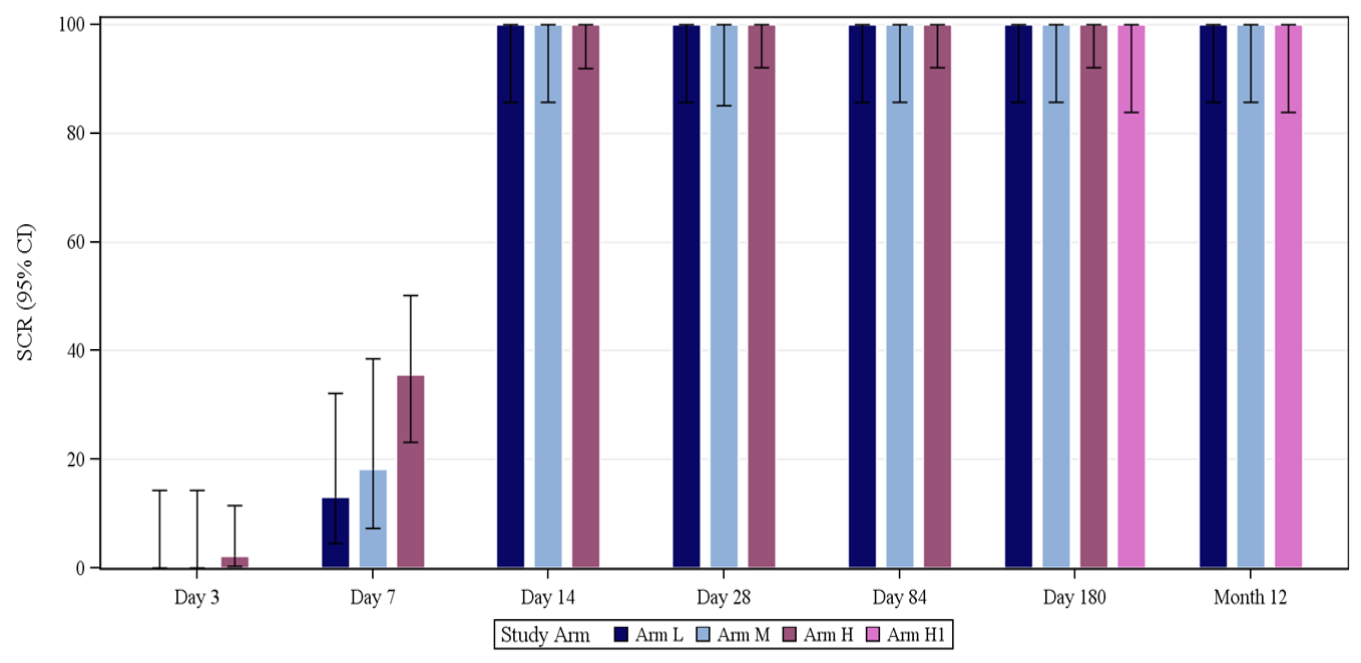
1 Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553 ; **2** Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study; **3** Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate; **4** Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation; **5** Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; **6** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; **Photo credit**: James Gathany

VLA1553: Positive Phase 1 Data Published in *The Lancet Infectious Diseases*[1]

VLA1553 is a monovalent, live attenuated[2] Vero cell-derived vaccine targeting chikungunya virus neutralization

✓ **Neutralizing antibodies developed in 100% of volunteers, sustained for 1 year**

- 100% SCRs achieved at day 14 after a single vaccination



✓ **VLA1553 well tolerated at the dose level selected for Phase 3[2]**

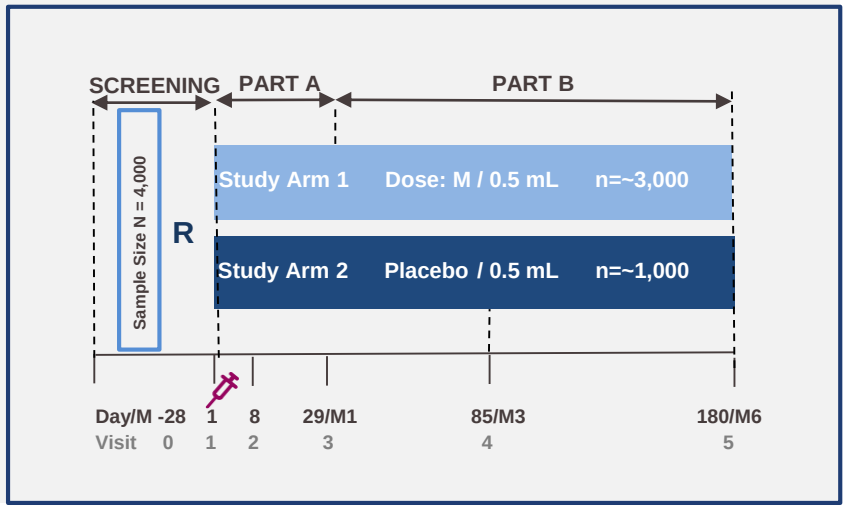
- No vaccine-related Serious Adverse Events were reported during 12 months of follow-up

1 Single-shot live-attenuated chikungunya vaccine in healthy adults: a phase 1, randomised controlled trial; **2** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase); **3** Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation

VLA1553-301: Pivotal Phase 3 Study Currently in Progress

1. **Objectives:** pivotal safety and immunogenicity; Seroprotection rate at Day 29 based on an immunological surrogate (defined in non-human primates for baseline negative subjects).[1]
2. **Population:** Healthy subjects aged 18 years and above, randomized 3:1 to VLA1553 or control
3. **Sample Size:** approx. N=4,060; Safety: VLA 1553 (n=3,000) vs. control (n=1,000); IMM subset (n=500)
4. **Trial Sites:** Multicenter study in non-endemic regions of the U.S.
5. **Primary Endpoint:** Seroprotection rate at Day 29
6. **Schedule:** Single-shot i.m. immunization at Day 1
7. **Expected Duration:** 9 - 12 months[2]

Initial Phase 3 data expected in Q2 2021



1 Seroprotection threshold subject to final approval by regulators
2 Duration may be impacted by different parameters, including adverse clinical operations implications due to ongoing COVID-19 pandemic

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

Valneva's Response to the Global COVID-19 Crisis

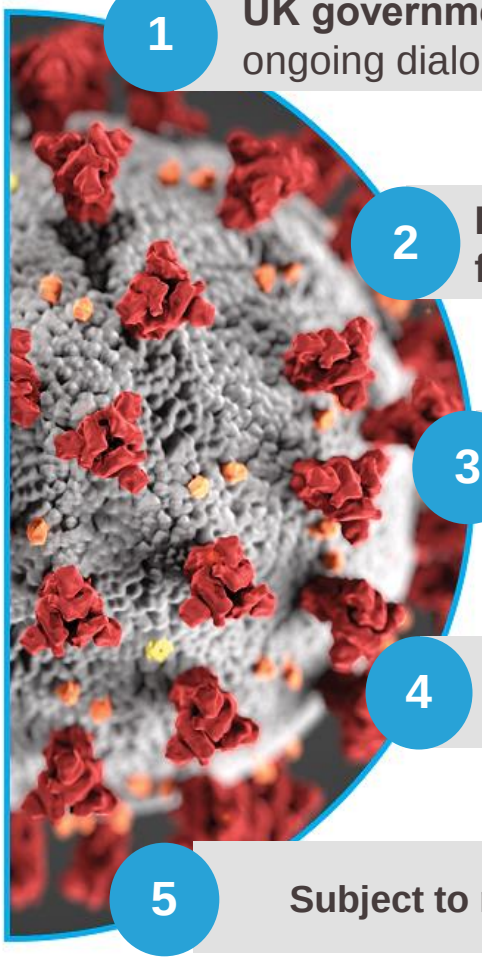
Early in the pandemic, Valneva's Scientific Advisory Board designed a potential SARS-CoV-2 vaccine candidate leveraging our capabilities

Spring/summer 2020: R&D resources reallocated to COVID-19

Valneva is leveraging its strengths and manufacturing platform

- BSL3 labs recommissioned for pre-clinical activities;
- Using Valneva's FDA-approved manufacturing facility in Livingston, Scotland

VLA2001: First Inactivated COVID-19 Vaccine in EU Clinical Trials



1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding; ongoing dialogue with other potential customers
2. **Facilitated program acceleration through use of Valneva's FDA-approved facility; commercial manufacturing expected to commence January 2021**
3. **Combines Valneva's proven approach with Dynavax's advanced CpG 1018 adjuvant**[2]
4. **Phase 1/2 clinical trial initiated in December 2020**[3]
5. **Subject to regulatory approval, deliveries planned for H2 2021**

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; **3** Valneva Initiates Phase 1/2 Clinical Study of Inactivated, Adjuvanted COVID-19 Vaccine Candidate; **Photo credit**: CDC/Alissa Eckert, MSMI; Dan Higgins, MAMS

VLA2001: Collaboration to Provide up to 190 Million Doses of Inactivated, Adjuvanted 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]

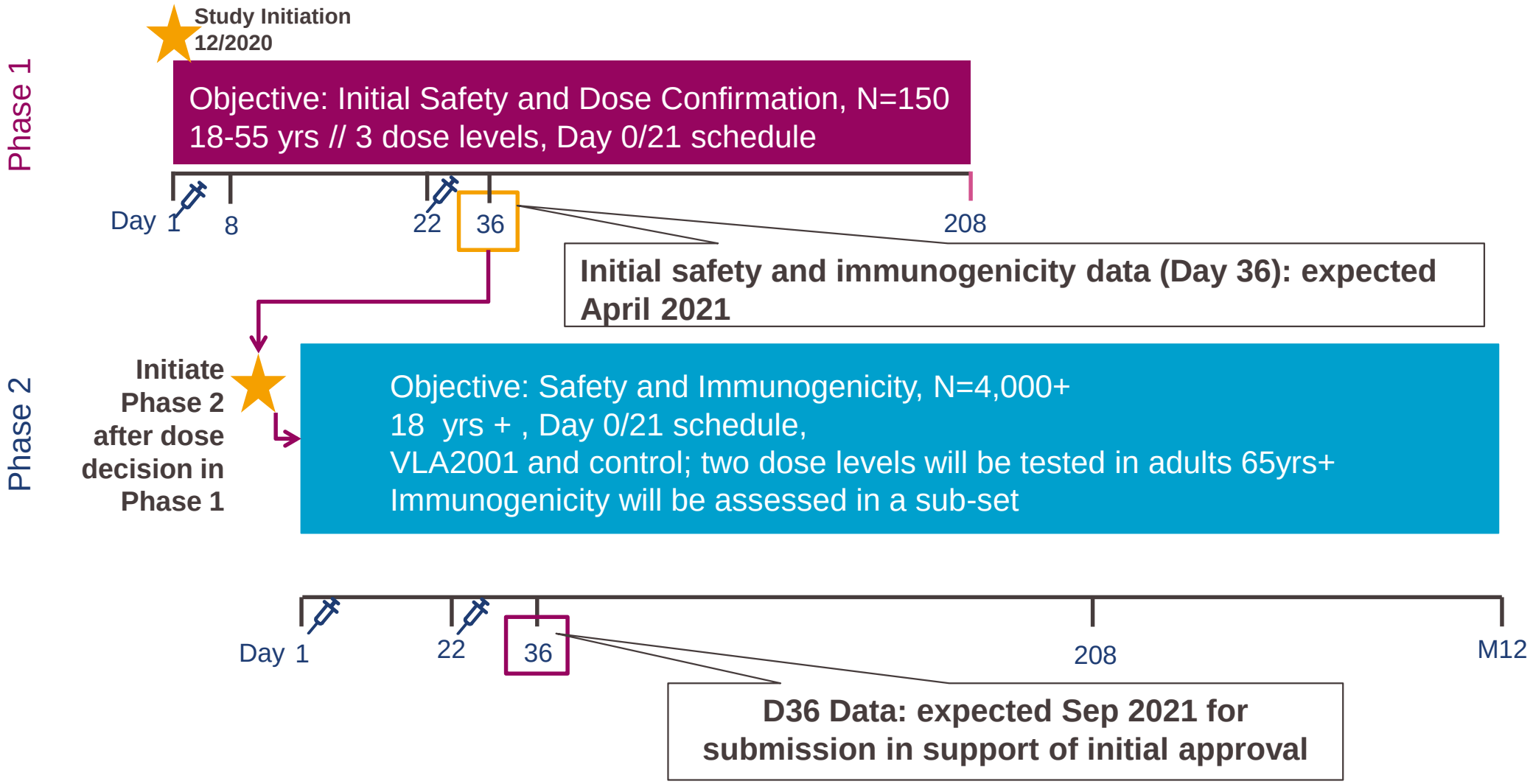
- Including 60 million doses worth approximately €470 million for 2021
  - › Options to purchase up to 130 million doses worth up to €900 million between 2022 and 2025

Agreement includes funding for expansion of Valneva's UK-based manufacturing facility and Phase 1/2 clinical trials in the UK

- Vaccine being manufactured at Valneva's facilities in Livingston, Scotland[2]
- Valneva also investing in its Scottish and Swedish facilities

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

VLA2001: Clinical Trials Underway, Targeting Approval in Q4 2021



Commercial Products

Valneva has a Specialist Travel Vaccine Business and is a Contractor to the US Military

- **Prior to the pandemic, Valneva demonstrated a strong track record of sales growth** built upon the solid foundation of its business relationship with the US DoD
  - €129.5m of product sales in 2019 (+25% AER, +22% CER)[1]

- **Direct sales channels in the US, Canada, UK, France, Nordics, and Austria**

- Distributors in Germany, Australia, Southern Europe and smaller markets

- Valneva believes the commercial business is a key asset for the future, e.g. chikungunya route to market, once the travel industry recovers

1 Valneva Reports Record Product Sales and Major Pipeline Progress in 2019

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**
- **Strong track record with US military**
- **Limited competition** - local producers exist in endemic regions and mainly serve public markets

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 commenced 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** https://www.who.int/bulletin/volumes/90/3/11-093427/en/; **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

Corporate Highlights and Newsflow

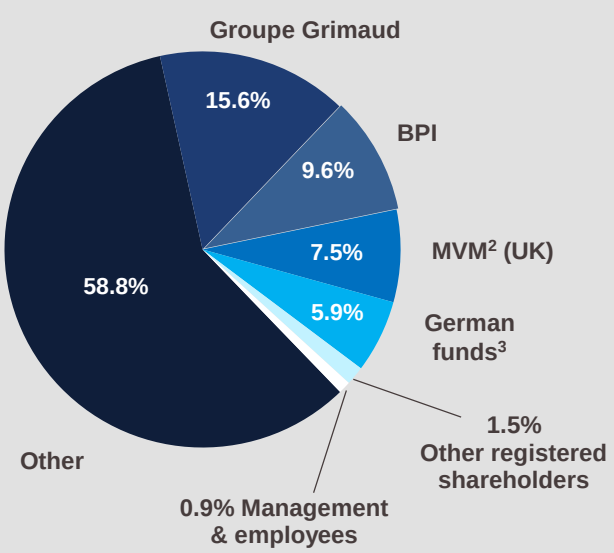
Company Well Positioned for Growth

- Well funded (2020 year end cash expected to be €180m - €200m)
  - UK COVID-19 collaboration is self-funding
- Executing on capital raising and growth strategies
- Driving key, late-stage programs to market
  - Including Lyme collaboration with Pfizer
- COVID-19 represents major upside for the Company

Strengthened shareholder base including US blue-chip healthcare investors

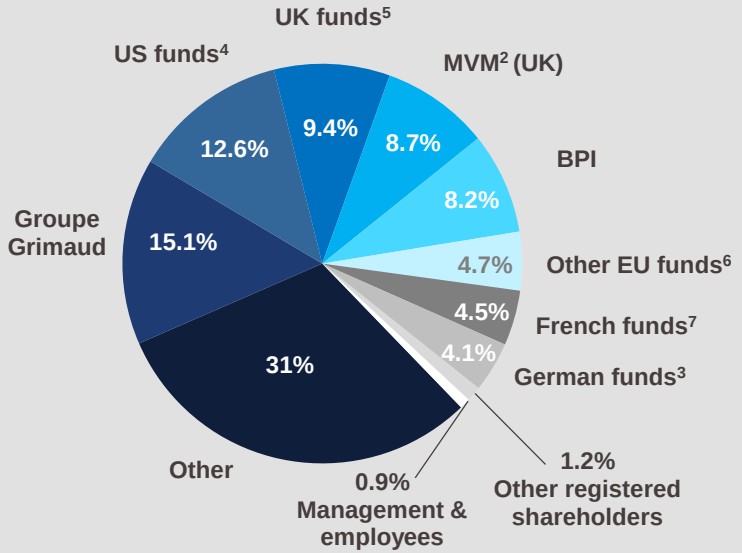
January 2018

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



December 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, General American, Acadian AM, 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, and Luxembourg; **7** Combined positions of CDC Entreprises Valeurs Moyennes, AXA Paris, Eiffel Investment Group and OFI AM.

Key Upcoming Newsflow

Lyme disease vaccine candidate VLA15

- Valneva and Pfizer announced acceleration of pediatric development with Phase 2 study VLA15-221, initiation planned for Q1 2021

Chikungunya vaccine candidate VLA1553

- Phase 3 recruitment completion expected early 2021, initial data Q2 2021

Phase 1/2 COVID-19 vaccine clinical trial initiated

- Initial data expected and Phase 2/3 planned to commence April 2021
- Deliveries planned in H2 2021

Thank you
Merci
Danke
Tack

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