valneva

Advancing Vaccines for Better Lives

Company Presentation

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Valneva in Summary

Fully integrated specialty vaccine company focused on development and commercialization of **prophylactic vaccines for infectious diseases** with significant unmet medical need

- **Highly specialized and targeted approach to development of unique prophylactic vaccines**
- **Advanced pipeline of differentiated clinical-stage assets** designed to address large target populations
- **Highly experienced leadership team with vaccine development and regulatory expertise;** clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization
- **Highly developed, nimble and sophisticated manufacturing infrastructure**
- **Specialist sales infrastructure: three commercialized vaccines; distribution rights for third-party vaccines**

- **Total revenues of €93.2 million in H1 2022, compared to €47.5 million in H1 2021**
- **Cash position of €336.2 million at June 30, 2022**

Research & Development

Valneva has an Advanced Clinical Pipeline and Three Approved Products[1]

[1]As of June 24, 2022, VLA2001 has received emergency use authorization in Bahrain and in the United Arab Emirates, as well as Conditional Marketing Authorization in the UK and standard marketing authorization in Europe.[2] VLA1553 received Fast Track designation from the FDA, PRIME designation from the European Medicines Agency and is also potentially eligible for a U.S. Priority Review Voucher. [3] VLA15 received Fast Track designation from the FDA [4] 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

Lyme Disease Vaccine – VLA15

Lyme Disease is a Major Health Issue

Severe Tick-transmitted Infection, Increasingly Common in the US and Europe

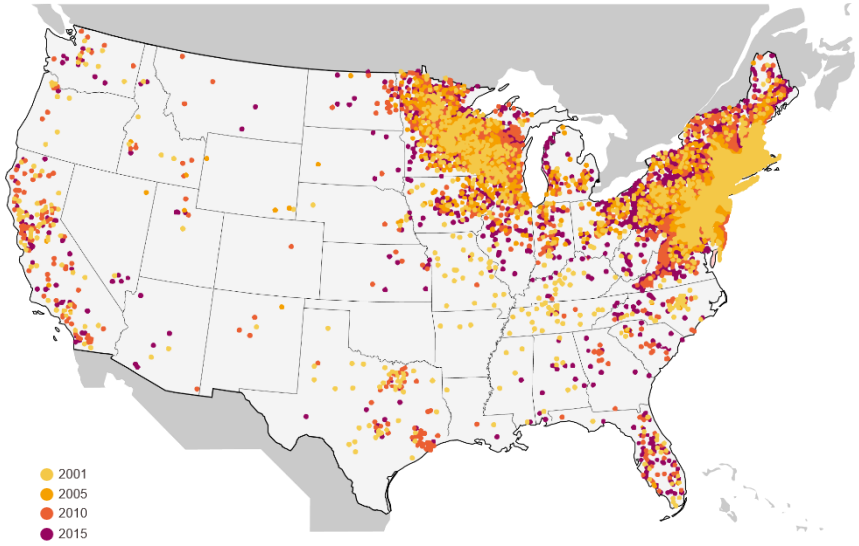
Early signs include **flu-like symptoms**[1] and **Erythema migrans rash**[2] which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

No available treatment to protect against Lyme disease

Global market estimated to reach $1 billion by 2030

Direct medical costs in the U.S. estimated up to $1.3 billion each year – indicating an attractive health economic benefit[3]

Spread of Lyme Across the US[4]



[1] Fever, chills, headache, fatigue, muscle and joint aches, swollen lymph nodes. [2] Occurs in approx. 70-80% of infected persons. [3] Adrion, E. et al PLOS ONE Feb 2015.
[4] Centers for Disease Control and Prevention

VLA15: Multivalent Lyme Disease Vaccine Candidate

Only Lyme Disease Program in Advanced Clinical Development Today

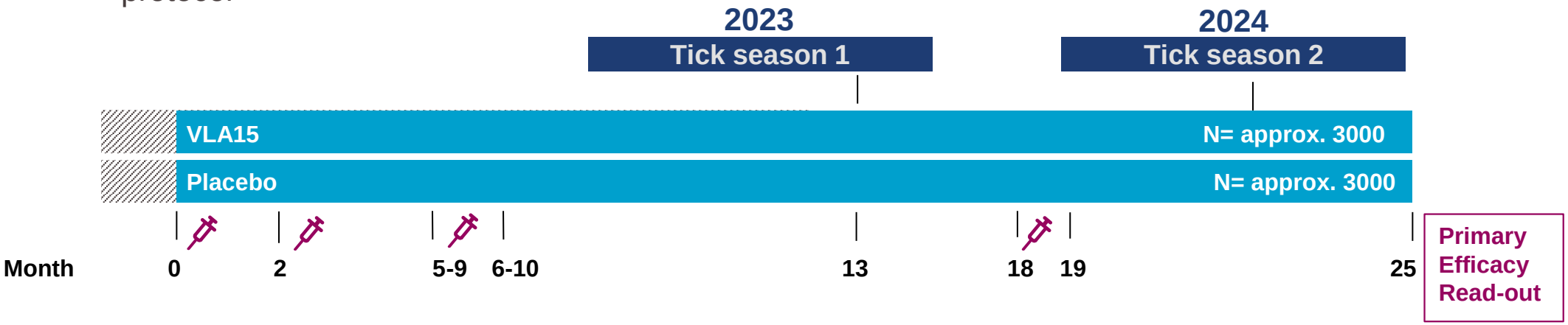
1. **Phase 3 study initated[1] following positive results for three Phase 2 clinical trials[2,3,4], including first pediatric data[5]**
2. **Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 ($95) million equity investment in Valneva[6]**
3. **Multivalent vaccine (six serotypes) to help protect against Lyme disease in the United States and Europe**
4. **Follows proven mechanism of action for a Lyme disease vaccine**
5. **FDA Fast Track Designation granted**

1 Pfizer and Valneva Initiate Phase 3 Study of Lyme Disease Vaccine Candidate VLA15; **2** Valneva announces positive initial results for Phase 2 study of Lyme Disease vaccine candidate**; 3** Valneva announces positive initial results for second Phase 2 study of Lyme Disease vaccine candidate VLA15. **4** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate **; 5** Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate/; **6** Valneva and Pfizer Enter into an Equity Subscription Agreement and Update Terms of Collaboration Agreement for Lyme Disease Vaccine Candidate VLA15;

VLA15: Phase 3 Efficacy Study Design

Randomized, Placebo-Controlled Phase 3 VALOR Study Currently Ongoing

- **Population**: 6,000 participants ≥5 years of age at high risk of Lyme disease (LD) (by residence and occupational/recreational activities) conducted in US and Europe (randomization approx. 2:1 US/EU)
- **Primary endpoint:** Rate of confirmed[1] LD cases after 2nd Lyme season (i.e., after completion of full vaccination series 3+1)
- **Secondary endpoints** include rate of confirmed[1] LD cases after 1st Lyme season (i.e., after completion of primary vaccination series) amongst other secondary endpoints as defined in Phase 3 protocol



Pending successful completion of the Phase 3 study, Pfizer could potentially submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2025.

1 Cases will be evaluated and confirmed by an Endpoint Adjudication Committee

VLA15: Three Positive Phase 2 Trials

Continuing to demonstrate strong immunogenicity with acceptable tolerability profile across 1,030 adult and pediatric participants

VLA15-221: First positive pediatric data (April 2022[1])

- Strong immunogenicity profile in adult [2] (ages 18-65) and pediatric participants (ages 5-17)
- More immunogenic in pediatric participants than in adults, with both two-dose and three-dose vaccination schedules; three-dose schedule selected for all ages in Phase 3
- VLA15 was generally safe and well tolerated across all age groups tested. No related SAEs were observed in any treatment group.

VLA15-202: First positive booster data (September 2021)[3]

- High antibody responses confirmed across all serotypes and dose groups after primary vaccination series (primary endpoint)[4]
- 12-month booster dose elicited strong anamnestic response
- VLA15 was generally safe and well tolerated. No related SAEs were observed in any treatment group.

VLA15-201: First positive immunogenicity data (July 2020)[5]

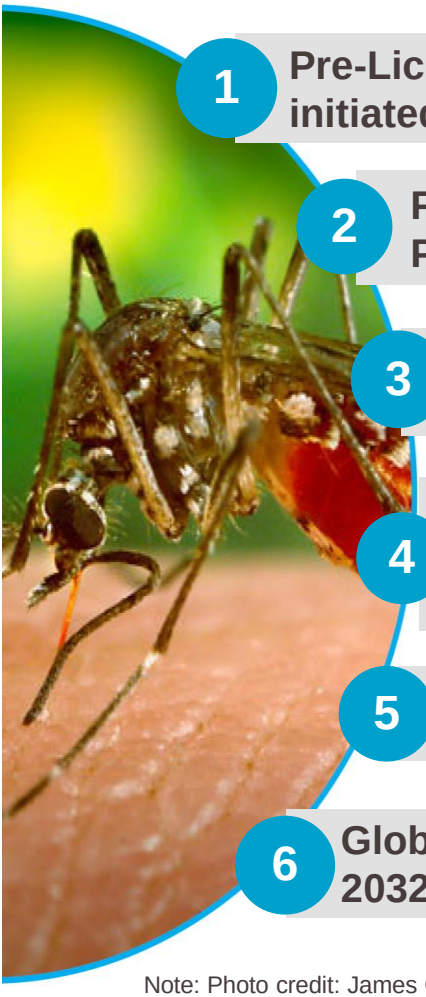
- Immunogenic across all serotypes and dose groups; higher doses elicited higher antibody responses
- Encouraging immunogenicity profile confirmed, including in older adults (ages 50-65)
- VLA15 was generally safe and well tolerated. No related SAEs were observed in any treatment group.

1 Valneva and Pfizer Report Positive Phase 2 Pediatric Data for Lyme Disease Vaccine Candidate; **2** Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate; **3** Valneva and Pfizer Report Further Positive Phase 2 Results, Including Booster Response, for Lyme Disease Vaccine Candidate, 4 Valneva Announces Positive Initial Results for Second Phase 2 Study of Lyme Disease Vaccine Candidate VLA15 **5** Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate

Chikungunya Vaccine – VLA1553

VLA1553: Single Shot Chikungunya Vaccine Candidate

Most Clinically Advanced Chikungunya Vaccine Program Worldwide



1. **Pre-Licensure Phase 3 clinical program successfully completed[1,2]; BLA rolling submission initiated in August 2022[3]; Targeting completion of BLA submission by end of 2022**
2. **FDA Breakthrough Therapy[4], Fast Track[5] & EMA PRIME[7] designations granted; Potentially eligible for Priority Review Voucher[6]**
3. **Single shot, live attenuated[8], prophylactic investigational vaccine targeting long lasting immunity**
4. **Up to $23.4 million awarded to Valneva for R&D by CEPI; Partnership with Instituto Butantan for LMICs[9]; Adolescent Phase 3 trial supporting potential further regulatory submissions initiated in January 2022[10]**
5. **Excellent fit with existing commercial and manufacturing capabilities**
6. **Global market, including endemic regions, estimated to exceed $500 million annually by 2032[11]**

Note: Photo credit: James Gathany. **1** Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate; 3 Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate; **4** Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate; **5** Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate; **6** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program; **7** Valneva's Chikungunya vaccine candidate awarded EMA prime designation; **8** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase); **9** Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-Income countries ; **10** Valneva Announces Initiation of Adolescent Phase 3 Trial for its Single-Shot Chikungunya Vaccine Candidate**; 11** VacZineAnalytics Chikungunya virus vaccines Global demand analysis. February 2020.

Chikungunya: A Major Public Health Threat

Mosquito-Transmitted Disease with Potentially Debilitating Consequences

Symptoms include **fever and debilitating joint and muscle pain;** infection can progress to **severe chronic symptoms** in many patients and substantial **health-economic impact**[1]

Large, explosive outbreaks affecting up to **one-third to three-quarters** of the population[2]**; difficult to predict** next outbreaks[3]

Majority of cases in **Asia, Africa and Latin** America[1] - outbreaks in **Italy, France** and **outbreak risk in US** [2,3,4] linked to mosquito spread

No vaccine or specific treatment is currently available for chikungunya

1. Silva LA et al. J Clin Invest. 2017 Mar 1;127(3):737-749 2. Staples et al. CDC Yellow Book 2020, Chapter 4. 3. Bettis et al, PLOS Neglected Tropical Diseases 16(1): e0010069.
4. Lindsey et al *Am J Trop Med Hyg*. 2018;98(1):192-197. doi:10.4269/ajtmh.17-0668

VLA1553: Clinical Data Highlights[1,2]

Live-Attenuated CHIKV Vaccine Candidate Targeting Long-Lasting Immunity with a Single Shot

Immunogenicity Data

- Seroprotective* levels of antibodies (SPR) in 98.9% of participants after a single vaccination[1]
- Immunogenicity profile maintained overtime: SPR of 96.3% of participants at Day 180[1]
- Older adults (≥ 65 years) achieved similar SPR and neutralizing antibody titers as younger adults (<65 years)[1]
- 100% seroconversion after 14 days and sustained to Month 12 in preceding trial[2]

Safety Data[1]

- VLA1553 was generally well tolerated among the 3,082 subjects evaluated for safety
- Approximately 50% of study participants experienced solicited systemic adverse events, most commonly headache, fatigue and myalgia
- Majority of solicited adverse events mild or moderate. 2.0% of study participants reported severe solicited adverse events, most commonly fever.

*CHIKV neutralizing antibody titer agreed with regulators to be used as a surrogate endpoint in Phase 3, determined by µPRNT (Micro Plaque Reduction Neutralization Test) for baseline negative subjects 28 days post-vaccination.

1 Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate. **2** Wressnigg et al, Lancet ID: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30238-3/fulltext

Chikungunya Global Market Segments

Global Market for Chikungunya Vaccines Estimated to Exceed $500 Million per Year by 2032[1]

Segments Targeted Directly by Valneva

Travelers from Non-Endemic Regions

Travel vaccine for individuals travelling to areas with risk of chikungunya

Military from Non-Endemic Regions

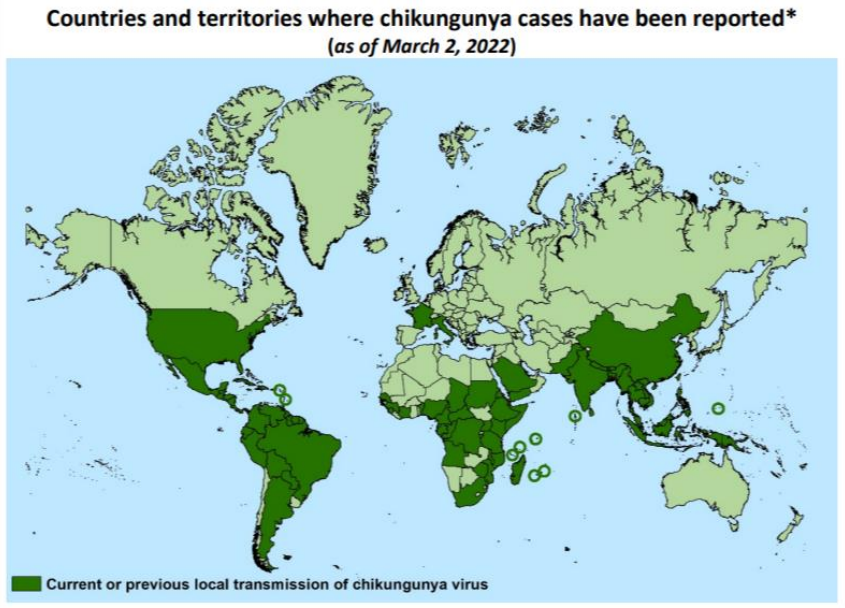
Vaccine for troops stationed in areas with risk of chikungunya

Outbreak Preparedness Non-Endemic Regions

Vaccine in areas in response to / at risk for a domestic outbreak

Endemic Region Use

Vaccine in endemic / LMIC markets, Targeted via **CEPI / Instituto Butantan Partnership**



1 VAMV005. Chikungunya virus vaccines. Global demand analysis. Feb 2020

Chikungunya Travelers Vaccine Market Segment

Launch to Leverage Existing Commercial Infrastructure & Travel Vaccine Experience

Risk areas for chikungunya include **popular tourist destinations in Latin America / Asia**

North to Central American air travel has recovered

Post-COVID, there is **increased likelihood of travelers to seek pre-travel health advice**

Recommendations for use of chikungunya vaccine in travelers will be **key to support uptake** of the vaccine, once approved

Valneva is engaging with public health policy makers to support development of recommendations

1 GAP database published by ARC. 2 International tourism, number of arrivals - Latin America & Caribbean | Data (worldbank.org) **3**. June 22 vs June 2019, IATA Air Passenger Market Analysis June 2022

Chikungunya Vaccine Program Progressing toward FDA Filing

ACIP Chikungunya Vaccines Work Group Established

Rolling submission initiated in August 2022[1]

- Pre-Licensure Phase 3 Clinical program completed, and all endpoints met [2,3]
- Breakthrough therapy designation: eligible for **priority review** request[4]
- Expected **completion of BLA submission late 2022**
- If the filing is accepted, the FDA will determine priority review eligibility and the date upon which it will complete its evaluation
- Sponsor of first BLA approved for a chikungunya vaccine is eligible for a **PRV**[5]

US CDC's Advisory Committee on Immunization Practices (ACIP) chikungunya vaccines work group constituted[6]

- No chikungunya vaccine previously licensed, therefore no existing ACIP chikungunya vaccine recommendations
- ACIP vote tentatively scheduled in Feb 2024 meeting

1 Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate **3** Valneva Successfully Completes Lot-to-Lot Consistency Trial for its Single-Shot Chikungunya Vaccine Candidate **4** Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate **5** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program **6** ACIP website: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/01-02-03-CHIKUNGUNYA-Bell-Hills-508.pdf

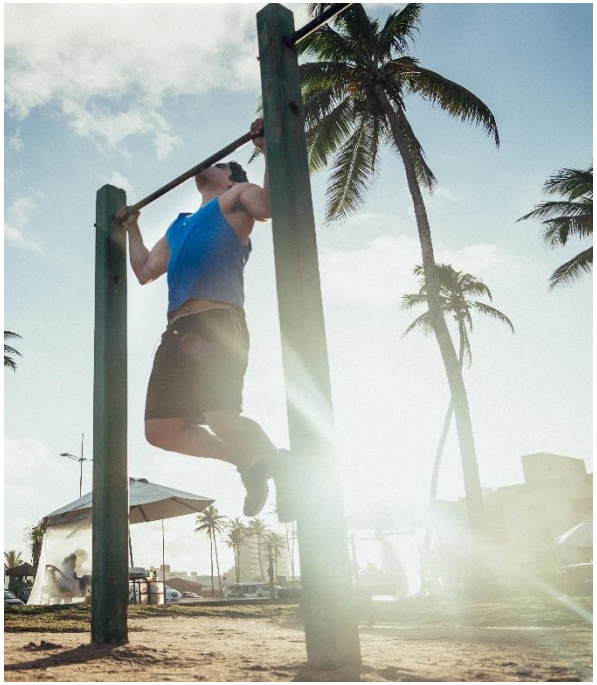
VLA1553: Development Plan & Outlook

Further Regulatory Submissions to Commence in 2023

Further regulatory submissions, including EMA, expected to commence in 2023

Ongoing clinical trials supporting future regulatory submissions

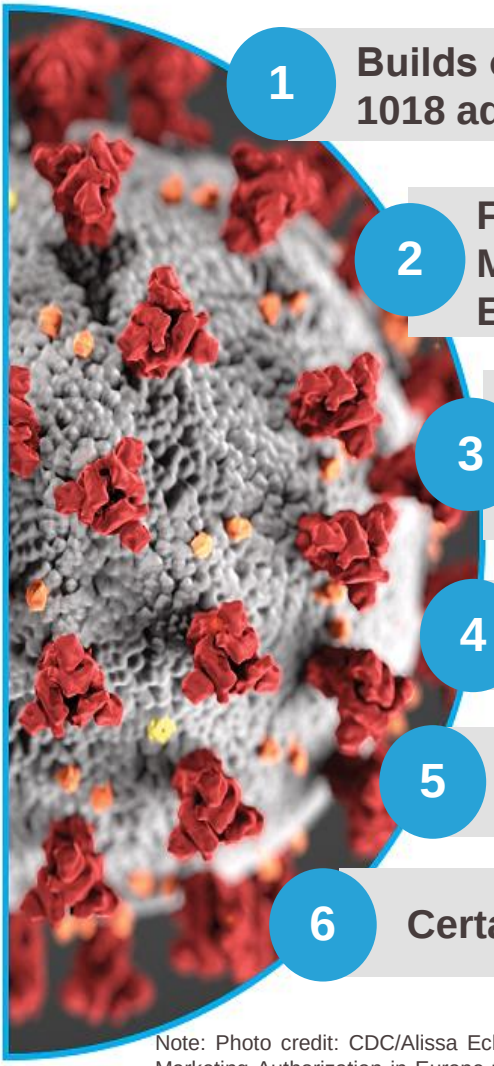
- **Adolescents clinical trial,** 750 volunteers aged 12-17 years, 12-months follow-up, Brazil
  - Data expected in H1 2023
- **Antibody persistence trial,** approx. 375 volunteers, follow-up for at least 5 years
  - 12-months data expected late 2022
- **Anticipated future trials**
  - Co-vaccination, pediatric and special populations, observational effectiveness trial



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

Valneva's COVID-19 Vaccine

VLA2001: Only Inactivated Whole-Virus COVID-19 Vaccine Approved in Europe



1. **Builds on Valneva's IXIARO® manufacturing technology, combined with Dynavax's CpG 1018 adjuvant[1]**
2. **First COVID-19 vaccine to receive standard marketing authorization in Europe[2]; UK MHRA Conditional Marketing Authorization[3] granted; Bahraini NHRA[4] and United Arab Emirates[5] Emergency Use Authorizations received; WHO recommendations received[6]**
3. **Pivotal Phase 3 trial showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability[7]; Positive homologous and heterologous booster data reported[8]; Shown to neutralize Omicron and Delta variants in laboratory studies[9]**
4. **First deliveries to EU member states including Germany in August 2022[10]; Supply of Valneva's COVID-19 vaccine to Bahrain[11]**
5. **Shelf life expected to be gradually extended to at least 24 months over time (from currently 15 months)**
6. **Certain ongoing trials will continue, in particular on the potential use as a booster**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. **1** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; **2** Valneva Receives Marketing Authorization in Europe for Inactivated Whole-Virus COVID-19 Vaccine VLA2001 **3** Valneva Receives Conditional Marketing Authorization from UK MHRA for its Inactivated COVID-19 Vaccine, **4** Valneva Receives Emergency Use Authorization from Bahrain for its Inactivated COVID-19 Vaccine VLA2001; **5** Valneva Receives Emergency Use Authorization from the United Arab Emirates for its Inactivated COVID-19 Vaccine; **6** Valneva Confirms WHO Recommendations for its Inactivated COVID-19 Vaccine; **7** Valneva Reports Positive Phase 3 Results for Inactivated, Adjuvanted COVID-19 Vaccine Candidate VLA2001 **8** Valneva Reports Further Positive Phase 3 Immunogenicity and the First Heterologous Booster Results for its Inactivated, Adjuvanted COVID-19 Vaccine VLA2001 **9** Valneva's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant **10** Valneva Confirms Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 **11** Valneva Signs Advance Purchase Agreement with Bahrain for Inactivated COVID-19 Vaccine VLA2001

Valneva to Reshape Operations to Reflect the Evolution of the COVID-19 Program

In light of reduced order volume from EU Member States[1], Valneva is evaluating its COVID-19 program and associated operations

- Valneva has suspended manufacturing of its COVID-19 vaccine
- Valneva aims to deploy approximately eight to ten million doses of remaining inventory into international markets
  - Valneva to retain inventory for potential additional supply to EU Members States participating in the APA, should demand increase
  - Valneva continuing discussions on potential additional supply and financing agreements with potential customers around the world

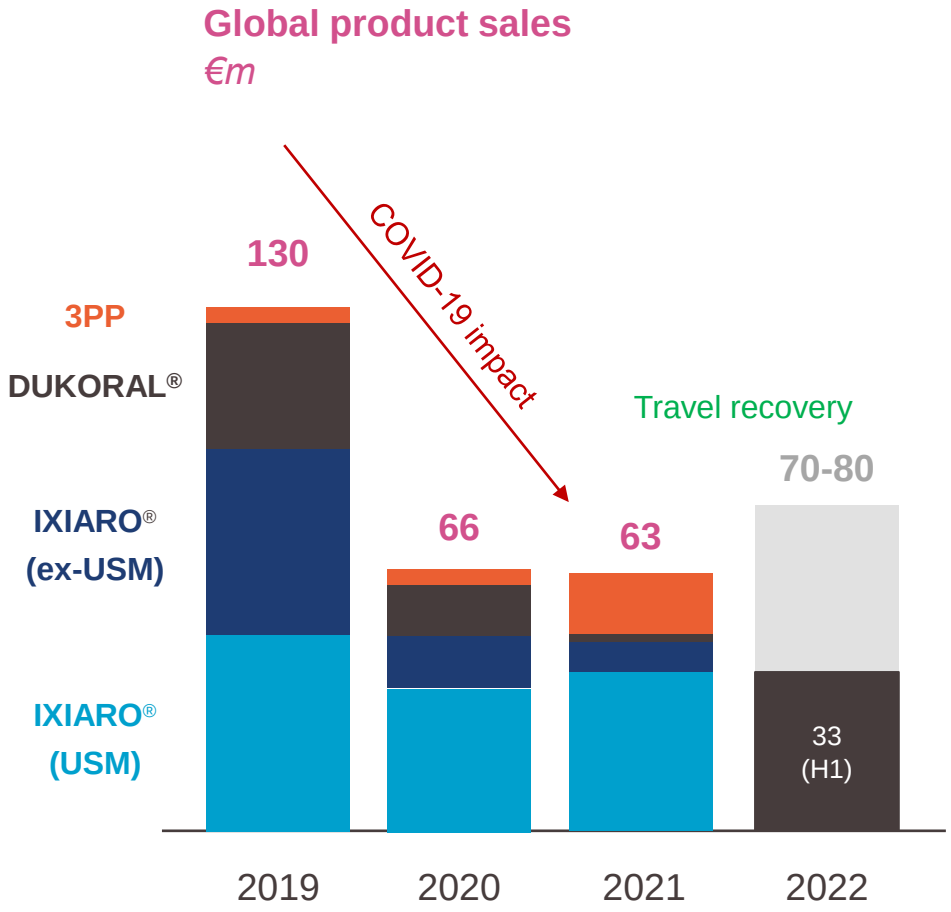
Valneva will invest in further development of its current or any potential second-generation COVID-19 vaccine only if it receives the necessary external funding or commitments to such funding in the short term

1 Valneva Confirms Amendment of Advance Purchase Agreement with European Commission for Valneva's Inactivated COVID-19 Vaccine

Commercial Products

Product Sales: Strong Growth Anticipated, Driven by Recovery of Travel Segment and Performance of 3rd Party Products

Travel Expected to Recover to Pre-COVID-19 Level by 2024[1]



DRIVERS

+ Pent-up travel demand
+ Re-establishment of Travel Medicine clinics/ramping up of resources
+ Elevated concern of infectious diseases amongst travelers
+ Increased troop deployment to Asia

BARRIERS

+ Airline capacity/staff shortages
+ Slowing economic growth and rising inflation
+ Impact of new COVID-19 waves
+ Demand for Valneva's travel vaccines may exceed Company's current supply capacity in the later part of 2022

1 IATA/ Tourism Economics (July 2022)

Commercial Strategy

Three Key Levers to Accelerate Commercial Performance

Travel health recovery

Customer engagement through Valneva Travel Health

- Building brand identity
- Elevate Valneva's reputation as a committed travel health partner for HCP and travelers
- Provide tools and services to customers supporting acceleration of travel health recovery

valneva TRAVEL HEALTH

Expand vaccine portfolio

Evaluation of new in-licensing and product acquisitions

Distribution partnerships in selected regions

- Bavarian Nordic for Rabies and TBE vaccines
- Seqirus for flu vaccines
- Kamada for Rabies IgG
- **NEW:** VBI for Hep B vaccine
- Adding complementary distribution partnerships

VLA1553 launch preparedness

Evolution of commercial infrastructure

- Optimize commercial infrastructure to support launch excellence
- Market access/ recommendations
- Market and brand development

Corporate Highlights and Newsflow

Financial Position

Cash position of €336.2 million (June 30, 2022)[1] includes:

- $20 million of an additional $40 million made available in April 2022 via upsized financing arrangement with Deerfield & OrbiMed[2]
- €90.5 ($95) million investment in Valneva by Pfizer through an Equity Subscription Agreement in June 2022[3]

Successfully raised ~$210 million in 2021

- Nasdaq listing (Q2); $107.6 million[4]
- Follow-on (Q4); $102.0 million[5]

2022 Guidance: Total revenues of ~€340 to €360 million[1], including:

- €30 to €40 million of COVID-19 vaccine sales
- €70 to €80 million of other vaccine sales
- ~€240 million of Other Revenues, primarily driven by revenues recognized from EC and UK COVID-19 contracts

1 Valneva Reports H1 2022 Results and Provides Corporate Updates; **2** Valneva Announces Upsized Financing Arrangement with Leading US Healthcare Funds Deerfield and OrbiMed; **3** Valneva and Pfizer Announce Closing of Equity Investment ; **4** Gross proceeds from U.S. public offering and EU private placement; **5** Gross proceeds from global public offering in the U.S. and Europe

Delivering on Valneva's Value Proposition

Sharpened Focus after Two Years of COVID-19

Building on Key Achievements

Continued success in R&D - differentiated assets addressing unmet medical needs

- Lyme disease in Phase 3
- Chikungunya BLA submission initiated
- Promising pre-clinical portfolio
- First full marketing authorization in Europe for COVID-19 vaccine

Execution Strategy

Continue progressing Valneva's advanced programs

- Achieve chikungunya product approvals, prepare market entry and launch
- Support Pfizer in progressing Lyme

Progress new candidates from pre-clinical to clinical stage

- Advance promising early-stage candidates
- Evaluate clinical assets for potential in-licensing

Maximize value from commercial products

- Profit from resurging travel
- Continue to increase contribution from further 3rd-party distribution deals
- Sell available COVID-19 vaccine doses

Right-size operations in view of commercial prospects for COVID-19 vaccine

Key Upcoming Catalysts and News Flow

Lyme disease vaccine candidate VLA15

- Phase 3 trial enrollment completion expected in Q2 2023

Chikungunya vaccine candidate VLA1553

- Targeting the end of 2022 for completion of the Biologics License Application (BLA) submission
- 12-month antibody persistence data expected in late 2022
- Adolescent study results expected in H1 2023

COVID-19 vaccine candidate VLA2001

- Further clinical data expected Q4 2022[1]
- Leverage approvals to commercialize in key territories; explore strategic options
- Maximize value from remaining inventory

1 From an ongoing heterologous booster trial of VLA2001, VLA2001-307, which aims to provide booster data following primary vaccination with an mRNA vaccine or natural infection caused by COVID-19

Thank you
Merci
Danke
Tack

valneva