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 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**

- **Product sales of €74.4 million YTD 2022 vs €45.5 million in first nine months of 2021**
- **Total revenues of ~€249.9 million YTD 2022, a ~3.5-fold increase vs 2021; FY 2022 guidance of €340 to €360 million**
- **Cash position of €261.0 million at September 30, 2022 (excludes €102.9 million in gross proceeds from October 2022 public offering)**

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

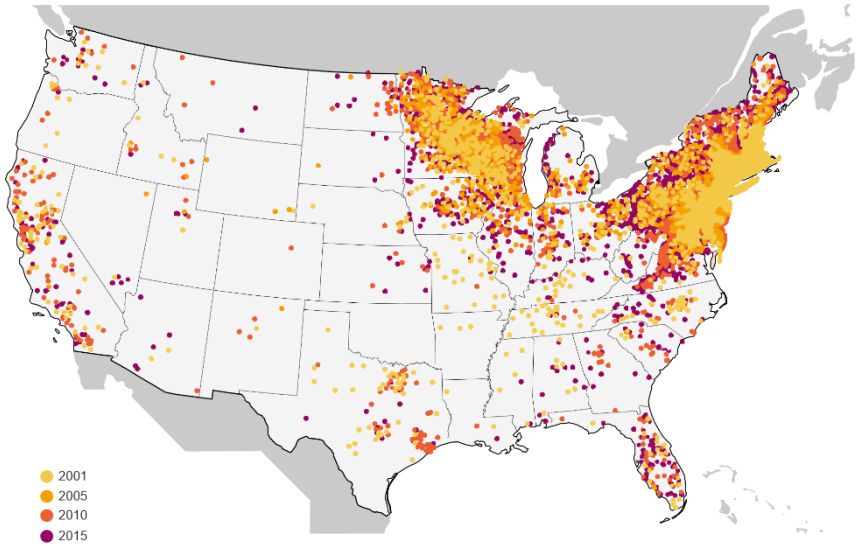
Early signs include **flu-like symptoms**[1] and **Erythema migrans rash**[2] which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

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

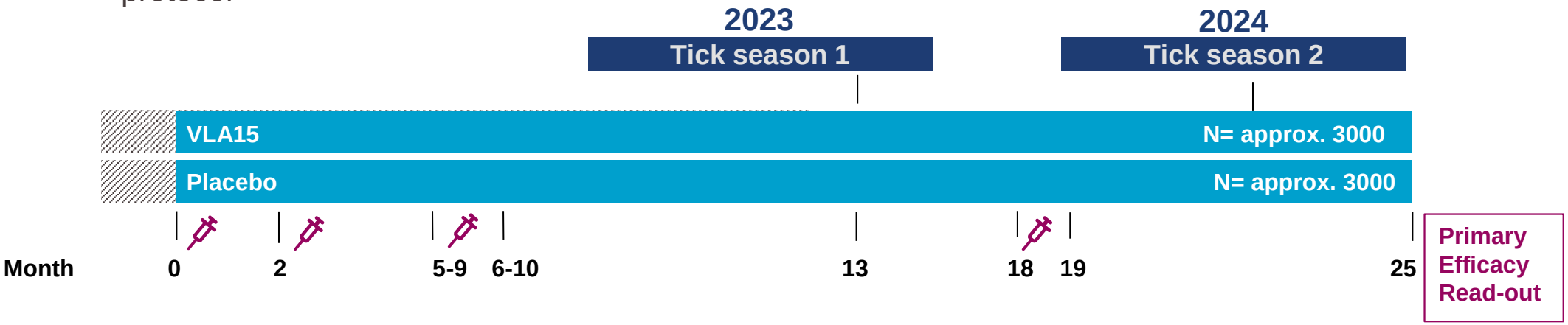
1. **Phase 3 study initated[1] following positive results for three Phase 2 clinical trials[2,3,4], including first pediatric data[5]**
2. **Exclusive, worldwide partnership with Pfizer; terms updated in June 2022 in conjunction with Pfizer's €90.5 ($95) million equity investment in Valneva[6]**
3. **Multivalent 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]

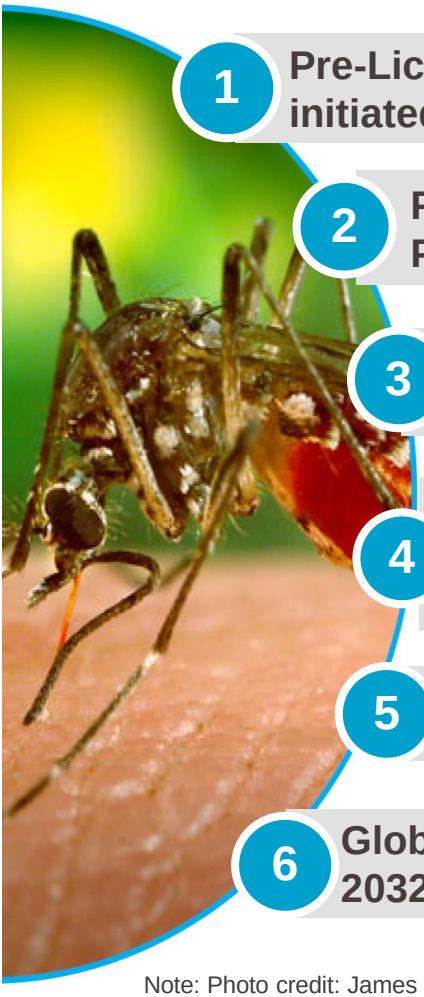
- Immunogenic across all serotypes and dose groups; higher doses elicited higher antibody responses
- Encouraging immunogenicity profile confirmed, including in older adults (ages 50-65)
- VLA15 was generally safe and well tolerated. No related SAEs were observed in any treatment group.

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

- Seroresponse[3] Rate (SRR) in 98.9% of participants after a single vaccination
- Immunogenicity profile maintained over time: SRR of 96.3% of participants at Day 180[1]
- Older adults (≥ 65 years) achieved similar SRR 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.

≥≥

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; **3** CHIKV neutralizing antibody titer of ≥150 by $\mu PRNT_{50}$ (Micro Plaque Reduction Neutralization Test), agreed with regulators to be used as a surrogate endpoint in Phase 3

Seroresponse Rate in Older Participants (VLA1553-301)

Additional Data in Adults >=65 Years Confirm High SRR Seen in Primary Analysis

	18-64 years		≥ 65 years	
Subjects with Seroresponse	**VLA1553** N=269	**Placebo** N=94	**VLA1553** N=107	**Placebo** N=33
Day 29[a] n (%)	251 **248 (98.8)**	88 **1 (1.1)**	104 **103 (99.0)**	33 **0**
Day 180[a] n (%)	241 **233 (96.7)**	87 **2 (2.3)**	104 **99 (95.2)**	33 **0**

- **107 participants aged >= 65 years were included in a secondary analysis population**
- **Day 29 Seroresponse rate (SRR):**
  - **99.0% (103/104, 95% CI: 94.8 – 100.0)**
- **High SRR was maintained after six months at 95.2% (99/104, 95%CI: 89.1 - 98.4)**

a. Number of µPRNT baseline negative (<20) subjects with non-missing titers at the specified time point.
Percentages are based on the number of subjects with non-missing titers at the visit.
Seroresponse is defined as $\mu PRNT_{50} \geq 150$ for µPRNT baseline negative (<20) subjects.

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

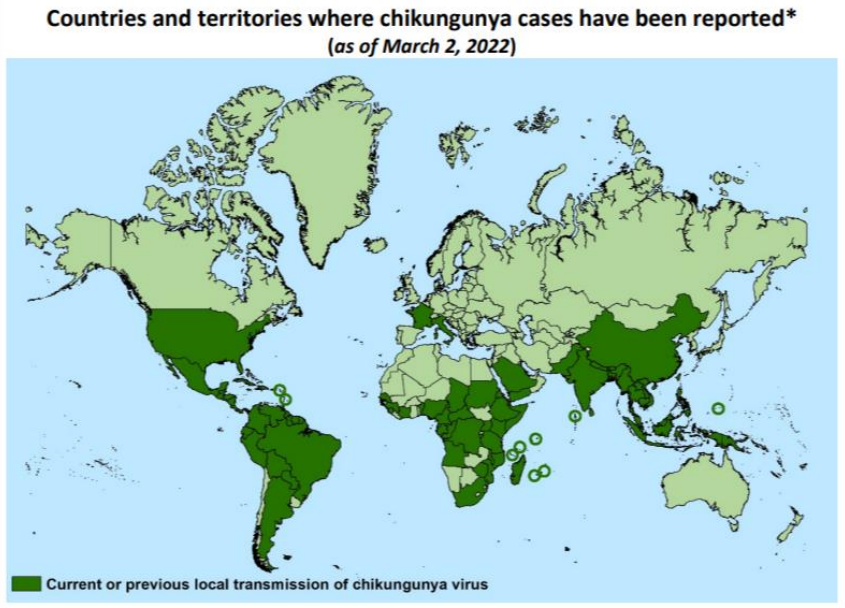
Vaccine for troops stationed in areas with risk of chikungunya

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

Valneva Presented VLA1553 at the US CDC's October ACIP[1] Meeting

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 by the end of 2022**
- If the FDA accepts the filing, it will determine priority review eligibility along with the action due date upon which it will complete its evaluation
- Sponsor of first BLA approved for a chikungunya vaccine is eligible for a **PRV[5]**

Valneva presented an overview of VLA1553 at US CDC's October ACIP meeting

- No chikungunya vaccine previously licensed, therefore no existing ACIP chikungunya vaccine recommendations
- The chikungunya working group[6] provided a preliminary review and timeline towards ACIP's recommendation decision
- Ahead of anticipated February 2024 ACIP vote, the working group plans to present further on CHIKV traveler epidemiology and disease burden, a more comprehensive review of immunogenicity and safety data as part of its GRADE[7] assessment, and longer-term additional data in younger age groups.

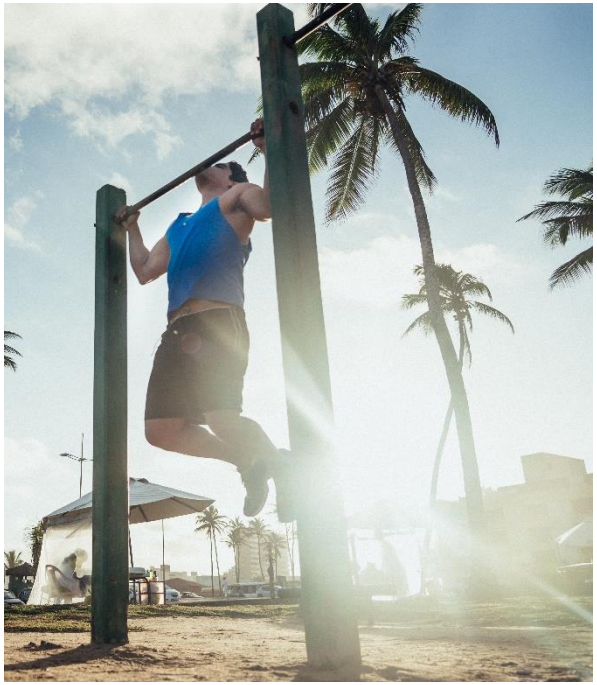
1 Advisory Committee on Immunization Practices (ACIP) **2** Valneva Initiates Rolling Submission of FDA Biologics License Application for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Successfully Completes Pivotal Phase 3 Trial of Single-Shot Chikungunya Vaccine Candidate **3** Valneva 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 **7** Grading of Recommendations, Assessment, Development and Evaluation

VLA1553: Development Plan & Outlook

Further Regulatory Submissions to Commence in the First Half of 2023

Ongoing clinical trials supporting future regulatory submissions

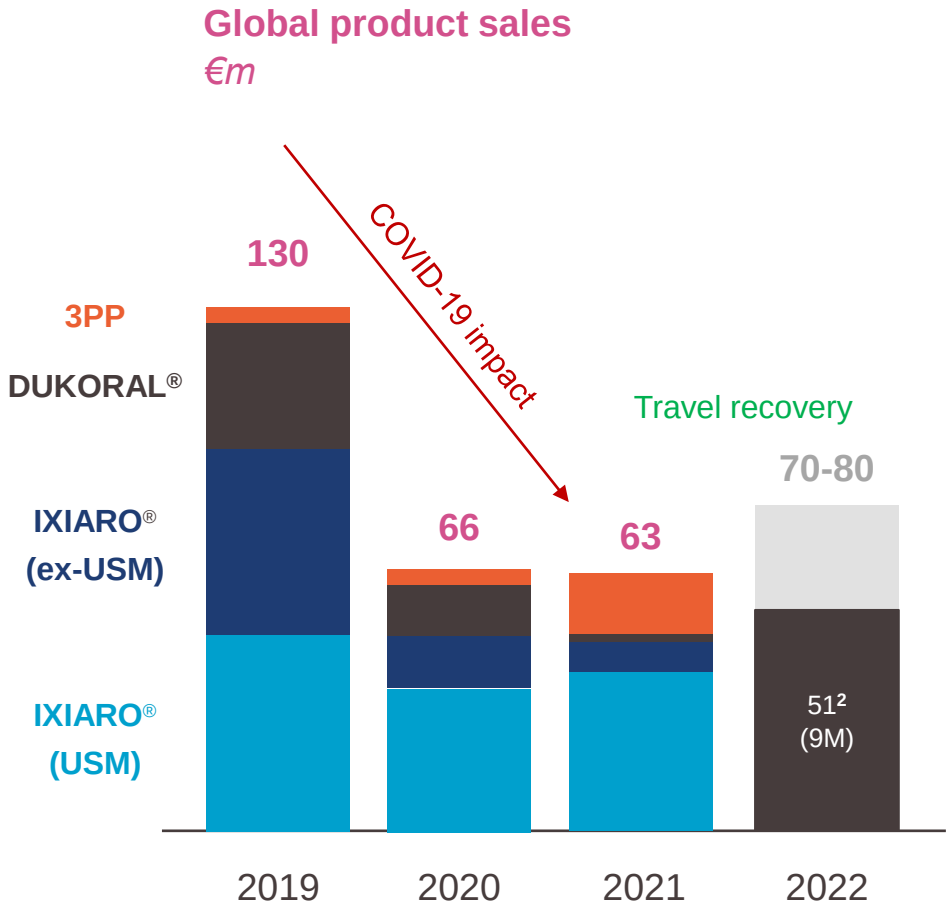
- **Antibody persistence trial,** approx. 375 volunteers, follow-up for at least 5 years
  - 12-months data expected late 2022
- **Adolescents clinical trial,** 750 volunteers aged 12-17 years, 12-months follow-up, Brazil
  - Data expected in H1 2023
- **Anticipated future trials**
  - Co-vaccination,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



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); **2** €50.6 million in product sales – excluding COVID-19 vaccine sales – as of September 30, 2022

Commercial Portfolio: Strong Sales Performance of €74.4 Million in the First Nine Months of 2022

Nine-Month 2022 product sales outside of COVID-19 grew by 11.2% vs. prior period

Significant recovery in travel markets

- Product sales of the **Japanese encephalitis vaccine** in the travel market increased to €19.4 million compared to €4.6 million (9M 2021)
- Product sales of the **cholera vaccine** increased significantly to €9.2 million compared to €0.5 million (9M 2021)
- **Third-party product** sales increased to €18.4 million from €11.2 million (9M 2021), driven by growth related to Valneva's distribution agreement with Bavarian Nordic

COVID-19 vaccine sales

- The **COVID-19 vaccine** generated sales of €23.9 million
- Deliveries to EU member states who participated in the APA
- Supply of Valneva's COVID-19 vaccine to Bahrain

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

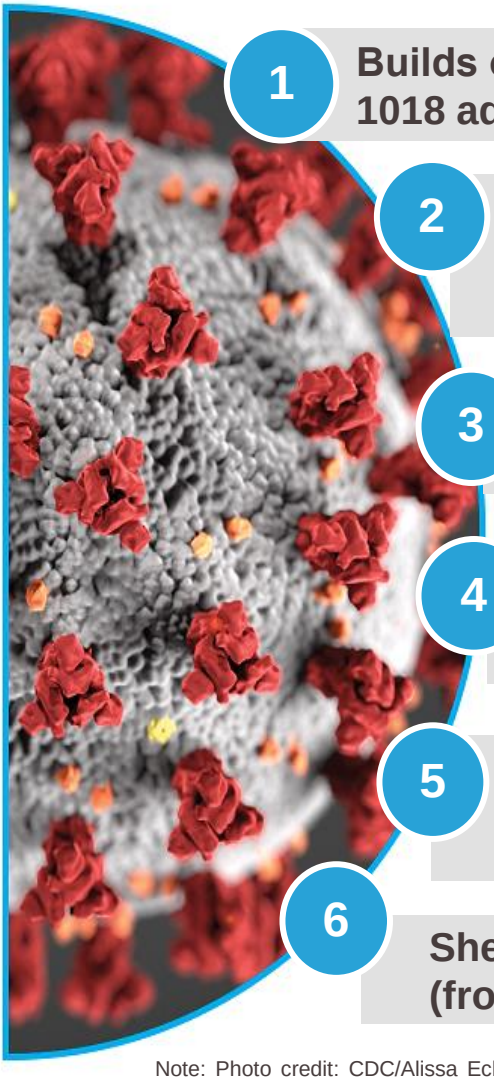
Evolution of commercial infrastructure

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

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**
3. **WHO recommended use of the vaccine, including for a booster dose of VLA2001 four to six months after completion of the primary series[6]**
4. **Pivotal Phase 3 trial showed superiority vs. AstraZeneca's Vaxzevria and significantly more favorable tolerability[7]; Shown to neutralize Omicron and Delta variants in laboratory studies[8]**
5. **Positive homologous and heterologous booster data reported[9], additional heterologous booster data following primary vaccination with an mRNA vaccine or natural COVID-19 infection expected in the fourth quarter of 2022**
6. **Shelf life expected to be gradually extended to at least 24 months over time (from 15 months currently)**

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's Inactivated COVID-19 Vaccine Candidate Shown to Neutralize Omicron Variant; **9** Valneva Reports Further Positive Phase 3 Immunogenicity and the First Heterologous Booster Results for its Inactivated, Adjuvanted COVID-19 Vaccine VLA2001

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

- In light of the reduced order volume from EU Member States[1], Valneva suspended internal and terminated external manufacturing of the vaccine
- Valneva retained inventory for potential additional supply to EU Members and is continuing discussions on potential additional supply agreements and financing with governments around the world to deploy remaining inventory
- Valneva is in the process of re-sizing its operations which is expected to result in a reduction of approximately 20% to 25% of its existing workforce
- Post restructuring, the Company's workforce is expected to be ~25% above pre-COVID levels enabling the Company to retain talents and expertise to successfully execute on its strategy
- This re-sizing will allow the Company to increase efficiency and focus on its operational and strategic business objectives
- It is also expected to result in annualized financial savings of approximately €12 million

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

Corporate Highlights and Newsflow

Delivering on Valneva's Value Proposition

Optimizing the Organization and Sharpening its Focus on Investments that Will Create Value for the Company

Continue progressing Valneva's advanced programs	Progress new candidates from pre-clinical to clinical stage	Maximize value from commercial products	Resize operations
▪ Prepare for the potential launch of chikungunya vaccine candidate in the U.S. ▪ Support Pfizer in progressing Lyme	▪ Advance promising early-stage candidates ▪ Evaluate assets for potential in-licensing	▪ Profit from resurging travel ▪ Increase contribution from further 3rd-party distribution deals ▪ Sell available COVID-19 vaccine doses	▪ Reduction of approximately 20 to 25% of existing workforce ▪ Expected savings of approximately €12 million annually expected

Key Upcoming Catalysts and News Flow

Lyme disease vaccine candidate VLA15

- Phase 3 trial enrollment completion expected in Q2 2023

Chikungunya vaccine candidate VLA1553

- Completion of BLA submission expected at the end of 2022
- 12-month antibody persistence data expected in late 2022
- Adolescent study results expected in H1 2023

COVID-19 vaccine 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