valneva

Advancing Vaccines for Better Lives

Company Presentation
Goldman Sachs Biotech Symposium

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Valneva in Summary

We are **a specialty vaccine company** focused on the **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
- **Product development and regulatory expertise** with clear demonstrated ability of rapidly moving new vaccines through the clinic to commercialization
- **Highly developed, nimble and sophisticated manufacturing infrastructure**
- **Two commercialized vaccines, a specialist sales infrastructure and distribution rights for third-party vaccines**
- **Highly experienced leadership team with expertise in the vaccine space**

Research & Development

Valneva Has An Advanced Clinical Pipeline

[1] VLA15 received Fast Track designation from the FDA. [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] 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
Note: We are developing VLA1601, a highly purified inactivated vaccine candidate for Zika Virus and VLA84, a vaccine candidate against Clostridium difficile

Lyme Disease Vaccine – VLA15

Lyme Disease Is a Major Health Issue

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

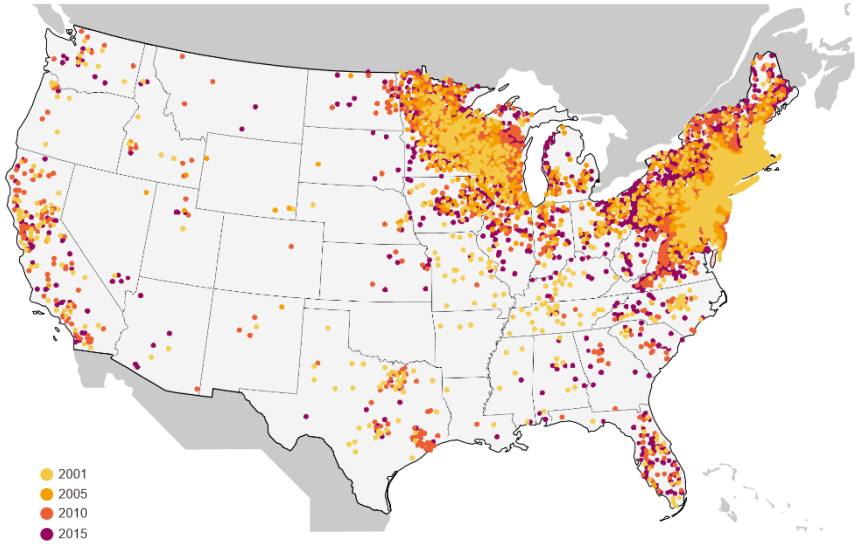
Early signs include **flu-like symptoms**[1] and **Erythema migrans rash**[2] which, if left untreated, can spread to joints (**arthritis**), heart (**carditis**) and cause **neurological problems**

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 – 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. **FDA Fast Track Designation granted**
2. **Initial results reported from Phase 2 trials [1, 2], Recruitment completed for Phase 2 trial VLA15-221 incl. pediatric participants[3]**
3. **Multivalent vaccine (six serotypes) to protect against Lyme disease in the United States and Europe**
4. **Follows proven Mechanism of Action for a Lyme disease vaccine**
5. **Exclusive, worldwide partnership with Pfizer**

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 and Pfizer Complete Recruitment for Phase 2 Trial of Lyme Disease Vaccine Candidate

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

Valneva's Response to the Global COVID-19 Crisis

Well-Known Inactivated Approach Based on Proven Technology

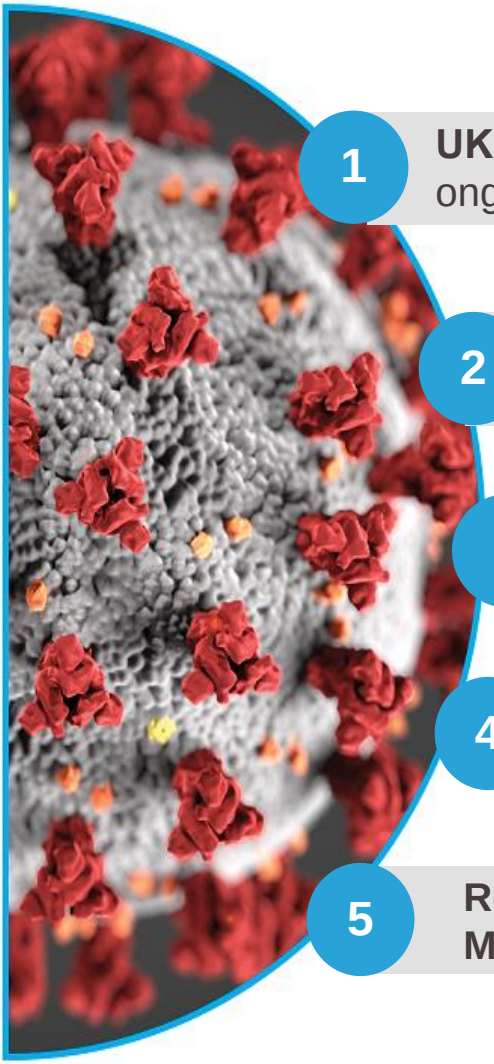
Intended for active immunization of **at-risk populations** to prevent carriage and symptomatic infection with COVID-19 during the **ongoing pandemic** and potentially **later for routine vaccination,** including addressing **new variants**

May be particularly well suited for boostering, as repeat booster vaccinations have been shown to work well with whole virus inactivated vaccines

Inactivated vaccines have historically been used in all patient groups, including the most vulnerable populations

Leverages the manufacturing platform used for Valneva's approved Japanese encephalitis vaccine, IXIARO®

VLA2001 – The Only Inactivated Vaccine in Clinical Development in Europe



1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding; ongoing dialogue with the European Commission
2. **Program acceleration enabled through use of Valneva's FDA-registered facility in UK; commercial manufacturing commenced January 2021**[2]
3. **Combines Valneva's proven approach of inactivated vaccines with Dynavax's advanced CpG 1018 adjuvant**[3]
4. **Phase 1/2 clinical trial results reported**[4]**, Phase 3 trial "Cov-Compare" fully recruited**
5. **Rolling submission to MHRA commenced in Aug. 2021. Regulatory submission to MHRA is planned in autumn 2021 and deliveries thereafter, subject to approval**

Note: Photo credit: CDC/Alissa Eckert, MSMI; Dan Higgins, MAM. **1** Valneva announces major COVID-19 vaccine partnership with U.K. Government.**2** Valneva commences manufacturing of its Inactivated, Adjuvanted COVID-19 vaccine, completes Phase 1/2 study recruitment. **3** Valneva and Dynavax announce commercial supply agreement for Inactivated, Adjuvanted COVID-19 vaccine; **4** Valneva Reports Positive Phase 1/2 Data for Its Inactivated, Adjuvanted COVID-19 Vaccine Candidate, VLA2001

VLA2001: Development Outlook

Phase 3 trial "Cov-Compare" Recruitment Completed[1]; Rolling Submission to MHRA has Commenced[2]

"Cov-Compare" (VLA2001-301) is a randomized, observer-blind, controlled, comparative immunogenicity trial in over 4,000 adults

- Immunological comparison against a licensed vaccine to reasonably predict efficacy (superiority of VLA2001 in a two-dose immunization schedule four weeks apart - GMTs of neutralising antibodies, at two weeks after the second vaccination)
- Study conducted in UK supported by DHSC/NIHR, including funding
- Protocol agreed with MHRA; discussion with other regulatory bodies ongoing
- Cov-Compare Phase 3 topline data expected early in the fourth quarter. Valneva has commenced rolling submission with MHRA and, subject to Phase 3 data, believes that initial approval may be granted by the end of 2021.

Valneva participating in the world's first COVID-19 vaccine booster trial in the UK[3]

Additional studies in process (inc study -304 in New Zealand)

Valneva studying other variants, to be in a position to manufacture variant-based vaccines

1 Valneva Completes Phase 3 Trial Recruitment for its Inactivated COVID-19 Vaccine Candidate, 2 Valneva Commences Rolling Submission to MHRA for its Inactivated, Adjuvanted COVID-19 Vaccine; 3 Valneva to Participate in the World's First COVID-19 Vaccine Booster Trial in the UK

Chikungunya Vaccine – VLA1553

VLA1553: Only Chikungunya Vaccine Candidate in Phase 3 Today

1. **Positive Topline Results for Phase 3 trial VLA1553-301 reported[1]; Use of surrogate marker for Phase 3 endpoint confirmed by FDA[2]; Accelerated Approval Pathway confirmed[3]**
2. **Potentially eligible for Priority Review Voucher[4]; FDA Fast Track[5] and EMA PRIME[6] designation granted**
3. **Single shot, live attenuated[7] prophylactic vaccine targeting chikungunya virus neutralization**
4. **Up to $23.4 million awarded to Valneva for R&D by CEPI; Partnership with Instituto Butantan for LMICs[8]**
5. **Excellent fit with existing commercial and manufacturing capabilities**

Note: Photo credit: James Gathany. **1** Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates **3** Valneva reports positive End-of-Phase 2 Chikungunya meeting with the U.S. FDA and sets stage for Phase 3 Study; **4** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program. **5** Valneva awarded FDA Fast Track Designation for Chikungunya vaccine candidate. **6** Valneva's Chikungunya vaccine candidate awarded EMA prime designation. **7** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase). **8** Valneva to partner with Instituto Butantan on single-shot Chikungunya vaccine for low- and middle-Income countries.

VLA1553: Development Outlook

Pivotal Phase 3 Trial – Final Data Expected Within the Next 6 Months

Most advanced clinical development program in the world

- Pivotal Phase 3 safety and immunogenicity trial progressing towards final analysis, expected within the next six months[1]
- Lot-to-Lot consistency trial fully recruited (VLA1553-302), data expected late 2021[2]
- Antibody persistence follow-up trial (VLA1553-303) ongoing – up to 375 volunteers from VLA1553-301 will be followed up annually for five years after a single immunization[1]

Valneva is discussing with the FDA to bring VLA1553 to a potential licensure as soon as possible

1 Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate; **2** Valneva Initiates Phase 3 Clinical Lot Consistency Study for its Single-Shot Chikungunya Vaccine Candidate. **3** In collaboration with development partner Instituto Butantan, under CEPI funding; **4** Valneva Announces Publication of 2020 Universal Registration Document and Provides Business Updates **5** https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.

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/NZ and smaller markets**
- **Marketing & Distribution of 3rd party specialty vaccines[2]**

- **Three year supply deal with US Military/Dept of Defense representing a base value of $118m if options are exercised. First year option exercised in Sep. 2021**

- **Valneva believes that 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, [2]Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership

Corporate Highlights and Newsflow

Strong Cash Position of €329.8 million at End of June including Proceeds from US IPO

- **Cash / cash equivalents of €329.8 million at end of June (including proceeds from Global Offering)**
  - The increase in liquid funds compared to December 31, 2020 results from payments made by the UK government within the framework of the UK COVID-19 partnership

- **Successful Nasdaq listing (Q2); $107.6 million of gross proceeds**
  - Raised in an initial US public offering and a concurrent private placement in Europe

Key Upcoming Catalysts and Potential Inflection Points

Chikungunya vaccine candidate VLA1553

- Final Phase 3 trial results
- Topline data of clinical lot-to-lot consistency Phase 3 trial

Lyme disease vaccine candidate VLA15

- Further Phase 2 milestones and read-outs

COVID-19 vaccine candidate VLA2001

- Clinical results including Cov-Compare and COV-Boost
- Marketing authorization submission, subject to data
- Further clinical development plans to complement UK trials

Thank you
Merci
Danke
Tack

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