Advancing Vaccines for Better Lives

Guggenheim Vaccines Day
October 5, 2020

valneva

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As a specialty vaccine company, Valneva currently focuses its development activities on three unique vaccine candidates:

Lyme disease

Partnered with Pfizer

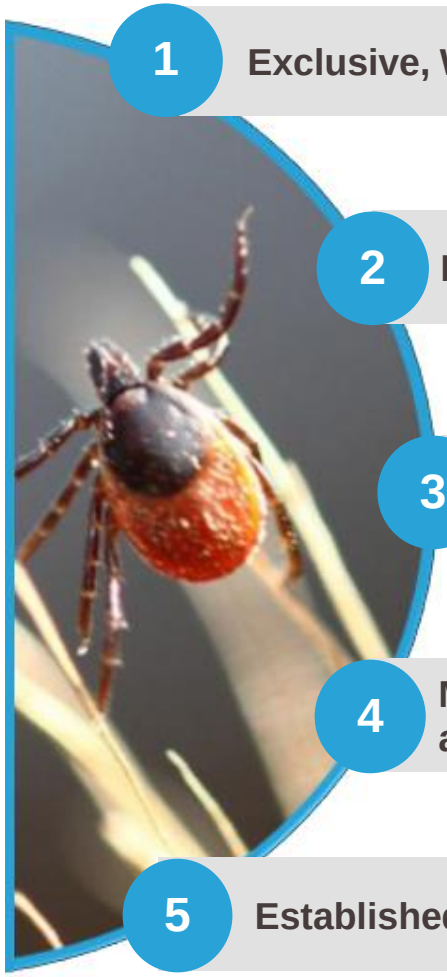
COVID-19

UK gov deal of up to €1.4B

Chikungunya

Only chik program in Ph3

VLA15: Only Lyme disease vaccine in clinical development today



1. Exclusive, Worldwide Partnering Deal with Pfizer
2. Positive initial results for first Phase 2 study (primary endpoint) released July 2020[1]
3. FDA Fast Track Designation granted
4. Multivalent vaccine (six serotypes) to protect against Lyme disease in N. America and Europe
5. Established and proven Mode of Action for a Lyme disease vaccine

1 Valneva Announces Positive Initial Results for Phase 2 Study of Lyme Disease Vaccine Candidate

VLA15: Exclusive, Worldwide Partnering Deal with Pfizer and Positive Initial Phase 2 Results

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

- Valneva and Pfizer working together throughout VLA15 development
- Pfizer to fund 70% of all development costs through program completion
- Valneva eligible to receive a total of $308 million upfront and milestone payments ($130 million already received[2])
- Pfizer to pay Valneva tiered royalties starting at 19%

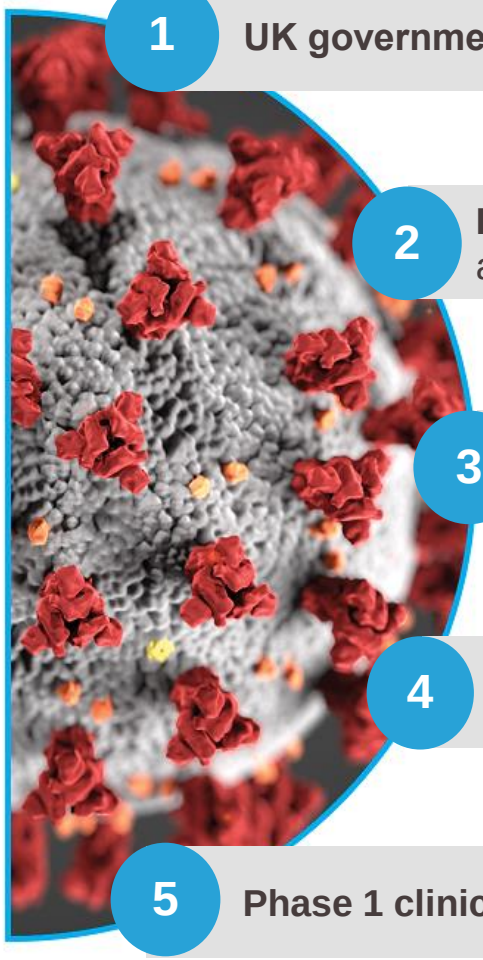
Positive initial results for first Phase 2 study (VLA15-201)[3]

- Phase 2 study VLA15-201 met its endpoints
- Compared to Phase 1, the higher doses used in this trial elicited higher antibody responses across all serotypes
- Encouraging immunogenicity profile confirmed, including in older adults (50-65 years)
- VLA15 generally safe across all dose and age groups tested

Initial results for second Phase 2 study, VLA15-202, expected in Q4 2020

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

VLA2001: Only inactivated Covid-19 vaccine candidate in US & EU



1. **UK government deal worth up to €1.4 billion**[1] with development and manufacturing funding
2. **Leverages Valneva's existing capabilities:** BSL3 labs recommissioned for pre-clinical activities**;** Plug-and-play at Valneva's FDA-approved Livingston manufacturing facility
3. **Facilitated program acceleration through use of Valneva's FDA-approved platform**
4. **Combines Valneva's proven approach with Dynavax's advanced CpG 1018 adjuvant**[2]
5. **Phase 1 clinical trials to commence by end of 2020 (subject to successful preclinical work)**

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; **Photo credit**: CDC/Alissa Eckert, MSMI; Dan Higgins, MAMS

VLA2001: Agreement to Provide 60-190 Million Doses of Inactived 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]
- UK gov has purchased 60 million doses worth approximately €470 million for 2021
  - Options to purchase up to 130m doses worth up to €900 million between 2022 and 2025
- Vaccine to be manufactured at Valneva's facilities in Livingston, Scotland[2]
  - Agreement includes funding for expansion of Valneva's UK-based manufacturing facility and Ph1/2 clinical trials
- Valneva plans further investments in both its Scottish and Swedish facilities

Benefits of an Inactivated Vaccine Approach

- Inactivated vaccines are well studied and widely used
- Can be used in at risk groups (i.e., pregnant women, older and certain immunocompromised patients)
- Some other SARS-CoV-2 approaches (e.g., RNA- and DNA-based) have never been approved in humans
- Expected to be stable therefore VLA2001 likely requires standard cold chain storage (2 to 8°)

VLA2001 to commence Phase 1 clinical trials before the end of 2020

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

Clinical Target Product Profile of Covid-19 Vaccines

Key considerations

- **Immunogenicity/efficacy**
  - › Induction of sustainable protection with rapid onset for use during outbreak in a broad population
  - › Protection in the population at risk for severe or lethal diseases

- **Safety profile**
  - › Acceptable risk - benefit profile

Vaccines solutions are needed as herd immunity will probably not be achieved by natural infections and treatments are not in sight

VLA1553: Most advanced single-shot chikungunya vaccine candidate

1. Phase 3 initiated in September 2020[1]; Positive EoP2 meeting with the FDA; Accelerated Approval Pathway confirmed[2]
2. Priority Review Voucher eligible; FDA Fast Track Designation granted[3]
3. Up to $23.4 million (€20.3 million) awarded to Valneva for R&D by CEPI
4. Seamless fit with existing commercial and manufacturing capabilities as a plug-and-play asset; Partnership with Instituto Butantan for LMICs[4]
5. Monovalent live attenuated[5] prophylactic vaccine targeting chikungunya virus neutralization
6. Currently no preventive vaccines or effective antiviral treatments exist for chikungunya

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 to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries; **5** CHIKV LR2006-OPY1 infectious clone was attenuated by deleting large part of gene coding nsP3 (alphavirus-replicase; Photo credit: James Gathany

VLA1553: First Phase 3 Clinical Program in the World

VLA1553-301 Initiated: Study Details

- Double-blinded, placebo-controlled, multi-center study
  - Conducted in the U.S.
- ~4,000 healthy adults aged 18 or above
  - Followed for a total of six months
- Randomized into two groups (receiving VLA1553 or placebo)
- **Primary endpoint**: Demonstrate safety and immunogenicity 28 days after a single-shot vaccination
- Subset of participants to be tested for sero-protection based on an immunological surrogate (under the Accelerated Approval pathway)

Study is expected to take nine months. BLA process thereafter.

1 Valneva Initiates Phase 3 Clinical Study for its Chikungunya Vaccine Candidate VLA1553

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**
- 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

New 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 to commence 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

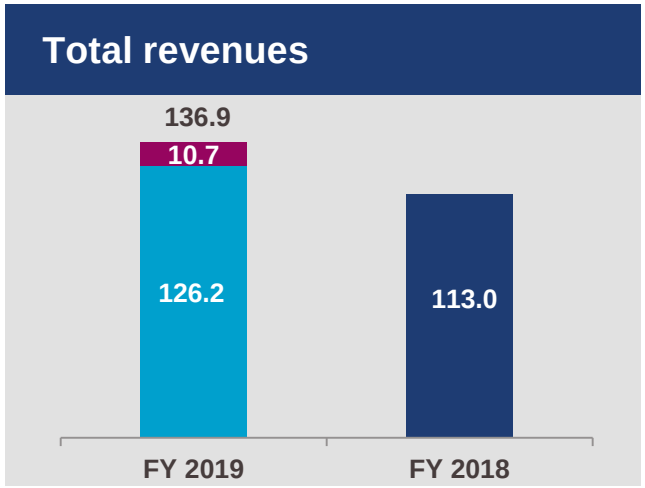
- In several markets, incl. EU, indicated for cholera only
- **Only approved cholera vaccine available for Canadian, European and Australian travelers**
  - ~3-5 million cholera cases, 100,000-120,000 deaths/year[2]
  - ~5-18 million reported ETEC cases/year[3] (ETEC is the most frequent form of traveler's diarrhea)
  - WHO pre-qualification widely used in other countries
  - Asian manufacturers predominantly serve local markets

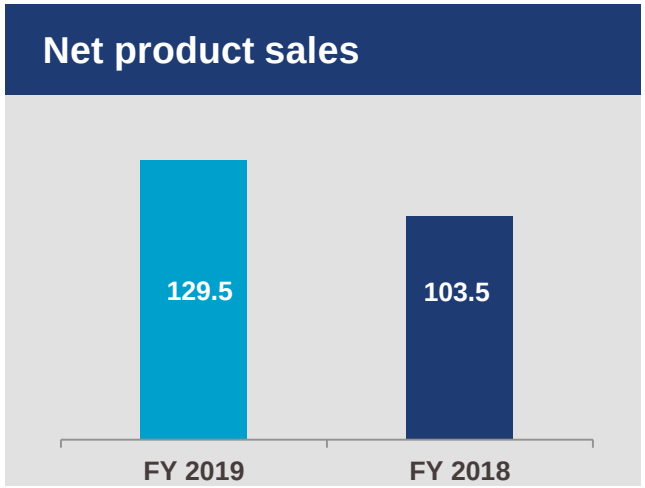
1 Indications differ by country - Please refer to Product / Prescribing Information (PI) / Medication Guide approved in your respective countries for complete information, incl. dosing, safety and age groups in which this vaccine is licensed, ETEC = Enterotoxigenic Escherichia coli (E. Coli) bacterium; **2** 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;

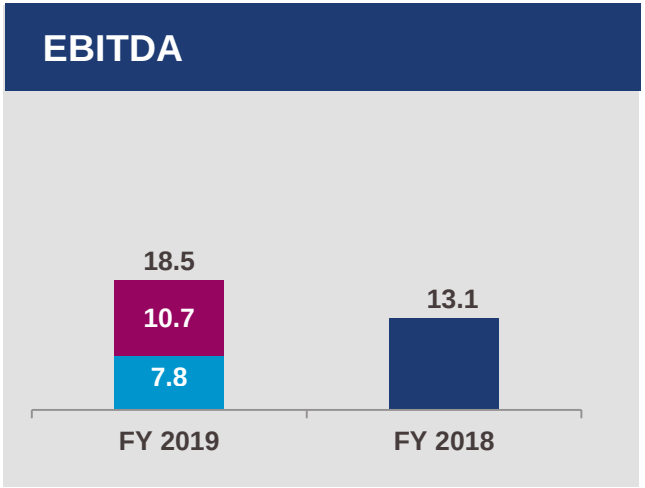
Strong Financials in 2019 (unaudited)

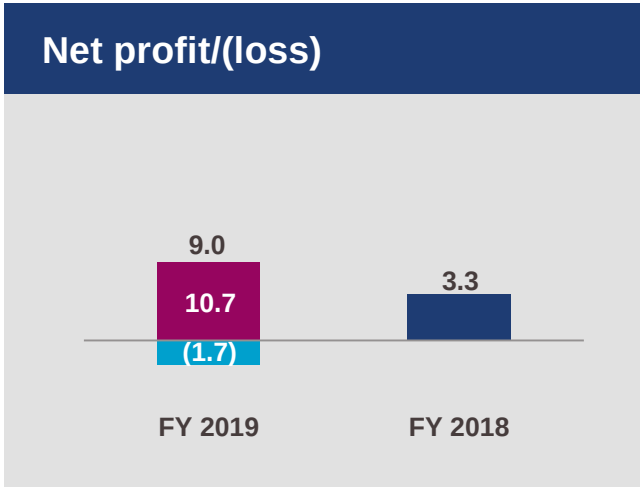
Financial results highlights (IFRS, € million) incl. GSK SAA termination effects

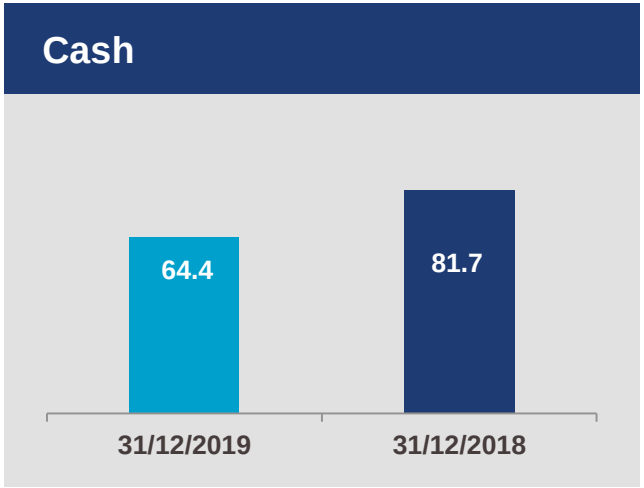
GSK SAA termination effects











Key Upcoming Newsflow

Lyme disease vaccine candidate VLA15

- **Further Phase 2 data expected Q4 2020**

Chikungunya vaccine candidate VLA1553

- **Phase 3 recruitment completion expected in Q4 2020**
- **Top line data end of Q1 2021**

Initiation of Ph1 COVID-19 vaccine clinical trial

- **Top line data end of Q1 2021**

Thank you
Merci
Danke
Tack

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