COVID-19 Webinar
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Rx Securities
October 2020

valneva

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Valneva: A specialty vaccine company focused on prevention against diseases with major unmet needs

3
unique vaccine programs

> 500
employees in six countries

2
commercial products

>100
people in R&D

Valneva's Value Proposition

Integrated business model with valuable R&D and commercial assets

R&D provides upside for shareholders

Lyme vaccine in Phase 2

US/EU market opportunity of ~$1bn per annum

- Only program in clinical development
- Strategic collaboration with Pfizer[1]

Chikungunya Phase 3 initiated Sept. 2020

Global market opportunity of ~$0.5bn per annum

- Huge synergy with existing infrastructure
- Possible Priority Review Voucher upside

COVID-19 vaccine candidate

Phase 1 to be initiated before the end of 2020

- Only inactivated vaccine candidate in US & EU
- UK Government Agreement Worth up to €1.4 Billion

Commercial Business

Total sales revenues of €129.5m in 2019, +25% vs. 2018

Marketing & Distribution partnership with Bavarian Nordic announced June 2020[2]

IXIARO®

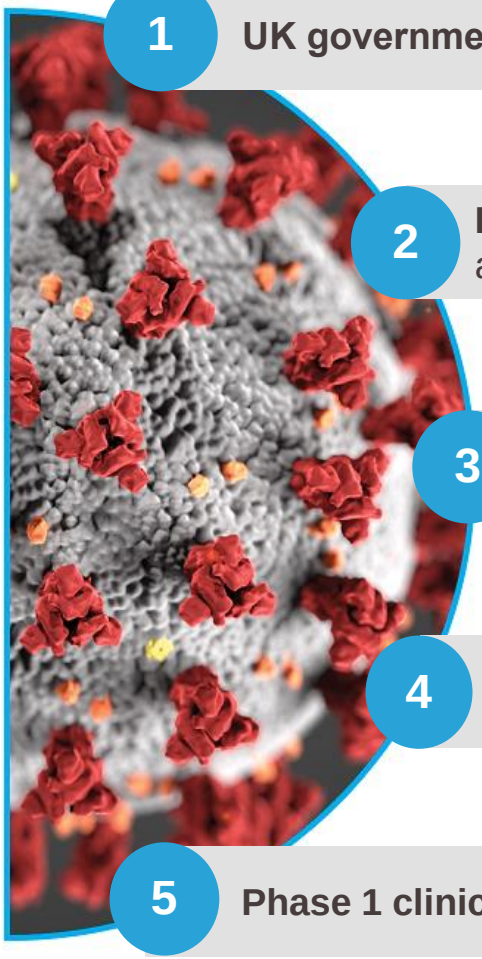
- Only licensed Japanese encephalitis vaccine for travelers in US CAN, EU; mandatory for US Military
- New US DoD supply contract worth up to $166 million[3]
- Sales > €90m in 2019

DUKORAL®

- Cholera (LT-ETEC) vaccine, licensed in CAN, EU, ROW
- Sales > €30m in 2019

1 Valneva PR: Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15; **2** : Valneva and Bavarian Nordic Announce Marketing and Distribution Partnership; **3** Valneva Announces New IXIARO® Supply Contract with the US Government worth up to $166 million;

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. **Leveraging 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 Inactivated 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 130 million 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

VLA2001 – SARS-CoV-2 inactivated vaccine

Target Product Profile

(20102020)

Based on platform experiences, expected to meet preferred/ critical criteria defined in WHO TPP*

	Vaccine Properties
Vaccine type	▪ Inactivated, adjuvanted (Alum, + „Th1“ adjuvant), whole virus, Vero cell substrate
Indication	▪ For active immunization of at-risk persons to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic; develop vaccine further for seasonal vaccination
Primary Target Population	▪ Persons at risk of COVID-19 aged 18 years and above, including high-risk populations (elderly and co-morbid i.e. immunocompromised, diabetics,) suitable for administration to pregnant and lactating women; step-wise broadening of age range (65-80 and 2-17 year of age)
Efficacy	▪ 70% (at least 50%)* efficacy regarding disease, severe disease, and/or shedding/transmission; protection lasts 12 months after priming *WHO position paper
Contraindications	▪ None expected, except severe allergic reaction after previous dose of vaccine or hypersensitivity to a component;
Co-vaccination	▪ Seasonal influenza, shingles and pneumococcal vaccines, pediatric vaccines
Initial Dosing, Administration	▪ Two doses administered i.m. 3 weeks apart
Booster	▪ Booster after ~ 12 months, 2nd booster after 10 years; pending further evolution of the pathogen, annual vaccination need to be confirmed and prepared for
Presentation	▪ 10-dose vial (pandemic); single dose vial (or syringe) TBD (seasonal)
Adverse Events	▪ Comparable to other inactivated vaccines

* https://www.who.int/blueprint/priority-diseases/key-action/WHO_Target_Product_Profiles_for_COVID-19_web.pdf?ua=1

Alum Adjuvanted whole virus inactivation is an established concept for SARS-CoV-2 vaccine candidates

Phase 1/2 data already available for some candidates

	Sinopharm/Wuhan Institute	Sinopharm/ Beijing Institute	Sinovac CoronaVac	Valneva VLA2001
Antigen	Whole virus inactivated	Whole virus inactivated	Whole virus inactivated	Whole virus inactivated
Cell line	Vero cells	Vero cells	Vero cells	Vero cells
Inactivation	β-propiolactone	β-propiolactone	β-propiolactone	β-propiolactone
Adjuvant	Aluminum hydroxide	Aluminum hydroxide	Aluminum hydroxide	Aluminum hydroxide + **CpG**
Buffer	PBS without preservatives		PBS and sodium chloride	PBS and sodium chloride
Injection	Intramuscular	Intramuscular	Intramuscular	Intramuscular
Current R&D status	Phase 3 study ongoing Start: July 2020	Phase 3 study ongoing Start: July 2020	Phase 3 study ongoing Start: July 2020	Phase 1/2 estimated start date: Dec-2020
Publications	Phase 1/2 Xia et al. JAMA	Phase 1/2: Xia et al. Lancet	Phase 2: Zhang et al. MedRxiv	

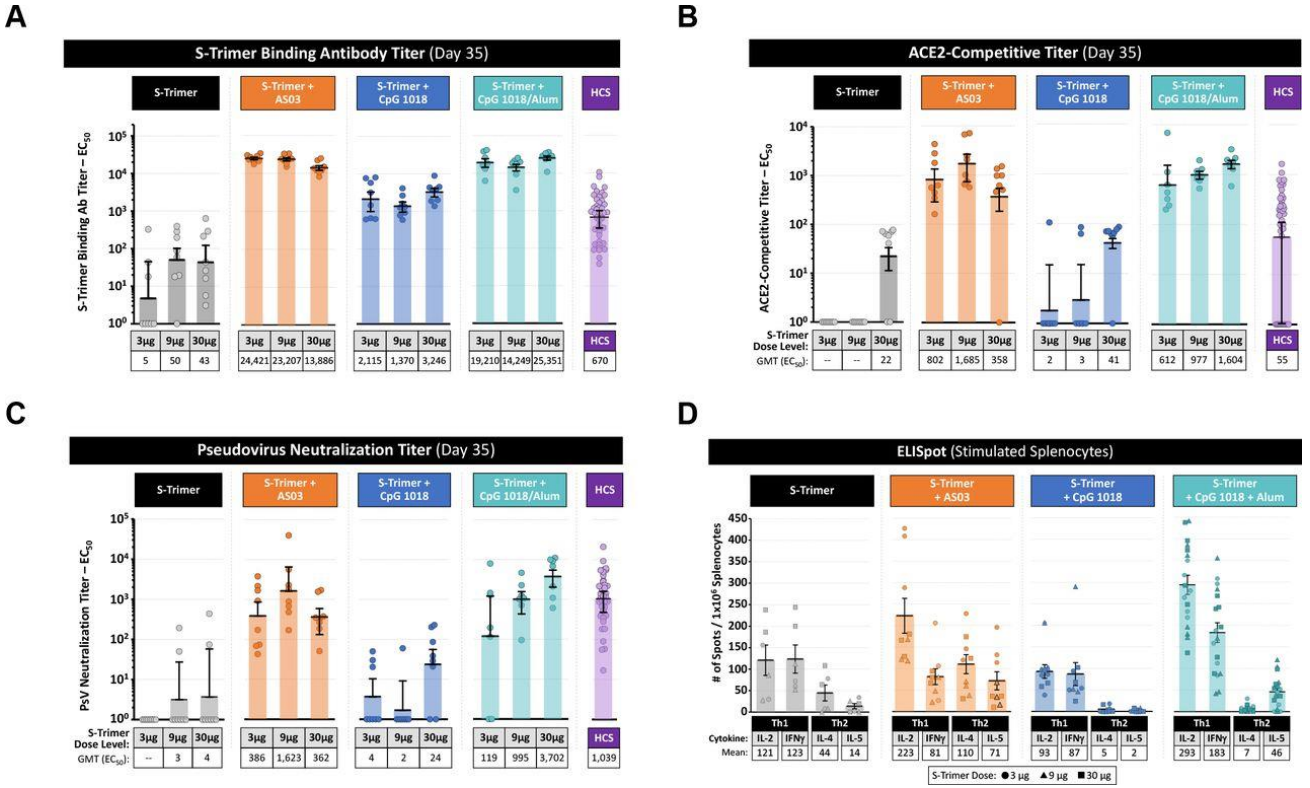
Rationale for Combination of alum plus CpG

Increased immunogenicity as well as Th1-polarization of immune response

- Immunization with sub-unit vaccine candidate (S-Trimer with either AS03 (oil-in-water emulsion) or CpG 1018 (TLR9 agonist) plus alum adjuvants induced high-levels of neutralizing antibodies (Graph A, B and C)
- Th1-polarized T cell response in rodents (see graph D).
- Absence of measurable viral load in lung tissue as well as other clinical measures in non-human primates challenged with SARS-CoV-2.

https://www.biorxiv.org/content/10.1101/2020.09.24.311027v1.full

Data from a COVID-19 subunit vaccine candidate

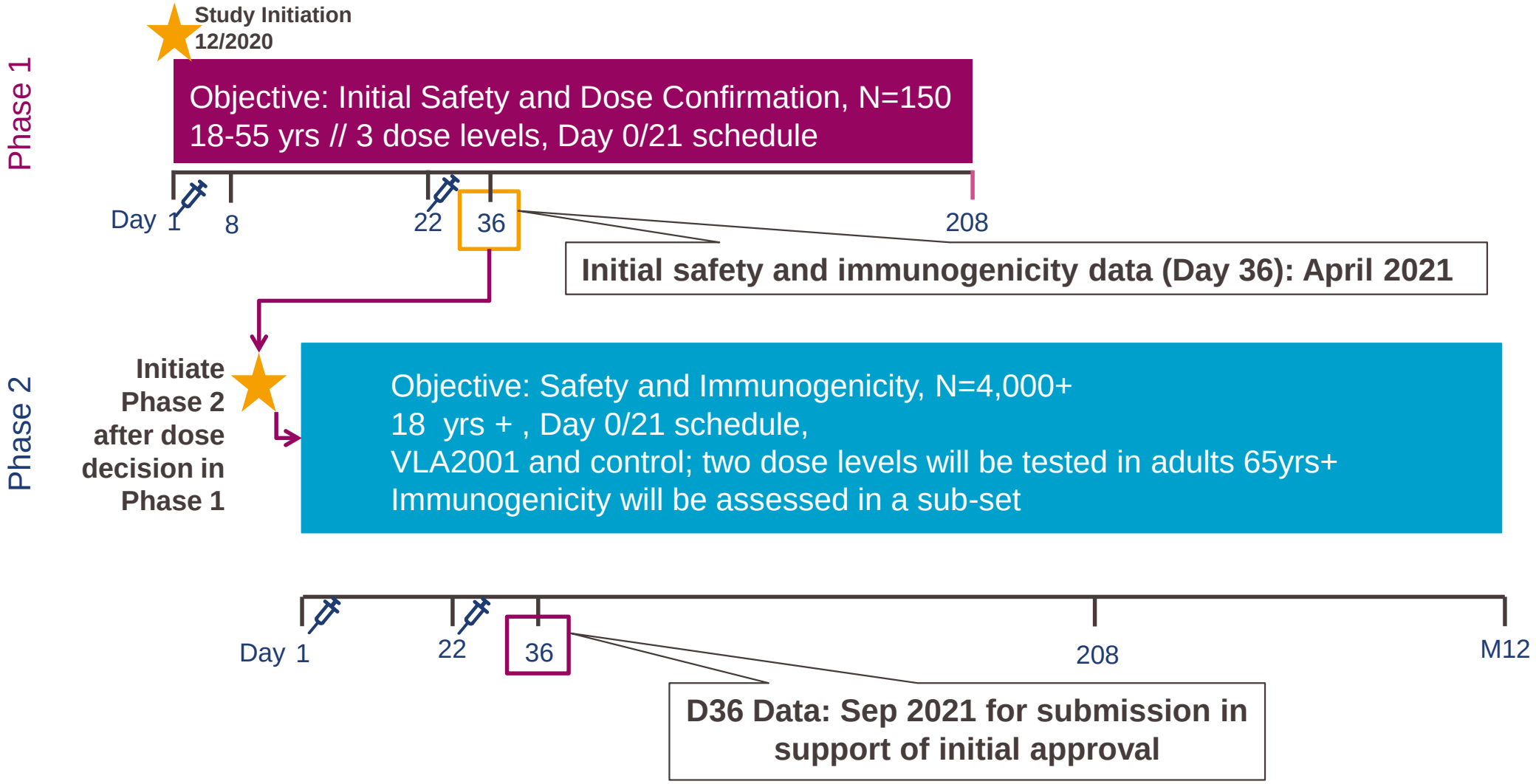


Immunogenicity of S-Trimer in Mice.BALB/c mice (n=7-8/group) were immunized with various doses of S-Trimer that was non-adjuvanted or adjuvanted with 25 µL AS03, 10 µg CpG 1018, or 10 µg CpG 1018 plus 50 µg alum twice on Day 0 and Day 21. The humoral immune responses on Day 35 were analyzed and compared with a human convalescent sera (HCS) panel (n=41), based on (A) S-Trimer binding antibody ELISA titers, (B) ACE2-competitive ELISA titers, and (C) SARS-CoV-2 pseudovirus neutralization titers. After necropsy, splenocytes were harvested from mice and stimulated with S-Trimer antigen, followed by (D) detection of Th1 (IL-2, IFNγ) and Th2 (IL-4, IL-5) cytokines by ELISpot. ELISpot data shown represents pooled data across S-Trimer doses. Points represent individual animals or humans; horizontal lines indicate geometric mean titers (GMT) for antibody assays and mean values for ELISpot assay for each group ± SEM.

VLA2001 – SARS-CoV-2 inactivated vaccine

Initial Clinical Development Phase

Clinical entry Dec 2020, initial safety & immunogenicity data: April 2021



VLA2001 – SARS-CoV-2 inactivated vaccine

Manufacturing summary

Drug Substance

- Valneva is **scaling up bulk production in Livingston,** Scotland
- Valneva's **facilities have already been refitted for CTM**, with commercial supply starting 2021
- Valneva's **second facility was recently acquired** and will be fully operational from June 2021

Drug Product

- Valneva's **fill/ finish operations will take place in Solna**, Sweden
- Valneva is currently **carrying out a facility upgrade** and installing a new high speed filling line for fill/finish of VLA2001

Adjuvant

- Valneva has now entered into a **supply agreement with Dynavax** for CpG 1018
- **Formulation will be taking place in Livingston**, Scotland

Timelines

- Drug Substances of **Phase 1/2 Clinical Trial Materials have been produced**, ready for filling in Nov 2020
- Valneva is expected to **commence commercial manufacturing early 2021**
- Valneva's VLA2001 SARS-CoV-2 inactivated vaccine product is expected to be **available at time of regulatory approval**, which is **expected in the second half of 2021**

VLA2001 is an inactivated, adjuvanted vaccine that follows proven approaches

- VLA2001 is a Vero-cell based**, highly purified inactivated vaccine candidate against the SARS-COV-2 virus**
- The **approach leverages the manufacturing technology for Valneva's Japanese Encephalitis Vaccine**
- This includes **inactivation with BPL to preserve the native structure of the S protein**
- The combination with CpG 1018 is **expected to induce a strong immune response** and has the potential to generate high titers of neutralizing antibodies
- VLA2001 will **conform with standard cold chain requirements** (2 degrees to 8 degrees centigrade).

Q&A

Thank you.

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