

Présentation « Anticovid » Franck Grimaud, Président & CBO Valneva

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





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 known to be in clinical development
- Strategic collaboration with Pfizer¹

Chikungunya Phase 3 initiated Sept. 2020

Global market opportunity of ~\$0.5bn per annum

- 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 currently in development in the US & EU
- UK Government agreement worth up to €1.4 billion

Commercial Business

**Total sales revenues of €129.5m in 2019;
Guidance for 2020 ~ €70m**

- Pandemic impact on travel industry
- Commercial infrastructure - important strategic asset capable of launching future brands
- Marketing & Distribution partnership with Bavarian Nordic announced June 2020²

IXIARO®

- Only licensed Japanese encephalitis vaccine for travelers in US, CAN and EU; mandatory for US military
- New US DoD supply contract worth up to \$166 million³

DUKORAL®

- Cholera (LT-ETEC⁴) vaccine, licensed in CAN, EU, ROW

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](#); 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

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



- 1 UK government deal worth up to €1.4 billion¹ 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 adjuvant²**
- 5 Phase 1 clinical study expected to commence in December 2020**

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 up to 190 Million Doses of Inactivated, Adjuvanted 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 billion¹
- Including 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



Agreement includes funding for expansion of Valneva's UK-based manufacturing facility and Phase 1/2 clinical trials in the UK

- Vaccine to be manufactured at Valneva's facilities in Livingston, Scotland²
- Valneva plans further investments in both its Scottish and Swedish facilities

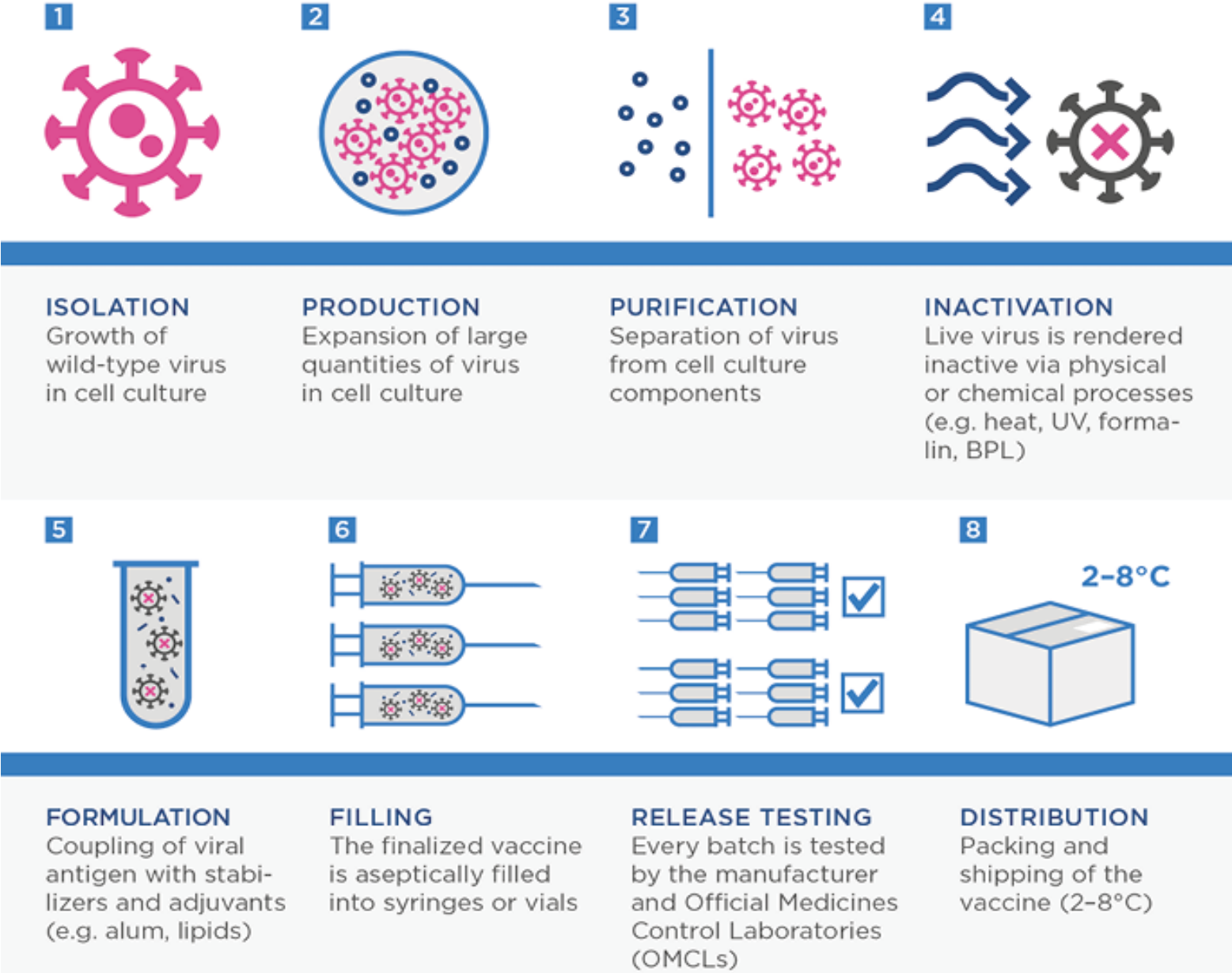
Pre-clinical and industrialization activities on track

Phase 1 clinical study expected to commence in December 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 is an inactivated, adjuvanted vaccine that follows proven approaches



VLA2001 – inactivated SARS-CoV-2 vaccine

Target Product Profile



(20102020)

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

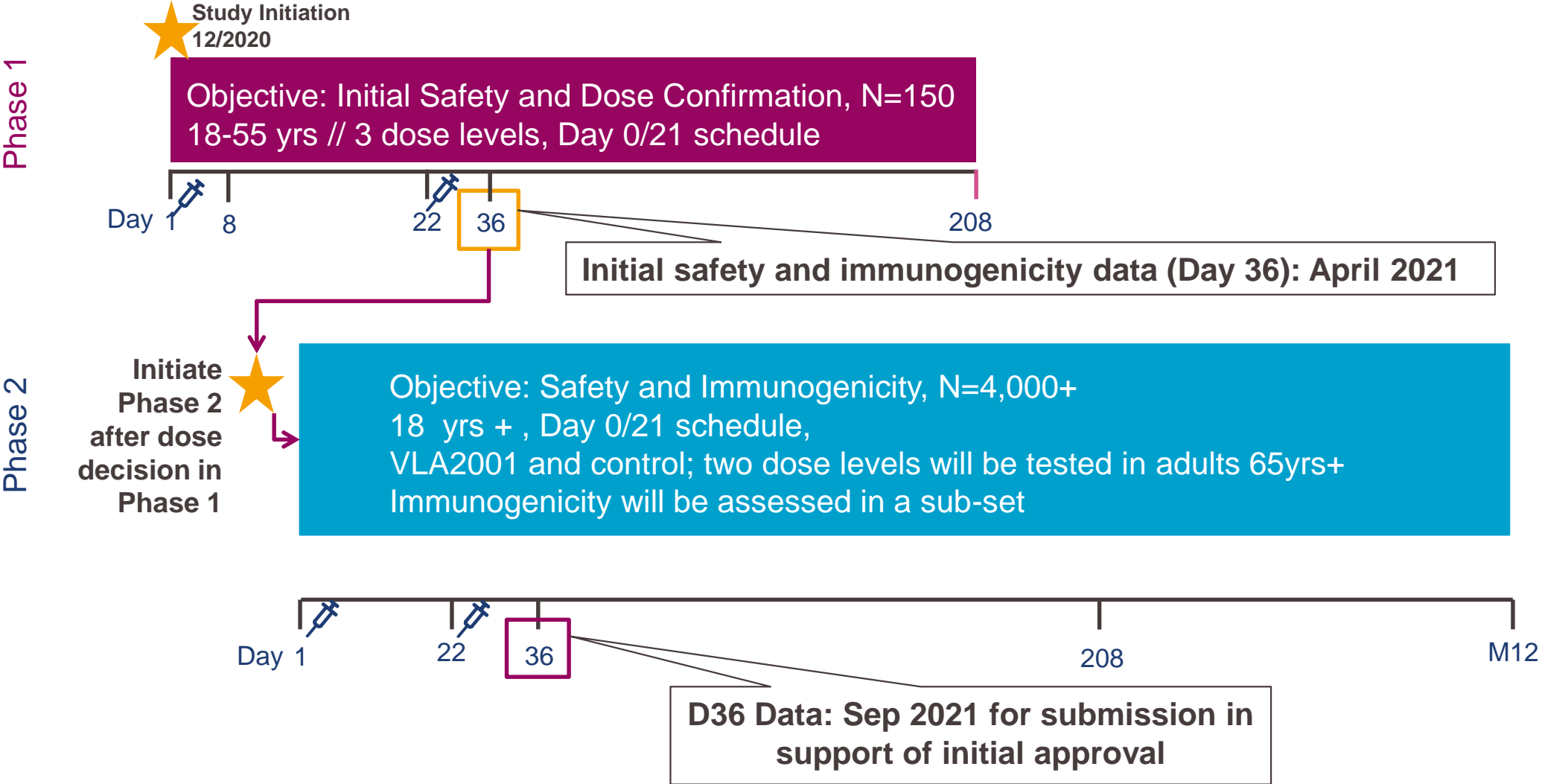
	Vaccine Properties
Vaccine type	<ul style="list-style-type: none"> Inactivated, adjuvanted (Alum, + „Th1“ adjuvant), whole virus, Vero cell substrate
Indication	<ul style="list-style-type: none"> For active immunization of at-risk persons to prevent carriage and symptomatic infection with COVID-19 during the ongoing pandemic; develop vaccine further for seasonal vaccination
Primary Target Population	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 70% (at least 50%)* efficacy regarding disease, severe disease, and/or shedding/transmission; protection lasts 12 months after priming *WHO position paper
Contraindications	<ul style="list-style-type: none"> None expected, except severe allergic reaction after previous dose of vaccine or hypersensitivity to a component;
Co-vaccination	<ul style="list-style-type: none"> Seasonal influenza, shingles and pneumococcal vaccines, pediatric vaccines
Initial Dosing, Administration	<ul style="list-style-type: none"> Two doses administered i.m. 3 weeks apart
Booster	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 10-dose vial (pandemic); single dose vial (or syringe) TBD (seasonal)
Adverse Events	<ul style="list-style-type: none"> 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



VLA2001: Inactivated SARS-CoV-2 Vaccine

Clinical entry December 2020, initial data April 2021





VLA2001 – SARS-CoV-2 inactivated vaccine

Manufacturing summary

Drug Substance	Drug Product	Adjuvant	Timelines
<ul style="list-style-type: none">Valneva is scaling up bulk production in Livingston, ScotlandValneva's facilities have already been refitted for CTM, with commercial supply starting 2021Valneva's second facility was recently acquired and will be fully operational from June 2021	<ul style="list-style-type: none">Valneva's fill/finish operations will take place in Solna, SwedenValneva is currently carrying out a facility upgrade and installing a new high speed filling line for fill/finish of VLA2001	<ul style="list-style-type: none">Valneva has entered into a supply agreement with Dynavax for CpG 1018Formulation will be taking place in Livingston, Scotland	<ul style="list-style-type: none">Drug Substances of Phase 1/2 Clinical Trial Materials have been producedValneva is expected to commence commercial manufacturing early 2021Valneva'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



Valneva's Vaccine Candidate VLA2001

Key Takeaways

- VLA2001 is the **only inactivated COVID-19 vaccine approach in Europe and the U.S.**
- **Phase 1 clinical study expected to commence in December 2020**
- **Inactivated virus vaccines are historically one of safest and most effective vaccine development strategies**; Billions have been vaccinated with this well-established technology over the past hundred years.
- **Inactivated vaccines can be used in people with weakened immune systems**, who are at the greatest risk of COVID-19
- VLA2001 **leverages the manufacturing technology for Valneva's FDA and EMA- approved Japanese encephalitis vaccine IXIARO®**
- 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 is expected to **conform with standard cold chain requirements** (2 to 8° C)
- **Valneva has already signed a major partnership with the UK to supply up to 190m doses for up to €1.4 billion.**
- The **expanded production capacities** at Valneva's facilities in Sweden and Scotland **allow Valneva to accommodate additional pre-orders**
- Valneva has shared its **own safety pledge** with the public ([Valneva Stands with Science](#))



Initiation of COVID-19 Vaccine Phase 1 Study expected in December 2020

- Top line data early Q2 2021

Lyme disease vaccine candidate VLA15

- Phase 2 study, VLA15-221, with pediatric population, planned to be initiated in Q1 2021

Chikungunya vaccine candidate VLA1553

- Phase 3 recruitment completion expected in Q4 2020

Q&A



Thank you.

