INFORMATION SHEET AND ASSENT FORM

(12 -15 years)

Study Title:	A Randomized, Observer-blind, Controlled, Superiority Study to Compare the Immunogenicity against COVID-19, of VLA2001 Vaccine to AZD1222 Vaccine, in Adults Including a Randomized, Observer-blind, Placebo Controlled Part in Adolescents (≥ 12 to < 18 years)
Study Number:	VLA2001-301
Principal Investigator (study doctor):	*<<name>>* *<<Institution>>* *<<Address>>* *<<Telephone Number>>* *<<Emergency and/or Other Contact(s) required by IRB/IEC>>*
Sponsor (a for-profit drug company):	Valneva Austria GmbH Campus Vienna Biocenter 3 A-1030 Vienna, Austria
CRO (company helping to manage the study)	Pharm-Olam LLC 1st Floor, One Station Square Bracknell, Berkshire RG12 1QB United Kingdom

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We would like to invite you to take part in a research study looking at a new vaccine (VLA2001) which could be used to protect against COVID-19.

Before you decide if you want to take part in the study, it is important that you read this form together with your parents or legal guardian. This information sheet may contain words you do not understand, please ask the study team to explain anything you do not understand.

What is this study about?

We are doing this research study to see if a new vaccine, VLA2001 is safe for use and if it helps people develop immunity against COVID-19 disease. Immunity is your body's ability to recognise an infection (such as disease-causing bacteria and viruses) and respond to protect you against disease.

At least 660 people between 12 and 17 years of age will be taking part.

What is the drug being tested?

VLA2001 is the new investigational drug being tested and it will be compared to a placebo.

> **Investigational** means that VLA2001 has not been approved for use.
>
> **Placebo** is an inactive material that will look identical to the study drug.

Can I talk about the study with anybody?

You can ask the study team questions at any time. You can also talk to your parents or legal guardian, friends and family.

How long will I be in the study?

You will be in the study for up to 12-14 months.

What will happen to me in this study?

If you decide that you want to be in the study, you will be randomised to either the VLA2001 group or the placebo group.

> **Randomised** is like flipping a coin, you will have a 1 in 2 chance of receiving either VLA2001 or placebo.

Both groups will receive a vaccination on Day 1 and Day 29. At Day 71 all participants will know what treatment they received (placebo or VLA2001). If you were in the placebo group, you will receive your 3rd vaccination (now with VLA2001) on Day 71 (Month 2.5), and the 4th vaccination (also with VLA2001) on Day 99 (Month 3.5).

If you received VLA2001 at the Day 1 and Day 29 vaccinations, you will receive a 3rd vaccination with VLA2001 at Day 208 (Month 7).

If you are in the VLA2001 group, you will receive 3 vaccinations of VLA2001. If you are in the placebo group your first 2 vaccinations will be placebo and your next 2 will be VLA2001.

Until Day 71, neither you nor your study doctor will know which drug you were given. This information can be found if there is an emergency.

At your first visit (screening)

The study team will ask you some questions, examine you and take some measurements including listening to your heart, taking your blood pressure and temperature. They will also use a needle to take a sample of blood from your arm and to prick your finger.

Later that visit, if combined or at your next visit (baseline)

You will have a nasal and throat swap collected, similar to what you might have done in school (Antigen lateral flow test).

If you are female and able to have children you will be asked to provide a sample of urine for a pregnancy test, you will need to do this before each vaccination.

A needle will then be used to give you the vaccination in your arm and you will be shown how to use an electronic diary which **must be completed for 7 days after you receive each vaccine**.

At your next visits

Nothing new will happen to you, you will be asked questions about how you have felt, and more measurements and blood will be taken. At D29 and D208 you will receive another needle with the vaccine. If you are in the placebo group you will get a fourth vaccine at Visit 5p (M3.5).

You are expected to attend site visits up to 8 times if you are in the VLA2001 group or 9 times if you are in the placebo group.

See page 8 for a more detailed overview

Will I get paid for taking part?

You will receive a:

- £20 voucher for your first visit and every time you receive a vaccination,
- £10 voucher for each time you fully complete your eDiary at home for 7 days after each vaccination,
- £15 voucher for every other visit you attend.

In total you will receive vouchers up to £170 if you are in the VLA2001 group or £200 if you are in the placebo group since you receive one more injection.

What if I don't feel well and what can I expect to feel?

Some people who receive a new medication may not feel well. This is called having a side effect. **If you do not feel well, you should tell your parents or legal guardian, and they will contact your study doctor.**

The vaccination and blood collections may also cause you possible discomfort, your arm where the needle has been used may feel sore or heavy, this is not expected to last very long.

The swab test may make you feel uncomfortable as the swab is inserted into your nose. You may flinch, have watery eyes, or cough. Bleeding after a swab is very rare but possible.

Will being in this study help me?

You may develop immunity against COVID-19 from taking part. Taking part in this study will also help us to discover if VLA2001 may help other people develop immunity against COVID-19 disease.

Do I have to take part in the study?

You do not have to be in the study if you don't want to. You will not get in trouble if you decide that you do not want to participate, just tell your parents or legal guardian and the study doctor. You can change your mind at any point in the study. We would like to keep any data collected from you up to the point that you come out of the study.

If you decide to take part, you will be asked to sign this assent form and you will be given a copy of your signed form.

What will happen with the information that I give to the study doctor?

You will be given a study number which will be used for all documentation. Therefore, only the study team will know that the information comes from you.

Only your study doctor, their team, the people from the company that is paying for the study (Valneva) and people who are working with Valneva will see the coded information about you. People who make sure that the study is being done correctly may also see it. However, your information will not be shared outside of the study.

If you change your mind, all information collected up to the point that you changed your mind, will be used and reported without your name on it.

THANK YOU FOR READING THIS

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ASSENT FORM FOR PARTICIPANTS

☐ No, I do not want to be in this study

☐ Yes, I do want to be in this study

Participant Number: 2001-2-_ _-_ _ _

Adolescents, please initial the boxes below to indicate you have read this form or had this form read to you.

The study has been explained to me	
I have been allowed to ask questions about the study and all my questions have been answered	
I am aware needles will be used to take samples of my blood and give the study vaccination	
I agree to my blood samples being saved for up to 15 years after the end of the study for potential future testing.	
I agree for information collected about me during the study to be shared outside of the UK	
If I change my mind after starting the study, I will tell the study doctor right away	
I understand that I won't get in trouble if I do not want to be in this study or choose to stop at any time	

If you want to be in this study, please print your name, the date and time and sign your name below. Please also write how old you are in the space below. You will get a copy of this signed form.

I want to be in this study:

_____	_____	_____(24h)	_____
Printed Name of Participant	Date	Time	Signature of Participant

_____

How old are you today?

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CONSENT FORM FOR PARENT OR LEGAL GUARDIAN

Participant Number: 2001-2-_ _-_ _ _

Parent or legal guardian please initial the boxes below to indicate you have read this form

I have read and understand the information sheet for parents/legal guardians [insert version and date] for the above study and have received a copy to keep.	
This study has been explained to me in detail and all my questions have been answered to my satisfaction.	
My child and I have been given ample time to decide whether to participate.	
I agree that my child's GP will be informed of their participation in this trial. I authorise the release of their medical records to the Sponsor, agents of the Sponsor, and other governmental agencies.	
I agree to my child's GP sharing relevant medical information on adverse events with the study doctor while they are taking part in the study.	
I understand neither me nor my child have waived any of the legal rights that we would have if they were not a participant in a research study.	
I agree to my child's samples being saved for up to 15 years after the end of the study for potential future testing.	
I understand that my child's personal, coded data will continue to be processed after the completion of the study or after they withdraw from the study if necessary, for reasons of public interest in public health, for archiving purposes in the public interest, for scientific research purposes, or for statistical purposes.	
I agree that my child's personal coded data will be transferred outside of the UK to other countries where personal data protection laws may be less strict for the purpose of conducting the study.	
I freely agree to my child participating in this research study as described and understand that I am free to withdraw my child at any time during the study.	

_____	_____	_____(24h)	_____
Printed Name of Parent/Guardian	Date	Time	Signature of Parent/Guardian

Participant Number: 2001-2-_ _-_ _ _

STATEMENT OF PERSON OBTAINING CONSENT

I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____	_____	_____(24h)	_____
Printed Name of Person obtaining consent	Date	Time	Signature of Person Obtaining Consent

Appendix 1 – Visit procedures table

Test/Procedure	First Visit (Screening)	Second visit or combined with your first visit (Baseline)	All Other visits
Physical examination	x		
Symptom-driven physical examination (done only if there is a sign that you may be sick)		x	x
Vital signs (blood pressure, pulse [how many times your heart beats per minute], and temperature)	x	x	Only on day of vaccinations
Blood test	x	x	x *(no blood test for placebo group at visit 7p)*
Pregnancy test (if you female and are able to have children)		x	Only on day of vaccinations
Receive vaccination (3 times for VLA participants and 4 times for Placebo participants)		x	Only on day of vaccinations
Complete electronic diary 7 days after each vaccination		x	For 7 days post each vaccination visit
Finger prick test to check the presence of COVID-19 antibodies (an antibody is a protein produced by the body's immune system when it detects harmful substances)	x		
Swab collection from the nostril to check if an active COVID-19 infection is present		x	
Assessment of side effects (throughout the study)		x	x
Recording medications	x	x	x