CONSENT TO PARTICIPATE IN RESEARCH

Sponsor / Study Title:	**Galapagos NV / "A randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of orally administered GLPG3667 in adult subjects with active systemic lupus erythematosus"**
Protocol Number:	**GLPG3667-CL-215**
Principal Investigator: (Study Doctor)	**C. Kent Kwoh, MD**
Telephone:	**520-626-8750** **(520) 694-6000 (24 Hours)**
Address:	**University of Arizona Arthritis Center** **1501 North Campbell Avenue** **Room 8303** **Tucson, AZ 85724**

What is a clinical research study?

You are being asked to join a clinical research study because you have Systemic Lupus Erythematosus (SLE). This study is testing whether an experimental (not yet approved) drug called GLPG3667 helps to treat systemic lupus erythematosus and is safe to use.

The doctor (called "the study doctor" in this form) is working with Galapagos, the sponsor, to run this study. Galapagos is a company that makes new drugs to treat diseases. The study doctor and Galapagos hope GLPG3667 can help patients with active SLE. The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

If you decide to join, there is no guarantee that your symptoms will improve. If you decide not to join, you don't have to say why, and you will continue to get the same quality of care you are getting now.

Here are a few important things for you to know:

- This is an Informed Consent Form – it explains why the study is done and any risks
- Joining this study is voluntary
- Please read this form carefully to help you decide if you'd like to join
- Discuss it with the study doctor, and ask as many questions as you need
- You may take this form home and discuss it with people you trust
- If you sign this form, you are agreeing to join this study

What is the purpose of this study and who can join?

This study is comparing 2 doses of GLPG3667 with a placebo to see if GLPG3667 helps to treat SLE and is safe to use.

- GLPG3667 blocks certain molecules (so – called "Tyrosine Kinases") that are parts of the inflammatory process seen in SLE.
- A placebo looks like GLPG3667 but does not contain any active drug (like a sugar pill).

In this form, GLPG3667 and the placebo are called "the study drug". The study drug will be taken on top of your current SLE treatment.

About 180 participants will be in this study.

Who can join?

The study doctor will ask you questions and do some tests to check if you can be in this study. For example, you may be able to join this study if:

- Your disease symptoms are severe enough
- You currently take certain medications for SLE

You cannot join this study, for example if:

- You have a too severe form of lupus (for example, a type of lupus that affects your kidneys severely).
- Some blood test results are not within the allowed ranges

Which study drug will I get?

All study drugs will be given as capsules (pills) to be swallowed. One GLPG3667 pill will have 75 milligrams (mg) of GLPG3667 in it.

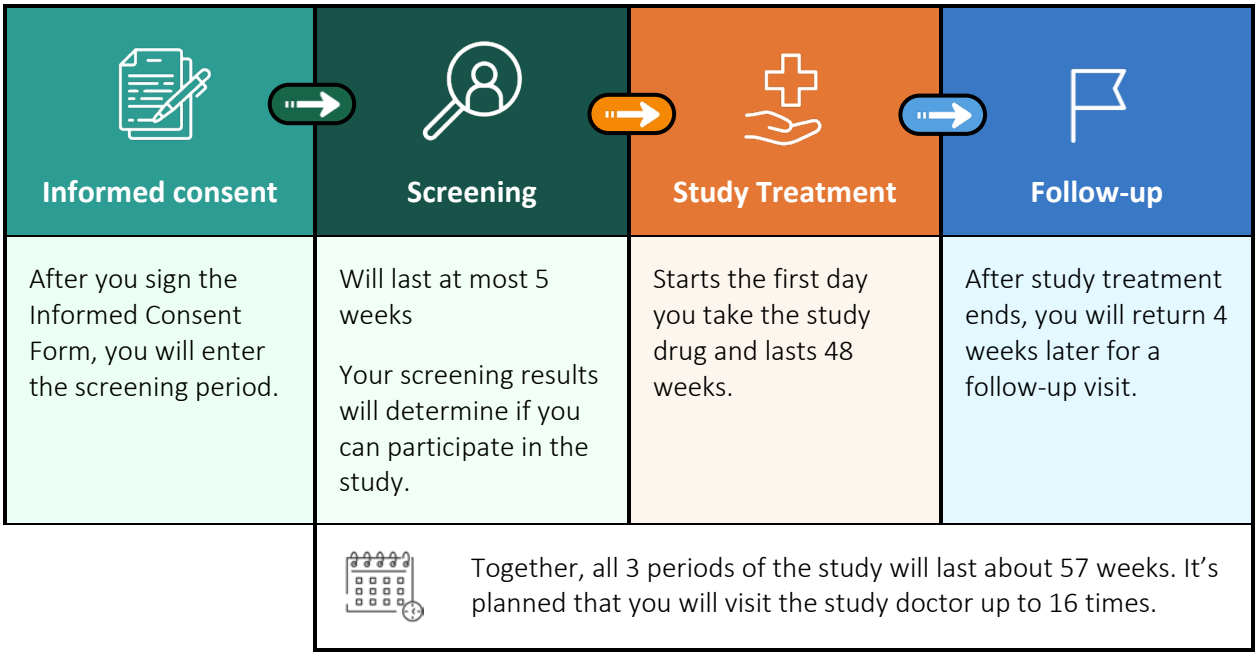
Which study drug you will get is determined by chance (like a coin toss). There is a 1 out of 3 chances of getting once a day :

- 150 mg GLPG3667
- 75 mg GLPG3667, OR
- Placebo

No-one will know which study drug you are taking but the study doctor can find out if they think it is needed. . To avoid that someone can guess which study drug you are getting, you will always take two pills (2 GLPG3667 pills, or 1 GLPG3667 plus 1 placebo pill, or 2 placebo pills).

What will happen in this study?

Below is a diagram of the study steps. In each step, you will visit the study doctor one or more times. The next pages tell you what happens during study visits.



The study visit table below describes all the tests and procedures during the study. These tests are done, for example, to monitor your safety, to diagnose a disease or to measure the severity of the disease. A visit will take about 2-4 hours. The Week 4 visit may take longer, about 6 hours, as more blood samples are taken.

It is important that you attend all planned visits. If there's an exceptional situation that prevents you from attending a planned visit (for example, a lockdown during a pandemic), the visit may be replaced by a phone call or a healthcare provider (such as a trained nurse) visiting your home. If this happens, local rules on hygiene and social distance will be followed.

You will need to complete an electronic diary on your own smart device (like a smartphone or tablet). If you don't have such a device, it can be provided to you. This is for you to record:

- When and how you take the study drug
- Any new medications or changes to your usual medications
- Any new symptoms
- Changes in your corticosteroid dose, if any

When your current treatment for your SLE includes medication that contains corticosteroids, your study doctor might lower your corticosteroid dose as of Week 8. This is done to better see the possible effect of GLPG3667 on your SLE and to possibly lower the side effects of corticosteroids. However, if your symptoms increase again or some of your diagnostic blood test results worsen, your study doctor will discuss the increase of your corticosteroid dose with you again, if needed.

Study visit table

	Screening	Study Treatment	Follow-up
	1 visit	14 visits Day 1, Week 2, Week 4 and then every 4 weeks until Week 48	1 visit
Questions the study doctor or staff will ask about			
You and your medical history, such as: • Age and sex at birth • Allergies, surgeries, or other illnesses • If and how much you smoke or use alcohol or drugs	x		
Your medicine use, such as if you've taken or take prescription or non-prescription medicine, or herbal or dietary supplements	x	x	x
How you're feeling and symptoms you've had, since your last visit		x	x
Questionnaires for you to complete			
About your symptoms and how you are feeling	x	x (except Week 2)	

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	Screening	Study Treatment	Follow-up
	1 visit	14 visits Day 1, Week 2, Week 4 and then every 4 weeks until Week 48	1 visit
Measurements			
Body temperature, blood pressure and heart rate	x	x	x
Height (screening only) and weight	x	x	x
ECG to measure the electrical activity of your heart	x	x (except Week 12, 20, 28, 40, 36 and 44)	x
Tests or exams			
Physical exam, such as listening to your heart and lungs	x	x	x
Exam of your joints	x	x (except Week 2)	
Blood samples for			
Diagnostic, general health, Tuberculosis and Hepatitis B & C and HIV tests (by law, positive viral tests may have to be sent to health authorities)	x	x	x
A pregnancy test and a test to check if you are menopausal (for women)	x		
Measuring the amount of GLPG3667 and/or breakdown products		x (except Day 1, Week 36 and 44)	
Measuring of disease markers and body responses	x	x	
Other samples			
Urine for diagnostic, general health tests, disease markers and body responses	x	x	x
Urine for pregnancy test (for women able to get		x (except	x

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	Screening	Study Treatment	Follow-up
	1 visit	14 visits Day 1, Week 2, Week 4 and then every 4 weeks until Week 48	1 visit
pregnant)		Week 2)	
Study diary			
Receive your study diary	x		
Check your study diary		x	x
Study drug			
Receive study drug		x (except Week 48)	
Return leftover study drug or empty packages		x (except Day 1)	

Taking the study drug

At each study treatment visit:

- You will receive enough study drug until the next visit with instructions on how to take it. In certain cases, the study doctor may send study drug directly to your house and will explain to you how this will work.
- Study staff will check if you've taken the study drug as instructed.

When you start taking the study drug, you will receive a participation card with study information and contact numbers. It is important that you keep this card with you at all times in case you need to visit a different doctor or get emergency care from people not familiar with this study.

How do I take the study drug?

Each morning (except on study visit days) at about the same time, you will take your study drug together with, or within one hour of, breakfast or a small meal. You must swallow the pills with water without chewing. If you miss taking the study drug, you may take it within 12 hours of your usual scheduled time or else skip it and record the missed study drug intake in your diary. On study visit days, you will take the study drug at the study doctor's office.

How do I store the study drug?

The study drug must be stored at room temperature 15-25°C/59-77°F.

All study drugs must stay in their packaging until it is time for you to take them.

Sample collection and testing

Blood samples

A qualified person will draw blood samples. The average amount of blood taken per visit will be about 35 mL (about 7 teaspoons). For reference, when you donate blood, you usually give about 450 mL (about 2 cups) during one session.

Other samples

You will collect your urine sample privately in a provided container.

Analysis and storage of samples

The study staff will send your samples to a lab. The lab will analyze the samples and send test results about your diagnosis and safety to the study doctor. The other study tests help to better understand the disease and the study drug but are not directly about your safety and diagnosis and the results may not be sent to the study doctor, but they are part of the study information.

The time to complete all study tests on your samples may be at most 5 years after the end of the study. After that period, Galapagos will ensure your samples are destroyed unless you sign an optional, separate Informed Consent Form to allow that your samples are stored for longer and used for other tests in new studies.

Will genetic research be done on my samples?

No. We don't study what your DNA molecules (the building blocks of genes) or RNA molecules (which come from your DNA) look like.

Your samples will not be used to identify you.

What are my responsibilities?

Please do…	Please do not…
Tell the study doctor everything about your health, medicine you're taking or have taken, and your symptoms. Some medicines are not allowed, and you may have to stop taking them.	Donate blood, get a vaccine, have surgeries or procedures, or take prescription or non-prescription drugs, or herbal, homeopathic, or dietary supplements, unless the study doctor approved it.
Lower your corticosteroid use, when and how your study doctor tells you and record this in your diary.	Take grapefruit or Seville oranges (or juices) and St. John's wort (hypericum). These affect how GLPG3667 is broken down in your body.
Contact the study doctor if you are not feeling well.	Join other clinical studies.
Take the study drug as instructed and record this in your diary.	Come to the study doctor's office when you have COVID-19 related symptoms. Inform the study doctor. You may have to have a COVID-19 test done.
Bring unused study drug, empty packages and the completed diary to each visit and tell your study doctor when you have missed a dose of study drug.	
Carry your participation card with you at all times so any doctor or emergency care staff you visit will know you're in this study and can contact the study doctor if needed.	

When will the study end?

The study ends for you when one of these 4 events happen:

- When you have completed all visits

The study ends for you when you have completed all visits as described in the study visit table.

- When this is best for your health

In this case, the study doctor will tell you to stop the study drug. You will then have an early discontinuation visit (tests similar to Week 48). However, the study doctor will ask you to continue the study visits until Week 48.

- When you want to stop your participation

At any time during the study, you may also change your mind and stop the study early without having to say why. If you want to stop the study, you have to tell the study doctor. You may:

- Decide to stop the study drug but continue the study visits as planned
- Decide to stop the study drug and agree to come back for an early discontinuation and follow-up visit as recommended by the study doctor
- Withdraw your consent to participate (this means that you stop the study completely and immediately)

Whether you finish the study or stop early, it's important to collect information on how you're feeling, including any symptoms you've had.

- When the study is stopped

Authorities (such as the Ministries of Health, the US Food and Drug Administration [FDA], state health departments), Advarra IRB or Galapagos may stop the study, for example, if new information no longer supports that the study continues.

If there is new information that could cause you to reconsider being in the study, for example, a change in the risks linked to the study drug, the study doctor will share this with you and will answer any questions. It is possible that you have to confirm that you want to stay in the study by signing a new Informed Consent Form.

When the study ends for you, you will continue to get the same quality of care that you were getting before being in the study. The study doctor will discuss other possible treatments with you. It is not certain that GLPG3667 will become available on the market in your country afterwards.

Are there any risks?

Please ask as many questions about the potential risks listed below as you need.

Risks related to the study drug GLPG3667

Any drug may cause side effects. Because a small number of people have received GLPG3667 so far, the side effects for GLPG3667 are not yet well known. The study doctor can explain all medical problems that were reported for GLPG3667 in previous studies. The most common were:

- Increase of some enzymes from the liver
- Headache

GLPG3667 could cause effects that are not yet known. For example, the side effects or symptoms listed below happened with other similar drugs or in animal studies with GLPG3667. It is not certain that these will happen to you while you are taking GLPG3667.

Please tell the study doctor right away if you have any changes in how you're feeling, including any symptoms, so that the study doctor can follow up.

- You may have lower counts of some types of blood cells
- You might be more prone to get infections, including serious infections
- Vaccines you get may work less (please discuss any vaccines with the study doctor)

The molecules (*Tyrosine* kinases) that are blocked by GLPG3667 are from the same "family" as molecules (*Janus* Kinases) blocked by other drugs. It is not known if side effects that happen with these other drugs might also happen with GLPG3667.

You might be the first to have a side effect or symptom not listed in this form.

Risks related to the study tests

- Blood samples: A qualified person will use a needle to draw blood. This can sometimes cause a bruise at the site where the needle goes into your skin. Rarely, the site can swell, bleed, or infect. Some people may feel faint during or after a blood draw.
- An electrocardiogram (ECG): A machine measures the electrical activity of your heart via sensors attached to your chest. To attach the sensors, study staff may need to shave an area of your chest. The sensors rarely cause skin irritation, and this usually disappears when the sensors are removed.

Terms of Use (TOU)

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research subject.

Risks that may be unknown (Unforeseen Risks)

Since the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

Risks related to GLPG3667 when having sex

GLPG3667 might pose a risk to the development of an unborn baby.

If you are a woman:

- You should not be pregnant or breastfeeding when starting the study
- You should not become pregnant during the study
- The study staff will do pregnancy tests before and during the study
- You must use birth control if you are able to get pregnant

You must do what the below table tells you to lower the risk related to GLPG3667 when having sex, unless you have an exception.

Risk	**What you need to do during the study if you are a:**
	Woman
GLPG3667 might harm an unborn child.	• From the time you take the first study drug and until 7 days after the last study drug, you must use birth control • Please discuss your birth control options and your choice with the study doctor
Exceptions to the above	**You do not need to take the above actions if you are a:**
	Woman
Some people do not have the risks related to having sex listed above, and do not need to take the above actions.	• Your preferred and usual lifestyle involves not having heterosexual intercourse • You or your male sexual partner are confirmed infertile (unable to get pregnant) • You are confirmed menopausal **If you plan to change your lifestyle or your choice of birth control, please discuss this with the study doctor.**

What if a pregnancy, injury, or illness happens?

What happens if you get pregnant?

If you are a woman and you think you might be pregnant:

- Tell the study doctor immediately

- Do not take your next dose of study drug
- Confirm the pregnancy as soon as possible.

To follow up on any pregnancy, Galapagos will ask you and your partner to sign a separate pregnancy Informed Consent Form. If you both agree to sign, Galapagos will collect information about the pregnancy and your baby to understand if the study drug affects pregnancies or the development of unborn babies. The information may include your baby's birth, date of birth, measurements such as height and weight, health, and sex.

What if an injury or illness happens?

If you experience illnesses or injuries related to your participation in the study, medical treatment will be provided to you. The medical costs of diagnosis and treatment may be covered by Galapagos as long as the GLPG3667 or placebo was given correctly, all study tests and procedures were followed correctly and according to Galapagos instructions, and the injury was not due to the natural progression of a pre-existing condition. Please speak with the study team if you have questions about coverage of costs for injury.

The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

What are the benefits of joining the study?

You may have fewer SLE symptoms. However, there is no guarantee these benefits will happen. Taking part in the study may help future patients with SLE.

Are there other treatments for my condition?

Yes. They include those that are already approved by government agencies and sold/marketed for your condition. You can discuss them with the study doctor before you decide whether or not you will take part in this study.

Costs related to the study

The GLPG3667 or placebo and services performed for research only will be provided at no charge to you or your insurance company. Routine medical care performed while participating in the study will be billed to you and/or your insurance company. This will include (but is not limited to) physical exams, electrocardiograms, lab work, administration of medications, and the treatment of side effects.

Not all insurance companies are willing to pay for services performed in a study. You will be responsible for any charges that your insurance does not cover including regular co-payments and deductibles. Please speak with your insurance company to find out what you may be financially liable for.

If you receive a smart device for the electronic diary, you will not have to pay for it. You will have to return the device when the study ends for you.

Compensation for participation

You will not be paid for your participation in this study or your contribution to the development of the study drug or generation of the study data. If your participation in the study would lead to the development of new drugs or tests, you will not get any income of these.

You will be reimbursed up to $100 for reasonable travel costs to and from the study doctor's practice, parking costs and accommodation costs (if required) when you present your receipt. Such reimbursement shall be made by the study site according to their procedures. Contact your study doctor for details.

For any reimbursement you receive, we are required to obtain identifiable information such as your name, address, and Social Security number for financial compliance purposes.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Privacy and protection of your personal information

Galapagos will collect your personal information but will not know your name. To protect your identity, all personal information and samples Galapagos collects will have a unique code instead of your name.

Galapagos will get your personal information in these ways:

- From the study doctor copying information from your medical records
- From systems in which you enter information (for example, electronic questionnaires)
- From the labs that analyze your samples

Why is my personal information collected?

Your personal information is needed for some purposes and legal bases allow its collection.

Purpose	Why may Galapagos do this?
To check if you can be in the study	Based on its legitimate interest (scientific research purposes) and your explicit consent
To see if your condition changes with the study drug	
To understand if the study goals were met	

Purpose	Why may Galapagos do this?
To present at meetings and to publish in medical books and journals	
To train medical personnel	
To help answer new scientific questions in the future	
To make sure that the conclusions are reliable	Based on its legal obligation, your explicit consent and because it is necessary for reasons of public interest in the area of public health
To seek regulatory approval for GLPG3667	
To understand if the study drug is safe	
To report to authorities (for example, safety incidents)	
To archive after analysis	

How is my personal information protected?

Galapagos' head office is in Belgium in the European Union and all personal information in the study is protected under the GDPR (the EU General Data Protection Regulation) and national legislation, if any.

Your samples will not be used to identify you.

Galapagos is responsible for the processing of your personal information and is named the "controller." Your coded information in your study-specific file is protected by appropriate technical and organizational security measures.

Will my study-related information be shared, disclosed, and kept confidential?

These people may see your personal information. Representatives of:	
Galapagos or a partner organization	To make sure that all collected information is correct by comparing the study records with your personal medical records
Ministries of Health, the FDA, state health	To check your personal information to see if the study was run correctly

departments, or Advarra IRB	
Data protection authorities	To check your personal information and how it was processed

These organizations outside Galapagos may get your coded personal information, for example:

- Companies and experts helping Galapagos in conducting the study
- Companies that are processing your personal information on behalf of Galapagos
- Universities or researchers
- Collaboration partners
- Regulatory agencies

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. If your information is transferred to countries where the GDPR does not apply, Galapagos will take steps to ensure that your information has the same level of protection as required by GDPR, but absolute confidentiality cannot be guaranteed. Your code will be used, and your identity will not be shared.

Your medical records will always stay at the study doctor's office. Everyone who sees your personal information (including your name) will treat it confidentially.

Also, when the results of the study will be published, your identity will remain confidential.

It is anticipated that there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups, which have not been included above, may include:

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- *Banner University Medical Group and Banner Health*
- The University of Arizona (UA) and the UA Institutional Review Board
- Your primary care physician or a specialist taking care of your health.

If you agree to take part in this study a copy of this signed informed consent form will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- Your name
- Address
- Phone number
- Information coming from your samples (for example, from your blood samples)
- Your medical history (such as allergies, surgeries, other illnesses) and medication use
- Demographics such as your age and sex (at birth)
- Study drug treatment, including test results and any symptoms
- Your responses to the questions asked at the visits, in questionnaires or in a diary
- Information described in separate Informed Consent Forms you sign, if any

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

When will my authorization expire?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. The Principal Investigators address and telephone numbers is listed on the first page of this form.

Will access be limited to your research study record during this study?

You may not have access to the research information developed as part of this study until it is completed. Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

How long is my personal information kept?

When the study ends for you, your collected information will remain part of the study data, but no additional information will be collected. Your previously collected samples can still be analyzed, and the results added to the study data unless you request your samples to be destroyed. By law, the study data must be kept for at least 25 years after study completion.

Your rights regarding your personal information

You have the right to:

- Request to have your personal information corrected if it is no longer accurate or up to date
- Request to have your personal information erased (in certain circumstances)
- Request to restrict the use of your personal information
- Request to object to how your personal information is processed
- File a complaint with the Belgian or with your national Data Protection Authority.

If you wish to exercise any of your rights, contact the study doctor who can best address your concerns. The study doctor will involve Galapagos when necessary. Or, you can contact the study doctor's office, or Galapagos' Global Data Protection Officer. The study doctor and/or Galapagos will assess your request in a timely manner and will inform you whether they can comply with your request and why.

Statement of Authorization

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Name of the participant	Date (DD/MM/YYYY)	Signature of the participant

Witness[1]/Interpreter consent (if applicable)

I was present during the entire Main informed consent process. I confirm that the purpose and procedure of collecting information was adequately provided and that consent to agree to the collection of information was freely given.

Printed name of witness/interpreter and relationship, role, or qualification	
Date (DD/MM/YYYY) (personally dated)	Signature of witness/interpreter

[1] A witness is required if the participant is unable to read (blind, illiterate) or if it is required by local law. The witness must be present for the entire informed consent process.

Where can I learn more about the study and study results?

A description of this clinical trial will be available on **www.ClinicalTrials.gov,** as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This study is registered in the European Union clinical study database at **euclinicaltrials.eu** under 2023-503183-16-00. About 12 months after completion of the study, the study results and a summary in which you cannot be identified will be available to you in the EU database.

Whom to contact about this study?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00070853.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at BannerResearchCompliance@bannerhealth.com.

To cancel your authorization for access to PHI you must notify the study doctor listed on page one of this document.

Additional contact information

For questions about…	Contact
Questions about the study or study drug	You can always contact the study doctor at the phone number listed on the first page of this form.
Questions about your personal information	You can always contact the study doctor at the phone number listed on the first page of this form or Galapagos' Global Data Protection Officer e-mail: dpo@glpg.com and address Galapagos NV Generaal De Wittelaan L11 A3, 2800 Mechelen, Belgium

Consent

Participant

- I had enough time to read this Informed Consent Form and my questions were answered.
- I know why the study is being done, how long it lasts, what will happen, tests I will undergo, any costs and what is expected of me.
- I understand that my participation is voluntary.
- I understand any risks and potential benefits.
- I understand how my samples are stored and how my personal information is protected, and I agree that my personal information can be processed.
- I agree that representatives of Galapagos or regulatory authorities may inspect my medical records, keeping my identity confidential.
- I know who to contact if I have questions or if something happens.
- I have the right to leave (stop) the study at any time.
- I agree to participate in this study and agree to take the study drug
- I understand that my family doctor (primary care doctor) will be informed that I've joined this study. This is recommended by the international standard for conducting and reporting clinical studies (ICH/GCP). It is mandatory in some countries.
- I understand that the original of this signed Informed Consent Form will remain on file with the study doctor. I will receive a signed and dated copy of this Informed Consent Form.
- I understand that by signing this Informed Consent Form, I am not waiving any of my legal rights.

Name of the participant	Date (DD/MM/YYYY)	Signature of the participant

Optional

I agree that the information collected about me will be used to answer new scientific research questions in the future.

Name of the participant	Date (DD/MM/YYYY)	Signature of the participant

Person conducting the Informed Consent discussion

I have explained the study (nature, purpose, foreseeable effects) to the participant whose name is above. The participant consented to participate by personally signing and dating this form.

Name of the person conducting the discussion	Date (DD/MM/YYYY)	Signature of the person conducting the discussion

Witness[1]/Interpreter consent

I was present during the entire Main informed consent process. I confirm that the purpose and procedure of collecting information was adequately provided and that consent to agree to the collection of information was freely given.

Printed name of witness/interpreter and relationship, role, or qualification	
Date (DD/MM/YYYY) (personally dated)	Signature of witness/interpreter

[1] A witness is required if the participant is unable to read (blind, illiterate) or if it is required by local law. The witness must be present for the entire informed consent process.