I. Patient Information Sheet

Study Title: A Phase 2A, Randomized, Double-Blind, Placebo-Controlled, Clinical Trial Evaluating the Safety and Efficacy of CM-101 in Subjects with Primary Sclerosing Cholangitis
Short Title of Study: The Spring Study
Protocol No.: CM-101-PSC-101
Name and Address of Sponsor: ChemomAb Ltd. Kiryat Atidim, building 7, entrance B, Tel Aviv, P.O. 58288, Israel
Principal Investigator Name: Dr Stephen Barclay Monday to Friday 8am – 5pm: 0141 201 3770 Out of hours: Call 0141 211 4000 and ask for on-call gastroenterologist
Institution: Clinical Research Facility, Glasgow Royal Infirmary

Introduction

The term "patient" in this document refers to people taking part in a research study and may also be referred to as subjects, participants, or volunteers.

The term 'study site' in this document refers to the hospital that is taking part in this research study and has invited you to participate. There are 15 study sites taking part in the research study in the UK.

You are being invited to voluntarily take part in a clinical research study to test the study drug CM-101 for patients with Primary Sclerosing Cholangitis.

This document tells you about the study and includes information about the reason why the study is being done, what will be required of you if you take part in the study, and the possible risks and benefits of this study. Please take time to read this document carefully and please feel free to talk about it with your partner, family members, family doctor or others.

Your study doctor will also talk to you about the information in this document in detail. Please ask your study doctor or the study staff to explain anything that is not clear.

If you choose to take part in this study, you will be asked to sign this document. You will receive a fully signed and dated copy of this information sheet and consent form.

Even if you choose to take part in the study and sign the consent form, you are still free to withdraw from the study at any time without giving a reason. If you withdraw from the study, we will ask you to return to your study doctor for a post-study assessment to check your health.

1. What is the Purpose of this study?

The purpose of this study is to find out the safety, tolerability and impact of the study drug (named CM-101) in adult patients with Primary Sclerosing Cholangitis (PSC).
In Primary Sclerosing Cholangitis, it is thought that some substances released in excess by your body induce the migration of various kind of cells to your liver, leading to liver damage. CM-101 is a drug in development that is believed to be able to block the activity of these substances and thus limiting the liver damage.
The study team would like to assess the way in which the study drug works in the human body, the effect it may have on the body and on disease progression, as well as to understand how well the study drug is tolerated by the body and to identify any possible side effects of CM-101.
This will be done through monitoring factors in the blood (called biomarkers) that are a measure of your health and physical condition, and through a measurement of your liver stiffness and scarring using an imaging method.
CM-101 is an experimental drug which is not currently approved by Health Authorities including the MHRA (The Medicines and Healthcare products Regulatory Agency) in the UK for the treatment of Primary Sclerosing Cholangitis.

About 45 people will take part in this study at a number of different locations in the UK and in Israel. You are being invited to participate by one of the hospitals taking part in this study which is listed on the first page of this document. The main study doctor at that hospital, the Principal Investigator, is also named on the first page. The main study doctor will be helped by other study staff throughout the duration of the study.

This study has been reviewed and approved by the MHRA and given favourable opinion by London - South East Research Ethics Committee so that the study can take place. These bodies are responsible for making sure that the rights of people who take part in clinical research studies are protected. The approval by the MHRA and the favourable opinion of London - South East Research Ethics Committee should not be thought of as encouragement for you to take part in this study.

2. What are the Study Procedures?

Patients who qualify for this study and decide to take part will be required to attend 8 study visits over a period of 19 weeks followed by 2 follow-up phone calls. The total duration of your participation in the study will be up to 31 weeks, of which the total treatment period with study drug is 12 weeks.
Patients, who qualify for this study will be assigned randomly to receive one of the following treatments:

- Treatment 1: CM-101
- Treatment 2: placebo

Two thirds of patients in the study will receive Treatment 1 so you will have two chances out of three of getting Treatment 1 and one chance out of three of getting Treatment 2.
A 'placebo' looks like the study drug but does not have any active substance in it. You and your study doctor will not know your treatment group.

This is a double-blind study, which means you and your study doctor will not know which treatment you are receiving. This is the best way to measure the effect of the study drug in the study. As a result, you cannot be told the exact treatment option you are receiving until after the study has ended and the results have been analysed. Your study doctor can find out which treatment you are receiving if there is an emergency or if this information is needed for the purpose of your health.

The treatment will be given as an intravenous infusion (i.e. through a drip into one of your blood vessels); you will need to remain lying down for 60 minutes while the study drug is being infused.

If you agree to take part in this study, you will first have some screening tests to be completed at your study site to find out if you meet the requirements.

Screening Period:

The screening tests will take place five days up to 28 days prior to first study drug treatment. The study doctor will ask you questions about your medical history and about any treatments or medications that you may be taking, including non-prescription medication, vitamins or herbal remedies. You will be asked to fill out a questionnaire that will assess the level of your itchiness (Pruritus), and you will undergo various tests:

- Physical examination including height and weight measurement
- Vital signs: Your study doctor will measure your blood pressure, heart rate, body temperature and breathing rate

- Blood and urine samples will be collected (up to approx. 15 mL of blood; just over 1 tablespoon), you will be asked to fast for 10 hours prior to arriving at the study site for blood sampling (drinking water will be allowed). Blood and urine samples will be collected to:
  - Check the activity of your liver, kidneys, blood, and other body systems.
  - Check if you are pregnant (female patient only who are not post-menopausal)
  - Check a marker of cancer (CA19-9)
  - Check if you have HIV or Hepatitis B or C – Your blood sample will be tested for HIV, which is the virus that causes AIDS. If your test results show that you have HIV, you will be told and given information on counselling services. The results of your HIV test will be kept confidential.
  - Test for Hepatitis B and C. If your test results are positive, your study doctor or staff will tell you and explain any further assessment or follow up required. The results of Hepatitis B, or C testing will be kept confidential and disclosed only as required by law.
- An Electrocardiogram (ECG) will be performed: This test measures your heart's electrical activity; electrical activity controls your heartbeat. You will have small sticky pads placed on different areas on your body. Wires connected to the pads will send information on the electrical activity back to a machine for recording and measuring. This test only takes a few minutes
- Transient Elastography and Transabdominal Ultrasound: Transient Elastography is a scan of your liver which measures how elastic (or how stiff) your liver is. It is a painless procedure similar to an ultrasound scan. This test will be done on two occasions during the study (before you receive the study treatment and after the study treatment is stopped. Transabdominal Ultrasound is another painless procedure to examine your liver. This will be done once during the screening period.

Although we aim to perform all these tests at a single screening visit, we may ask you to have some of these tests on a different day at a different part of the study site (e.g., your imaging tests).

You will be asked not to change your lifestyle habits with emphasis on physical exercise and the use of on-going medication for the screening period and the entire duration of the study should you be willing and able to take part.

Once all of the screening results are obtained, your eligibility to participate in the study will be assessed by one of the study doctors. If you are found to be eligible for the study, you will be invited to receive the first dose of treatment at a given date.
If for some reason the 4-week screening period ends and you have not started treatment, a re-screening visit will take place (with your consent) where an additional 8 mL of blood (just

over 1.5 teaspoons), and another urine sample will be collected for repeat testing, an ECG will be taken and your vital signs will be measured.

Treatment period:

A total of 12 weeks. The study drug treatment will be given through a drip into one of your blood vessels (intravenous infusion), once every 3 weeks, for a total of 5 treatments. This will be carried out at the study site each time.

Treatment Visit 1 (Day 0)

Please note that treatment visit 1 and visit 5 will take more than 7 hours. They will start early in the morning and will end in the afternoon.
You will be asked to fast for 10 hours prior to arriving at the study site for the first treatment visit (drinking water will be allowed).

Pre-Dose (before the study drug is administered)

You will be admitted to the study site in the morning and you will be asked about any change in medication or any change to your health since the screening visit. Your health and eligibility to participate in the study will be checked again.

Several tests (checking the site of the planned infusion site, vital signs, weight, physical examination, ECG, and completion of the itch questionnaire) will be performed within 2 hours prior to dosing. Urine and blood samples will be taken for:

- Routine tests to check the activity of your liver, kidneys and other body systems
- Routine tests to check if you are pregnant (if you are a female patient of child-bearing potential)
- Routine test to check the drug level in your blood
- Biomarker research tests: Blood samples will be tested to analyse biomarkers: these are substances that may provide information about how the drug works, the causes of disease and its individual course, identification of patients who may benefit from the study drug, or are at risk for certain side effects. This information could improve the treatment for patients in the future.

You will be allowed to eat a light breakfast before receiving the treatment. You may need to remain at your study site for several hours before receiving the study treatment allocated to you.

Post-Dose (after the study drug has been administered) – Medical observation

After the administration of the study drug is complete, you will need to stay at the study site under direct observation of the research team for 1-hour. You will be allowed to eat 2 hours after the end of drug administration (drinking water is allowed at all times).

Several tests (any reactions to the site of injections, vital signs, physical examination, and completion of the itch questionnaire) will be performed. Further urine and blood samples will be taken periodically within the clinic for 6 hours' post-dose:

- Routine tests to check the activity of your liver, kidneys and other body systems
- Routine test to check the drug level in your blood
- Biomarker research tests: Blood samples will be tested to analyse biomarkers:

You will be able to go home after receiving the study doctor's approval. You will be able to drive and resume work after this visit, providing your study doctor or nurse confirms that it is safe to do so.

Safety Visit (Day 7)

You will be asked to come to the study site for a safety visit a week after Treatment Visit 1. You will be asked about the medications you are taking and any change in your health since your last visit.

You will be examined by a study doctor, the injection site will be evaluated for any reactions, your vital signs will be collected, and further blood samples (approx. 25 ml; just over 1.5 tablespoons) will be drawn. After a second treatment visit is scheduled you will be able to go home.

This visit will take around 3 hours.

Treatment Visits 2-5

Treatment visits 2, 3, 4 and 5 are similar to Treatment Visit 1.
Blood quantity drawn will differ at each visit, and there will be different fasting and observation requirements, as follows:

Treatment Visit	Week	Fasting?	Total Blood Volume Drawn for Tests	Post Treatment Medical Observation	Total Hours Spent at Site (approx.)
Screening	Week (-4,-1)	10 hours fasting	Approx. 15 ml (approx. 1 tbsp.)	NA	5
Treatment 1	Week 0	10 hours fasting	Approx. 75.5 ml (approx. 5 tbsp.)	6 hours	9
Safety Visit 1 (Day 7)	Week 1	NA	24ml (approx. 1.5 tbsp.)	NA	3
Treatment 2	Week 3	No fasting	Approx. 29 ml (approx. 2 tbsp.)	2 hours*	6
Treatment 3	Week 6	10 hours fasting	Approx. 41 ml (approx. 3 tbsp.)	2 hours*	5
Treatment 4	Week 9	No fasting	Approx. 29 ml (approx. 2 tbsp.)	2 hours*	5
Treatment 5	Week 12	10 hours fasting	Approx. 52.5 ml (approx. 3.5 tbsp.)	6 hours	5
Safety Visit 2/ End of treatment	Week 15	NA	47.5 (approx. 3 tbsp.)	NA	3

* You will remain at the site for 6 hours of observation if the study doctor thinks this is necessary

After completing the post treatment tests and observation period, scheduling the next visit, and receiving the doctor's approval, you will be able to go home. You will be able to drive and resume work after each visit.

Safety phone call

A member of the study team will contact you by phone 3 days after each treatment visit to enquire about your physical condition and about any changes that might have been made to the medications you are taking.

Follow up period: A post treatment follow-up visit (safety visit 2) will occur 3 weeks after your last treatment visit, followed by a phone call every 6 weeks for 12-weeks for safety monitoring.

Follow-up visit (safety visit 2)

You will return to the study site for one follow-up visit 3 weeks after the last treatment is given. You will be asked about your medications and any change in your health since the last visit.

A study doctor will examine you and several tests (any reactions to the site of injections, vital signs, weight, ECGs, transient elastography, completion of the questionnaire) will be performed. Blood (approx. 47.5 ml; approx. 3 tablespoons) and urine samples will be drawn:

- Routine tests to check the activity your liver, kidneys and other body systems.
- Routine tests to check if you are pregnant (if you are a female patient of childbearing potential)
- Routine test to check the drug level in your blood
- Biomarker tests

Follow-up calls

You will receive a call from the study team after 6 and 12 weeks, after the safety follow up visit, so they can ask you about physical condition and any changes made to the medications you are taking. The second call will mark the end of your active involvement in the study.

Early termination visit:

If you are withdrawn from the study or choose to withdraw from the study before the completion of the study treatment period, you will be asked to meet with your study doctor for a final visit to check on your health. This visit would be the same as the follow-up visit (safety visit 2) described in the previous section.

Human Biological Samples

While you are in this study, sample(s) of blood and urine will be collected. These samples will be used for safety testing during the study and for this study's medical research. The tests will be performed by the laboratory described below. These samples are valuable to this study and may help identify a cure for disease or identify a biomarker to help with treatment of disease.

What samples will be used for:

a. Your samples will be used for safety tests during the study and for the research purposes explained in the procedures section of this form.
b. Your samples will not be sold or used directly for the production of commercial products.
c. In case of any commercial gain based on research results from your samples, ChemomAb will have the ownership of the research results and may file patents. The research done with your samples may help to develop new products, new medical tests or treatments in the future that have commercial value. There will be no financial benefit to you for any

commercial findings or products as a result of the use of your samples in this study. By agreeing to take part in this clinical research study, you agree to give up your rights for any commercial value resulting from your samples and data.

d. Your samples will be coded to protect your identity, so that it will not be possible to directly link your details and the code on the samples.
e. Your samples may be provided to a third party for testing and research use and storage purposes done for and on behalf of the sponsor of this study and its third-party collaborators. Samples being collected will be sent to:
    - *Eurofins Pharma Bioanalysis Services UK Limited, United Kingdom*
    - *William Rosenberg RFH, United Kingdom*
    - *Nordic Laboratories, Denmark*
    - *Immunologix Laboratories, USA*

    but may need to be shipped to other locations which may be in other countries during the course of the study.
f. Your samples will be stored for 10 years. Your samples may be stored for longer than these specified periods if this is required by a regulatory or government agency.

Safety blood samples:

During the Study, blood and urine samples will be taken for routine laboratory tests to check if your liver, kidneys and other body systems are working normally.
These samples will be stored in a secure laboratory and once the samples have been tested, they will be destroyed within 60 days of the test results being confirmed.

Reports about research done with your samples will not be put in your health/medical record and will be kept confidential to the best of our ability within the law.

3. What are your Responsibilities for this study?

If you decide to take part in this study, it is important that you agree to:

- Come to your study visits. As soon as you know that you will not be able to go to a study visit, please contact your study doctor or the study staff to schedule a new visit.
- Complete the Itch Questionnaire following the instructions of the study team.
- Truthfully answer any questions from your study doctor or the study staff when asked about any changes in your health, visits to other doctors or hospital admissions, or changes in your medication, including prescribed medications, over the counter medications, herbal remedies, vitamins, and food supplements.

- If you are or are planning to take part or have taken part in other clinical research studies, please inform your study doctor. Do not take part in any other clinical research studies without the consent of your study doctor while you are taking part in this study.
- Tell the study doctor or research study staff if you believe you or your partner may be pregnant.
- Tell your study doctor or research study staff if you change your mind about taking part in the study at any point.
- Try and follow the guidance requested by your study doctor:
  - Fasting requirements as describe above
  - Refrain from any strenuous physical activity (e.g. competitive sports, running, fast cycling, climbing, etc.) from the screening visit throughout the entire course of the study.
  - Keep your alcohol intake lower than 14 units/week for both females and males One unit of alcohol equals ½ pint (250 mL) of beer or lager, 1 small glass (about 80 mL) of wine, or ⅙ gill (25 mL) of spirits.

4. What are the Possible Risks?

We ask you to think carefully about the possible risks or discomforts involved in taking the study drug before you agree to take part in this study.
If, you are placed into the placebo group in the study, you will not be receiving the study drug for your health problem, so your condition may not improve and could potentially get worse.
As the study drug is experimental, even if you receive the active drug, it may not help your health problem(s), which may stay the same or might get worse.

Side effects of the study drug

- The study drug has been found safe in animal testing. There have been no adverse reactions noted after injection of the study drug to animals in doses up to 10 times higher, and for a longer length of time than the doses you will receive.
  In healthy humans, the drug was found to be safe in single administrations of up to 10 mg/kg, and in multiple administrations of up to 2.5 mg/kg. That being said, as with any new drug, there may be side effects that the researchers do not expect or do not know about. These reactions may be different from person to person. For some, they may be severe, prolonged or permanent.
- Since the drug is a protein (antibody), an allergic reaction may develop: you may feel chills, your temperature may rise, you may have a skin reaction (pruritus), itching, a sensation of swelling of the tongue or throat, irritation in the nasal passageways, coughing or shortness of breath.

- Experience gained through single and multiple dose administrations of this drug and multiple administrations of similar drugs to humans shows that side effects are typically mild, and only a minority of the subjects' experience significant allergic reactions which subside with or without treatment.

These types of reactions are the reason why you will be asked to stay in the clinic for observation for 6 hours after the first dose and to come in for safety follow up visits. It is very important that you let the study doctor or staff know of any changes in your health throughout the duration of the study.

Pregnancy risks

Female participants

The effects of the study drug on an unborn child and on a breast-fed baby are not known. Because of this, it is very important that you are not pregnant and are not breast-feeding and you do not become pregnant during the course of the study. You will not be allowed to take part in the study if you are pregnant, trying to become pregnant or are breast-feeding.

- If you can become pregnant, the study doctor will ask you to have an initial blood pregnancy test before you start the study, and urine pregnancy test during the study to make sure that you are not pregnant.
- If you can become pregnant, you must use a reliable birth control method(s) during the study and for 18 weeks after receiving the last dose. The study doctor will let you know which birth control methods are acceptable. The following birth control methods are recommended: Barrier method (such as condom with spermicide or diaphragm with spermicide); intrauterine device; vasectomy (partner); hormonal (e.g., contraceptive pill, patch, intramuscular implant or injection); abstinence. If you do become pregnant while taking part in the study, you should let your study doctor know right away. Your study doctor will remove you from the study and talk to you about the need for further medical attention if appropriate.

Male participants

There are no known risks with taking part in this study if your partner gets pregnant, yet as in every clinical study:

- You must use a reliable birth control method during the study and for 90 days after you receive the last dose. The study doctor will let you know which birth control methods are acceptable. The following birth control methods are recommended: barrier method (condom with spermicidal jelly, foam suppository, or film; diaphragm with spermicide; or male condom and diaphragm with spermicide) or abstinence for the duration. If your partner does become pregnant while you are taking part in the study, you should let your study doctor know right away.

Other Possible Risks or Discomfort

There are also possible risks and discomforts from the procedures you may experience during the study. These include:

- Discomfort during the 60 minutes of intravenous administration: Infusion may cause pain, discomfort or local redness in or around the injection site
- Discomfort due to lying in bed during drug administration, and for 1 hour afterwards or during blood collection for the follow up tests
- During the 12-Lead ECG pads will be placed on different parts of your body. There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.
- The risk of blood drawing includes discomfort at the site of the blood draw with bruising, bleeding, infection, and rarely fainting or nerve damage. During the study, up to 330 mL (approx. 22 tablespoons) of blood will be taken from you.
- Transient Elastography and Transabdominal Ultrasound: Both procedures are a painless procedure similar to an ultrasound scan during pregnancy.

5. What are the Possible Benefits?

Possible benefits from taking part in this study may include:

- Your health problem may or may not get better from taking part in this study. It is hoped that the study drug may provide relief of, or lessening of, the signs and symptoms of your health problem, however such benefit cannot be guaranteed. In this study you may be receiving the placebo which means you may not be taking the actual study drug.
- Taking part in this study will help doctors to learn more about the study drug, CM-101. This may help others with the same health problem in the future.

We cannot promise that you will get any benefits from this study.

6. What are the Alternative Treatments?

If you decide not to take part in this study or study treatment is stopped, you may want to think about other treatments for your health problem and your study doctor can talk with you about these other treatments and their risks and benefits.

Treatments for primary sclerosing cholangitis routinely focus on managing symptoms, complications and monitoring liver damage.

- Itching, a major symptom, is managed with bile acid sequestrants, antihistamines, opioid antagonists, or Ursodeoxycholic acid (UDCA).
- To prevent or treat infections antibiotics may be used.

- Bile duct blockages may be treated surgically or with an endoscope.
- In the event that a liver failure or life-threatening complications occur, a liver transplant may need to be considered.

7. What are the Costs?

You will be paid for your inconvenience up to £99.00 for workday loss per visit. You will be reimbursed for incurred travel and meal costs related to attendance of study visits up to an amount of £59.00 (£49.00 for travel and £10.00 for refreshments when more than 3 hours are spent at site) per completed visit. Higher travel reimbursement can be authorised with preapproval for example if an overnight stay is required due to the length of the stay at site. For more information, please talk to your study doctor.

You will not have to pay for the study drug, visits, or for the procedures needed for you to take part in this study. The sponsor of the study will pay for the costs of the study drug, as well as the costs of the tests and procedures needed in this study.

8. What is the Compensation for any Injury?

The sponsor has obtained an insurance policy which covers the risks and the damage which could occur from this study. If you or your rightful claimants (family) suffer any damage which is connected to this study, this damage will be compensated by the sponsor of this study in accordance with the existing legislation in the UK.

The Sponsor, ChemomAb Ltd will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).
We will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol;
- Any test or procedure you received as part of the trial.

Any payment would be without legal commitment (Please ask if you would like more information on this). The Sponsor, ChemomAb Ltd would not be bound by these guidelines to pay compensation where: the injury resulted from a drug or procedure outside the trial protocol, or the protocol was not followed.

9. Confidentiality

Your identity and your personal health data will be kept confidential.

Without your consent, your data or samples cannot be used. This is why you will not be able to take part in the study if you do not give your consent to use your personal data.

During the course of the study, the study doctor will collect personal data, including personal health data about you and your samples, which will be used for the purpose of the study as described in section 1 of this form and may help develop new tests, procedures, and commercial products.

You must give your authorisation before the study doctor can use or share your personal data with others. This section will describe how your personal data will be collected and used and explain your rights.

By signing this form, you consent to the study doctor and his or her study staff collecting and using personal data about you for the study ("Study Data") as permitted by the applicable laws and regulations.

Your consent to the use of Study Data for the purposes of the Study does not have a specific expiration date. However, you may withdraw your consent at any time. If you do take away your consent, no new information or biological samples will be taken, and you may also request that no new analysis on your samples will be done.

How will we use information about you?

We will need to use information from you, your medical records and your GP for this research project.

The Study Data that will be collected are:

- Personal data
    - your name, address, telephone number, email address, health insurance number (if applicable) and NHS number.
    - your age, gender, ethnic and racial background
    - information about your lifestyle, health, medical condition and medical history and medications you take
- Biological Samples (see section 2 above): blood [up to 330mL, approx. 22 tablespoons]; urine [3 samples]
- Information about your study treatments and response to study treatments (which includes the procedures described in this form) and data resulting from analysis of biological samples and images

- Information about side effects and medical history and test results while you are taking part in the study

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be sent to within and outside the EU. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from your study doctor
- by asking one of the research team
- by sending an email to the Data Protection Officer at spring@chemomab.com

Data Protection

We would like to assure you that all data will be handled in accordance with Data Protection Act (DPA) 2018 and that the separate document provided to you will provide additional detail on data protection.

Publication

On completion of the study, results and data from the study that will not include any personal identifiers may be published in accordance with regulatory requirements.

Although information about this study, including the results, may be published for scientific purposes, presented or posted electronically (for example, in a clinical trials registry database) or

presented to scientific groups, your name and personal information will not be used and your identity will not otherwise be revealed.

A description of this study will be available on https://www.clinicaltrialsregister.eu/ as required by EU 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.

Storage of Personal Data and Biological Samples

Your personal data will be stored for as long as required by law which will be 15 years or until at least 2 years after the drug's last approval and the sponsor does not intend to apply for any further approval, whichever is longer. Information on how long your biological samples will be stored is provided in the biological samples section.

What are your Rights Concerning the Processing of Your Personal Data?

The data recorded at the time of this study may be held on computers or as paper records by the sponsor or by someone else for the sponsor. You have a right of access to, and, if needed, you have the right to correct your data. You have the right to request from the sponsor removal of your personal data, to obtain from the sponsor restriction of processing, to object to processing, and to receive personal data provided to the sponsor for transfer to a third party (i.e., right to data portability). However, certain personal data collected before you make such a request may need to be processed by the sponsor in order to comply with regulations governing clinical research in the UK and cannot, therefore, be erased. You also have the right to withdraw your consent to the processing of your personal data at any time. However, if you withdraw your consent to the processing of your personal data after you have started your participation in the study this will result in your withdrawal from the study.

If you have any questions about the collection and use of information about you or would like to exercise rights that you may have regarding this information, you should ask your study doctor at 0141 201 6368. We take your concerns and rights very seriously. However, if you believe that we did not acknowledge any complaints and concerns, you are entitled to lodge a complaint with the information Commissioner's Office (ICO) at https://ico.org.uk/ or on 0303 123 1113.

10. How will you find out about any New Information?

During the study, new information about the risks and benefits of the project may become known. Your study doctor will talk with you about any important new information that is learned during the course of the study that may affect your willingness to continue to take part in the study. This

new information may also mean that you can no longer take part in this study. In all cases, you will be offered all available care to suit your needs and/or medical condition.

11. Voluntary Participation/Withdrawal

Taking part in this study is entirely voluntary. You do not have to take part in this study.

If you choose to take part and you change your mind later, you are free to take back your consent and to stop being in the study at any time without giving a reason. In that case, we ask you to tell your study doctor or study staff. You may be asked to take part in a final visit or follow-up. If you do take away your consent, no new information or biological samples will be taken, and you may also request that no new analysis on your samples will be done.

If you change your mind about allowing your coded samples to be used for this study, contact the study doctor or nurse and let them know. Your **samples** will no longer be made available for testing and will be destroyed. If you do choose not to have your samples that are required for the study to be used, you will no longer be able to take part in this study but you will not lose any benefits to which you are otherwise entitled.

Your choice to take part or to stop taking part in this study, will not affect your routine/regular treatment, your relationship with those treating you or your relationship with the place where you are getting treatment. You will still receive care for your condition and will not lose any benefits to which you are otherwise entitled.

12. What will happen if there is a Premature End of the Study or Study Treatment?

This study or the study treatment may be stopped without your consent.

Reasons why the sponsor can stop the study or put the study on hold include:

- The study drug CM-101 has been shown not to work.
- The study drug CM-101 has been shown to cause damage to participants.
- Decisions made in the business or commercial interests of the sponsor.
- Decisions made by the Regulatory Authorities or Ethics Committees.

Reasons why the study doctor can stop your study treatment include:

- Taking part in the study is not beneficial to you.
- You are having bad side effects.
- You are not coming to study visits or taking the study drug, as told.

- You need to start taking other treatments for your medical condition that the study does not allow.

13. Will the study drug be available after the end of trial?

This drug will not be provided/available once the trial has ended as this is an early stage of the study and the efficacy of the IMP has not yet been approved.

14. Who to contact for more information?

Contacts in case of emergency and for questions about the study

Please contact the study staff if you have any questions about this study, its procedures, risks and benefits, or alternative courses of treatment or in case of emergency.
You will be provided with a card that you should carry with you while participating in the study: this card contains emergency numbers and study details.

Contact for questions about your rights

If you have any complaints about any part of the study, the way it is being done or any questions about your rights as a study participant, you may contact:

Name of Contact Person: **Patient Advice & Support Service**

Telephone Number: **0800 917 2127**

Address: **www.cas.org.uk/pass**

If you have questions about your rights as a research patient, you may contact your local hospital's Patient Experience Team.

Contact details are: NHS Greater Glasgow and Clyde Complaints
Telephone: 0141 201 4500
Email: Complaints@ggc.scot.nhs.uk
For further details contact: www.nhsggc.org.uk

IEC REVIEW

Any new research studies beyond the current study using your coded samples will be reviewed by the study doctor's Independent Ethics Committee (IEC), a special committee that oversees medical research studies to protect the rights and welfare of the human patient volunteers.

II. INFORMED CONSENT FORM

Study Title: A Phase 2A, Randomized, Double-Blind, Placebo-Controlled, Clinical Trial Evaluating the Safety and Efficacy of CM-101 in Subjects with Primary Sclerosing Cholangitis

Short Title of Study: The Spring Study

Protocol #: CM-101-PSC-101

Sponsor: ChemomAb Ltd.

Site Number: P03

Name of Investigator: Dr Stephen Barclay

		Please initial
1	I have read (or someone has read to me) the information in this document in a language that I understand well.	
2	The content and meaning of this information have been explained to me.	
3	I have been given an opportunity to ask my questions in private as well as to meet with a study doctor to discuss this study. I have had a chance to consider the information, including the risks and benefits of taking part in this study, to ask questions, and to discuss the study. My questions have been answered to my satisfaction.	
4	I have asked the staff any questions I may have and have had enough time to decide if I want to take part in this study.	
5	I consent to my personal data, including personal health data, being collected, processed and stored as described in this consent form, in accordance with the procedure defined in this consent form.	
6	I consent and agree that my encoded personal data may be transferred out of the EU to Israel, for the purposes discussed in this consent form. I am aware that laws in these countries do not provide the same level of data protection as do the laws of the EU and UK. I understand that reasonable steps will be taken to ensure the confidentiality of my encoded personal data.	
7	I consent to the transfer of my biological samples to Denmark and possibly another country, for the purposes discussed in this consent form. I am aware that laws in these countries do not provide the same level of data protection as do the laws of the EU and UK. I agree to the processing and storage of my	

	biological samples in Denmark and if necessary, another country. I understand that reasonable steps will be taken to ensure confidentiality.	
8	I also agree to the HIV testing as described in this document.	
9	I agree that my GP can be told that I am taking part in this clinical research study.	
10	I am free to stop taking part in this study at any time for any reason and my choice to stop taking part will not affect my future medical care. I agree to follow the study doctor's instructions and will tell the doctor at once if I have any changes in my health. By signing this document, I am not giving up any of my legal rights.	
11	**I have decided to take part in this clinical research study. I understand I will receive a signed and dated copy of this document.**	

Sign this ONLY if all of the above statements are true:

_____
Printed Name of Patient

_____ _____
Signature of Patient *Date of Signature*

I, the undersigned, investigator / study personnel, confirm that I have verbally given the necessary information about the study, that I answered any additional questions, and that I did not exert any pressure on the patient to participate in the study.

I declare that I acted in full accordance with the ethical principles described in GCP Guidelines, and other national and international legislation in effect.

A copy of this patient information letter and consent form, signed by both parties, will be provided to the patient.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent *Date of Signature*