I. Patient Information Sheet

Protocol Title: A Randomized, Double-Blind, Placebo-Controlled, Two-Arm Parallel-Group, Multi-Center Phase 3 Pivotal Trial to Investigate the Efficacy and Safety of Recombinant Human Alkaline Phosphatase for Treatment of Patients with Sepsis-Associated Acute Kidney Injury
Protocol No.: AP-recAP-AKI-03-01
Short Title: Recombinant human alkaline phosphatase SA-AKI survival trial (REVIVAL)
Name and Address of Sponsor: AM-Pharma B.V. Stadsplateau 6 3521 AZ Utrecht The Netherlands
Principal Investigator:
Institution: < *Include name, address, and phone number*>

Introduction

You are being invited to voluntarily take part in a clinical trial called REVIVAL to investigate recombinant human alkaline phosphatase (recAP) for patients with sepsis-associated acute kidney injury (SA-AKI; this term is explained below).

In this consent form the expressions “you” and “I” refers to the patient. If you are a legally authorized representative of a patient, please remember that “you” or “I” means the patient and not you as the representative except for circumstances where you act on behalf of the patient.

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

Your trial doctor or a member of the clinical trial team will also talk to you in detail about the information in this document. Ask your doctor or a member of the clinical trial team to explain anything that is not clear to you.

If you choose to take part in this clinical trial, you will be asked to sign this document. You will get a signed and dated copy of this information letter and consent form.

AM-Pharma B.V. (a pharmaceutical company) is organizing and funding this clinical trial. AM-Pharma B.V. (“AM-Pharma”) will pay the clinical trial site to cover their costs of conducting this clinical trial. If applicable, your trial doctor will disclose to you any financial links or other interests that he/she may have to AM-Pharma.

1. Purpose of this trial

Sepsis is a condition that may occur when the body overreacts to an infection. Sepsis often leads to injury of one or more organs (multi-organ dysfunction); the kidney is a frequently injured organ. The term sepsis-associated acute kidney injury (SA-AKI) is used under these circumstances. SA-AKI is associated with an increased risk of dying from sepsis. Currently, there is no drug approved for the treatment of SA-AKI. Filtering the blood by a dialysis machine is the only treatment option available for patients with SA-AKI.

Some of the procedures performed for this clinical trial will be in addition to your standard of care. If you have questions about any of the procedures, you should ask the trial doctor or a member of the clinical trial team involved in this clinical trial.

Alkaline phosphatase (AP) is a compound normally present in many human tissues. AP has many functions including helping the body fight infection and reducing organ injury during sepsis.

recAP is the short name given to the clinical trial drug that AM-Pharma is investigating as a way to reduce the mortality of patients with SA-AKI and to improve the function of their kidneys. It is a recombinant (the *rec* in recAP) molecule which means that it was made artificially.

recAP is given to patients by a small tube inserted into a vein which is called an intravenous infusion. The purpose of this clinical trial is to determine if recAP is safe and effective in reducing the severity of SA-AKI. recAP is an experimental drug as it has not been approved by any Health Authority for any treatment.

At least 450 patients and up to 1,600 patients will take part in this clinical trial at a number of locations predominately across Europe and North America. This hospital (see name, address and phone number of the hospital on the first page of this document) is one of a number of hospitals taking part in this clinical trial. The main trial doctor for REVIVAL at this hospital is named as the Principal Investigator on the first page of this document. The main trial doctor will be helped by other trial team members.

Remove this language for US: This trial has been reviewed and approved by <*Specify local Health Authority if approvals are issued*> <and> given favorable opinion by <NAME OF IRB/IEC> that the trial can take place, that are responsible for making sure that the rights of people who take part clinical trials are protected. The approval by the <*Specify name of local Health Authority if approvals are issued*> <and> given favorable opinion <NAME OF IRB/IEC> should not be thought of as an encouragement for you to take part in this trial.

2. Trial Procedures

If you are eligible and choose to participate in REVIVAL, you will be randomly assigned (like the flip of a coin) to a treatment group by a computer. You will receive either recAP or placebo (inactive treatment). You will have a 50% chance of receiving recAP and a 50% chance of

receiving placebo. A 'placebo' looks like recAP but does not have any active substance in it. No matter which treatment group you are assigned to, you will still receive all standard treatments for SA-AKI as directed by your treating physician(s). No one among the people taking care of you or among the clinical trial team will know what treatment you received until after the entire clinical trial is over. This setup creates the best way to objectively measure the effect of recAP. Your trial doctor can find out the treatment if it is needed for your health.

All trial assessments done up to the time the trial drug is started is referred to as Screening or as Baseline. From the day the trial drug is started, each day is given a number beginning with Day 1. Day 1 and Baseline procedures may be performed on the same day.

The planned duration of your participation in the clinical trial will be approximately 6 months.

Screening and Baseline:
If you agree to take part in this clinical trial, you or your legal representative will need to sign this consent form. You may have some tests to check if you can start the trial drug and information about your health status before the start of the trial drug will be collected.

- Demographic information (age, gender, race, etc.) and information about whether you were living at home, at a rehabilitation site or nursing facility before you were admitted to the hospital will be collected.
- Information will be collected about your current health, vital signs, medical history, medications and treatments you have received, and your weight and height will be measured or estimated.
- If you are able, you will complete a quality of life questionnaire.
- If you are a woman able to have children, you will have a pregnancy test. If you are pregnant, you cannot participate in the trial.
- If not already done as part of standard care, blood will be collected for standard safety tests and to see how your kidneys are functioning. In addition, a blood sample will be taken to check whether you have antibodies against recAP, and for biomarker testing. Biomarkers are substances that may provide information about how recAP works, or the causes of disease and its individual course. Biomarkers may also help identify patients who may benefit from recAP, or identify patients at increased risk for side effects.
- *For applicable sites:* A urine sample will be collected for biomarkers.
- If not already done, an ECG (electrocardiogram) which records the electrical activity of the heart will be done.
- You will be randomized to receive trial drug (either recAP or placebo).

The trial drug will be administered by intravenous infusion over 1 hour on Days 1, 2, and 3. The dose will depend on your weight.

Days 1-3:
Procedures that are to be performed on Day 1 through 3:

- Information will be collected about your current health, any side effects you may have, and medications and treatments you receive.

- Blood will be collected for kidney function tests and biomarker testing. On Day 3 only, blood will be collected for safety tests and pharmacokinetic (PK) testing. PK measures the amount of recAP in your blood at different time points.
- *For applicable sites:* A urine sample will be collected to measure the levels of biomarkers.
- You will be administered the trial drug by intravenous infusion.

Days 4-7

Procedures that are to be performed on Days 4 through 7:

- Information will be collected about your current health, any side effects you may have, and medications and treatments you receive.
- Blood will be collected for kidney function tests (while you are in ICU or Intermediate care). On Days 4 and 5 only, blood will be collected for biomarker testing. On Days 4, 5 and 7 blood will be collected for PK testing.
- *For applicable sites:* On Day 4 only, a urine sample will be collected to measure the levels of biomarkers.

Days 8-27

- If you are still in the hospital, information about certain medications and treatments you receive will be collected.
- The clinical trial team will continue to monitor and collect information on any side effects you may experience.
- If you are being discharged from hospital during this period, you will have a blood sample taken for standard safety tests before leaving the hospital.

Day 28

If you have been discharged from the hospital, you will be asked to return to the hospital on Day 28 if you are able. If you are not able to return to the hospital, you may be contacted by telephone and receive a visit at home (off-site visit by trial staff or third party vendor). Procedures that are to be performed on Day 28:

- Information will be collected about any side effects you may have, medications and treatments you have received, whether you have been in the hospital since you were discharged, and whether you are living at home, are in the hospital or living in another facility.
- If you are able, you will complete a quality of life questionnaire.
- Blood will be collected for kidney function tests and to see if you have developed antibodies against recAP. An antibody is made by the immune system to protect the body from harmful substances and may sometimes be made against certain types of medications.
- If you are still in hospital on Day 28, blood will be collected for standard safety tests.

Day 90

You will be asked to return to the hospital around Day 90 if you are able. If you are not able to return to the hospital, you may be contacted by telephone and receive a visit at home (off-site visit by trial staff or third party vendor). Procedures that are to be performed on Day 90:

- Information will be collected about whether you have been in the hospital since you were discharged and whether you are living at home, are in the hospital or living in another facility.

- If you are able, you will complete a quality of life questionnaire.
- Blood will be collected for kidney function tests and to see if you have developed antibodies against recAP.

Day 180
Data to be collected at Day 180 can be collected over the telephone:
- Information about whether you are living at home, are in the hospital or living in another facility will be collected.
- If you are able, you will complete a quality of life questionnaire.

Early Termination Visit:
If you are withdrawn from the clinical trial or choose to withdraw from the clinical trial, you will be asked for a final blood sample to perform safety tests and to see if you have developed antibodies against recAP.

If you are withdrawn or choose to withdraw from the trial, or contact with you is lost, your trial doctor will contact you (your family or caregiver) or may access your medical records or publicly available records, to determine your health/survival status.
If you wish/decide you do not/no longer want to be contacted or allow access to your medical records for follow-up information, tell your trial doctor.

Off-site Visits by trial staff or third party vendor:
If you and your trial doctor agree, it is possible that you may have procedures for Days 28 and/or 90 performed at your home where a mobile research nurse will visit you. If possible, the mobile research nurse will meet with you while you are still in the hospital to discuss and plan the home visit(s).

The mobile research nurse will be from the trial site or a company called Illingworth Research Group. If you agree to off-site visit(s) performed by this company, the site research team will complete a registration form to provide your contact information to Illingworth. Your personal data collected by Illingworth personnel for the purpose of carrying out the off-site visit(s) will be treated with strict confidentiality. During the trial, your identifying information may be held on Illingworth's restricted access server and deleted at the end of the trial. Any paper copies used by the mobile research nurse that include your identifying information will be shredded after use. Illingworth will not release your information to any third parties, except of contact information to the courier vendor if applicable.

Where couriers are involved in off-site visits for the purpose of sending your samples to a laboratory, your address will be provided to a secure group for the service to take place. Based on your location, your contact information and address may be transferred outside of your country *<and European Union>*.

Human Biological Samples

While you are in this clinical trial, you will have biological samples taken. The maximum amount of blood collected specifically for the clinical trial will not be more than 100 mL. These samples are necessary to evaluate your health and the effects of recAP and may provide new information to help better understand your disease and how recAP works. Samples will be analyzed at either the institution where you are being treated or sent to a central laboratory for analysis. Samples will be discarded after results have been obtained. The below section refers to the use of your samples.

WHAT SAMPLES MAY BE USED FOR:

a. Your samples will be used 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, AM-Pharma B.V. will have the ownership of the research results and may file patents. The research done with your samples may help 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 your sample use. By agreeing to take part in this clinical trial, you agree to give up your rights for any commercial value resulting from your samples and data.

d. Your samples may be provided to a laboratory for testing and research use and storage purposes done for and on behalf of AM-Pharma and its third party collaborators. Some samples being collected will be sent to Covance Central Laboratory Services in *Switzerland* or *USA* but may need to be shipped to other locations which may be in other countries during the course of the clinical trial or following completion of the clinical trial.

e. All identifiable samples will be handled in a manner to maintain your confidentiality and will be labelled with a code number and kept in locked storage. Only your clinical trial team will be able to link your samples with your identity. No one outside the trial hospital working with your samples will know your identity.

f. Your samples will be stored for up to five years after the clinical trial is published.

g. Your samples may be stored for longer than these specified periods if this is required by a regulatory or government agency.

h. If additional tests are to be performed with your samples that are not associated with this trial, biomarker research related to the effects of recAP, or for better understanding your disease, we will inform you of those details. You can decide not to give consent for these additional tests using your samples. You have the right to be told about such new tests that use your samples for a new purpose not described in this document and you have the right to refuse these new tests on those samples.

Some reports from laboratory tests done for the clinical trial at central laboratories will not be put in your health/medical record and will be kept confidential to the best of our ability within the law. You will not be provided with the results of these laboratory tests.

3. Your Responsibilities for this trial

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

- Follow the instructions provided by your trial doctor or the clinical trial team;
- Go to your trial visits. As soon as you know that you will not be able to go to a clinical trial visit, please contact your trial doctor or a member of the clinical trial team to schedule a new visit.
- Truthfully answer any questions from your trial doctor or the clinical trial team 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, and vitamins.
- If you are or are planning to take part in other clinical trials, please inform your trial doctor. Do not take part in any other clinical trials without the consent of your trial doctor while you are taking part in this clinical trial.
- Tell the trial doctor if you believe you are pregnant.
- Tell your trial doctor or a member of the clinical trial team if you change your mind about taking part in the clinical trial.

4. Possible Risks

All drugs may cause side effects and discomforts. To date, a total of 219 patients and healthy volunteers have been exposed to recAP. In healthy volunteers, minor discomfort, such as temporary dizziness and pain at the infusion site where the trial drug entered the vein, were reported. In patients with your condition who received either placebo or recAP, the most commonly reported side effects were nausea, diarrhea, constipation, and some more severe symptoms that are seen in patients with sepsis. The number and severity of side effects was similar in the patients who received recAP and the patients who received placebo. There may be other side effects and discomforts that are not yet known.

Blood draws: Most of the blood tests will be taken from catheters (tubes) that are already in one of your veins so you should not experience additional discomfort. When a sample of your blood is drawn by using a needle, you may experience some temporary discomfort, bruising, swelling or, in rare circumstances, infection at the needle site. Tell the trial doctor or a member of the clinical trial if you do not feel well after having your blood drawn.

ECG: An ECG is an electrical tracing of the heart used to monitor heart function. Small wires are attached to your body using adhesive patches in several places. You may experience temporary discomfort (pulling on the skin/skin hair) during removal of the adhesive patches. After you have an ECG, you may have mild irritation, slight redness, and itching at the places on your skin where the recording patches are placed.

Questionnaires: You will be asked to complete questionnaires. Some of the questions may make you feel anxious or upset. You do not have to answer any questions that upset you. It is important that you answer all questions as completely and truthfully as possible.

Pregnancy risks

Women: The safety of recAP during pregnancy and breast-feeding has not been tested previously in either humans or in animal studies. Therefore, if you are pregnant or breast-feeding, you may not participate in this clinical trial. If you become pregnant during the clinical trial, it is important that you tell your doctor or a member of the clinical trial team so that you can discuss whether you should continue in the trial or whether it is best that you withdraw. In any case, you will be followed to determine the outcome of the pregnancy and status of you and your child.

Because alkaline phosphatase is present in the human placenta it is theoretically possible that you could develop anti-placental antibodies after receiving the trial drug. Such antibodies could potentially interfere with your ability to have a successful pregnancy in the future. While development of anti-placental antibodies have not been detected to date in human studies, the safety experience with recAP regarding this aspect is limited.

Men: As the trial drug is very similar to natural alkaline phosphatase already present in the body, it is not expected to affect your sperm or an unborn child.

Birth Control: The trial drug is not expected to affect the eggs or sperm so as soon as the trial drug is excreted from the body, there is no need for you or your partner to use birth control. As you will only receive treatment with the trial drug for three days while you are in the intensive care unit, it is expected that the trial drug will have been cleared from your body by the time you are discharged from the hospital.

5. Possible Benefits

Possible benefits from taking part in this clinical trial may include:

- Your health problem may or may not get better from taking part in this clinical trial, it is hoped that recAP may lessen the signs and symptoms of your health problem, however such benefit cannot be guaranteed. In this clinical trial you may get placebo which means you will not receive the active drug during the clinical trial.
- Taking part in this clinical trial will help doctors learn more about recAP. This may help others with your health problem in the future.

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

6. Alternative Treatments

The only alternative treatment for SA-AKI is supportive care such as dialysis. Regardless of whether you decide to take part in this clinical trial, you will receive all standard medical care including supportive care as clinically indicated. This is also the case if the trial drug is prematurely stopped. Your trial doctor can talk with you about the risks and benefits of supportive care.

7. Costs

You will not receive payment for participating in this clinical trial, but the trial drug will be made available to you at no charge and you will not be required to pay for any trial procedures. You may be reimbursed for any reasonable travel expenses incurred as a result of taking part in this clinical trial. You will need to provide receipts to the clinical trial site for your travel expenses.

If applicable, you will not be charged, nor will you receive payment from visits performed by the mobile research nurses.

8. Compensation for Injury

Whilst the clinical trial is not expected to pose any additional risk to you over your normal clinical treatment, if you are nonetheless injured as a result of your participation in this clinical trial, treatment for the injury will be made available through [name of physician] and [institution]. AM-Pharma will pay the costs associated with the treatment of your injury which means that these costs will not need to be paid by your medical insurance. No other compensation or payment will be available from either AM-Pharma or the trial doctor in the event of any injury. You are however not waiving any legal rights by signing this form, by accepting medical care or by accepting payment for medical expenses.

<insert insurance language as applicable>

9. Data Protection

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

<Note: this is not to be included for EU member states where consent is not considered to be the appropriate legal basis for processing personal data>: Without your consent, your data or samples cannot be used. This is why you will not be able to take part in the clinical trial if you do not give your consent to use your personal data. You must give your authorization before the trial doctor can use or share your personal data with others.

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

<Note: this is not to be included for EU member states where consent is not considered to be the appropriate legal basis for processing personal data>: Your consent to the use of Trial Data for the purposes of the clinical trial 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 be done.

If you decide to participate in the clinical trial, personal data will be collected by your trial doctor and/or a member of the clinical trial team. The Trial Data that will be collected are:

- Personal data
  - your name, address, telephone number, email address, health insurance number, national identification number.
  - your age, gender, ethnic and racial background.
  - information about your health, medical condition and medical history and medications you take.
- Biological Samples (see section 2 above): blood and urine (for applicable sites)
- Information about your treatments and response to treatments (which includes the procedures described in this form) and data resulting from analysis of biological samples.
- Information about side effects, medical history and test results while you are taking part in the clinical trial

Use of your Personal Data

Your full identity will not be revealed on any of the clinical trial documents or samples taken and kept by AM-Pharma for their studies.

The clinical trial team will send your personal data in pseudonymized form to AM-Pharma and to representatives working on behalf of AM-Pharma. Data that is pseudonymized (de-identified) means that the Clinical Trial Data given to and used by AM-Pharma is protected by the use of a subject identification number, which is a number specific to you. Only a unique subject identification number for the clinical trial will link the data or samples to you. These data may contain your gender, age, and race, as well as any medical and scientific data required by the clinical trial. Your race and ethnicity will be collected as it is needed to estimate your kidney function, and to assess whether race and ethnicity influence the effects of recAP and how quickly recAP is excreted from the body. The trial doctor maintains a confidential list that links the subject identification number to you. Only the trial doctor will be able to connect the subject identification number to your personal data. He/she will not share this information except as explained in this consent form. The clinical trial site will also establish the necessary technical and organizational measures to prevent your re-identification by AM-Pharma.

<EU ONLY (and only for member states where consent is not considered to be the appropriate legal basis for processing personal data)>: The processing of your personal data is necessary: (i) to comply with AM Pharma's legal and/or regulatory obligations; (ii) for AM Pharma's legitimate interests in conducting research in connection with the clinical trial; (iii) for the performance of a task in the public interest; (iv) when special categories of personal data are processed, for reasons of public interest in the area of public health; and (v) for scientific research.

Data Sharing

<EU ONLY: The trial doctor will transfer information concerning your age, gender, race, and clinical trial site location to a sponsor's service provider established in the United States, for the purpose of assigning your subject identification number. The protection of personal data in the

United States is not as strong as that provided in the European Union; however, appropriate measures will be taken to protect the data >

AM-Pharma, AM-Pharma's representatives, regulatory authorities, or other supervisory bodies may review any pseudonymized Trial Data held by the trial doctor and the clinical trial site. The reason these people may look at your pseudonymized Trial Data is to make sure the clinical trial has been done the right way and that the Trial Data are accurate and adequate for regulatory purposes. A data safety monitoring board has been established to oversee the trial and can access all pseudonymized Trial Data including information about the treatment you received.

The only circumstances in which AM-Pharma, AM-Pharma's representatives, regulatory authorities, data safety monitoring board, or other supervisory bodies may review Trial Data that is not pseudonymized would be where this is necessary to comply with the national law of your country, is necessary for the performance of a task carried out in the public interest, for verification of clinical trial procedures and/or data, and as part of an investigation of an adverse event that occurred during the clinical trial, without violating your confidentiality. All people and organizations, involved in personal data processing who could either directly or indirectly identify your identity, are all obligated to maintain confidentiality by the nature of their work, or are bound by confidentiality agreements.

If you are transferred or readmitted to a hospital other than the trial hospital, your trial doctor or a member of the clinical trial team will continue collecting your personal data as if you stayed at the trial hospital, for the purpose of the clinical trial. The trial hospital will ensure that any collection and transfer of your personal data is done in accordance with applicable laws.

AM-Pharma may share the pseudonymized Trial Data with its representatives, including authorized clinical trial monitors, with other companies within its group, with its service providers, its contractors and business collaborators, and with research institutions and research-based commercial organizations who will use the pseudonymized Trial Data for the purposes described above.

<***Note: this language to be added and adapted as needed to comply with country/site requirements>:*** In certain circumstances (e.g. in the event of medical emergency), AM-Pharma or AM-Pharma's representatives may be performing trial data verification through remote access of medical records. This means someone from the trial staff will provide Sponsor's representatives access to your medical records for only those data points that need verification.

<*Countries outside the EU:* AM-Pharma and those who work for or with AM-Pharma, the IRB/IEC and national and international Regulatory Authorities will be able to see your personal medical files at the clinical trial site, which contain your full name. All people involved in the clinical trial have the duty of confidentiality.>

<*EU ONLY:* Where the national law of <insert Country> so requires, pseudonymized Trial Data may be shared with the competent Ethics Committees overseeing this clinical trial, with [insert details of the competent regulatory authority of the concerned EU Member State], with other

competent regulatory authorities in other EU Member States, with the European Medicines Agency, as well as with the regulatory authorities of non-EU countries, including the U.S. Food and Drug Administration (FDA), the US Department of Health and Human Services, the US National Institutes of Health, and the US Office for Human Research Protections.>

<EU ONLY: You should be aware that non-EEA countries to which your pseudonymized Trial Data will be transferred, e.g., the United States, may not offer the same level of privacy protection as you are used to in the country where you live or where this clinical trial is conducted. However, AM-Pharma will keep any information it receives as confidential as required by applicable local law. AM-Pharma will take reasonable steps necessary to ensure that any Trial Data transferred are treated securely and in accordance with this form to the extent permitted by law. AM-Pharma has also entered into agreements and has, where required by applicable laws, entered into the European Commission approved Standard Contractual Clauses with third parties working with AM-Pharma to ensure the confidentiality of your data and samples. >

<EU ONLY: AM-Pharma B.V. Stadsplateau 6 3521 AZ Utrecht The Netherlands ("AM-Pharma") is responsible for processing your Trial Data. AM-Pharma will act as a controller within the meaning of the General Data Protection Regulation 2016/679 and is required by law to protect your personal data. This section explains how AM-Pharma processes your personal data. <*if required by country:* AM-Pharma's representative for the processing of your personal data in your country is <name and address of the data processing representative from the institution>.

Publication

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

Although information about this clinical trial, including the results, may be published for scientific purposes, presented or posted electronically (for example, in a clinical studies registry database) or presented to scientific groups, your name and personal information will not be used and your identity will not be revealed.

<FOR ALL EU SITES AND SITES OUTSIDE THE EU WHERE THIS REQUIREMENT APPLIES should include the specific statement verbatim:> A description of this clinical trial 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.

<FOR ALL US SITES AND SITES OUTSIDE THE US WHERE THIS REQUIREMENT APPLIES should include the specific statement verbatim:> A description of this clinical trial will be available on http://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.

<FOR ALL US SITES *include HIPAA language or reference to separate HIPAA>*

Storage of Personal Data and Biological Samples

Your personal data and biological samples will be stored for up to five years <*or include requirement for country if applicable* up to X years> after the clinical trial is published. Your samples may be stored for longer than these specified periods if this is required by a regulatory or government agency.

Rights Concerning the Processing of Your Personal Data

You have a right of access to, and, if needed, you have the right to correct your data. You may also have the right to request from sponsor erasure of your personal data, to obtain from AM-Pharma restriction of processing, to object to processing, and to receive personal data in a structured, commonly used and machine-readable format and have it transmitted to another third party provided to 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 AM-Pharma in order to comply with regulations governing clinical research in your Country 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 clinical trial this will result in your withdrawal from the clinical trial.

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 trial doctor at [Phone Number]. <***EU Only:*** You also have the right to submit a complaint with <*insert competent data protection authority in the EU Member State Concerned*>.

10. New Information

During the clinical trial, new information about the risks and benefits of the project may become known. Your trial doctor will talk with you about any important new information that is learned during the course of the clinical trial that may affect your willingness to continue to take part in the clinical trial. This new information may also mean that you can no longer take part in this clinical trial. 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 clinical trial is entirely voluntary. You do not have to take part in this clinical trial and you are free to withdraw at any time. You may withdraw from the clinical trial entirely or you may withdraw only from receiving trial drug and continue trial procedures and/or data collection. If you withdraw entirely, you will be asked to complete an end of trial visit. Unless you withdraw from all future contact, you will be contacted by telephone on Days 28, 90 and 180 to see how you are doing.

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 clinical trial (fully or partly) at any time without giving a reason. In that

case, we ask you to tell your trial doctor or a member of the clinical trial team. 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 biological samples to be used for this clinical trial, contact the trial doctor or a member of the clinical trial team and let them know. You can request destruction of collected samples that would otherwise remain in storage. If you do choose not to have your samples that are required for the clinical trial used, you will no longer be able to take part in this clinical trial.

Your choice to take part or to stop taking part in this clinical trial, 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. Premature End of the Clinical Trial or Clinical Trial Treatment

This clinical trial or the trial drug may be stopped without your consent.

Reasons why AM-Pharma can stop the clinical trial or put the clinical trial on hold include:

- recAP has been shown not to work.
- recAP has been shown to work and there is no need for the clinical trial to continue.
- recAP has been shown to cause serious side effects.
- Decisions made in the business or commercial interests of AM-Pharma.
- Decisions made by the Regulatory Authorities or Ethics Committees.

The trial doctor may also stop your treatment with trial drug if it is not in your best interest to continue.

13. Who to contact for more information?

Contacts in case of emergency and for questions about the clinical trial

Please contact a member of the clinical trial team if you have any questions about this clinical trial, its procedures, risks and benefits, or alternative courses of treatment or in case of emergency.

The names and telephone numbers of the clinical trial team to contact are listed in the table below.

Main trial doctor	<NAME>	<CONTACT NUMBER>
Other trial doctor	<NAME>	<CONTACT NUMBER >
Trial nurse	<NAME>	<CONTACT NUMBER >

Contact for questions about your rights

If you have any complaints about any part of the clinical trial, the way it is being done or any questions about your rights as a clinical trial participant, you may contact:
Name of Contact Person: <NAME>
Telephone Number: <NUMBER>
Address: <ADDRESS>

You will receive a card indicating that you are participating in this trial. The card will include the name and phone number of the trial doctor. Please have this card with you at all times, as long as you remain in the trial.

IRB/IEC REVIEW

Any new research studies beyond the current clinical trial using your coded biological samples will be reviewed by the trial doctor's Institutional Review Board (IRB)/Independent Ethics Committee (IEC), a special committee that oversees medical research studies to protect the rights and wellbeing of the patients / healthy volunteers.

***II*. INFORMED CONSENT FORM**

Sign this form ONLY if all of the following statements are true:

- I have read (or someone has read to me) the information in this document in a language that I understand well.
- The content and meaning of this information have been explained to me.
- I have been given an opportunity to ask my questions in private as well as to meet with a member of the clinical trial team to discuss this clinical trial. I have had a chance to consider the information, including the risks and benefits of taking part in this clinical trial, to ask questions, and to discuss the clinical trial. My questions have been answered to my satisfaction.
- I have asked a member of the clinical trial team any questions I may have and have had enough time to decide if I want to take part in this clinical trial.
- I agree that biological samples may be collected from me as explicitly stated in this consent form.
- **I have decided to take part in this clinical trial. I understand I will get a signed and dated copy of this document.**

- *<If applicable:>* I agree that my trial doctor/staff can access my medical records or publicly available records, to determine my health/survival status if contact with me is lost or I withdrew from the trial (initial on the appropriate line).
  ___ Yes ___ No

- *<EU Only (and to only be included where consent is an appropriate legal basis in the Member State):* I agree to the processing and use of my personal data for the purposes of my participation in the clinical trial as described in this information sheet and consent form. I acknowledge that without my consent, my personal data and samples cannot be used and that I will not be able to take part in the clinical trial (initial on the appropriate line)>
  ___ Yes ___ No

- *<EU Only (and to only be included where consent is an appropriate legal basis in the relevant Member State):* I agree to the use of my coded medical information for future medical or pharmaceutical research (initial on the appropriate line)>
  ___ Yes ___ No

- I agree that my primary doctor can be told that I am taking part in this clinical trial (initial on the appropriate line).
  ___ Yes ___ No __ Not applicable, I do NOT have a primary doctor

- *<If applicable:>* I agree to have some trial visits at home to be performed by trial site personnel:
  ___ Yes ___ No __

- *<If applicable:>* I agree to have some trial visits at home to be performed by third party vendor Illingworth Research Group:
  ___ Yes ___ No __

I am free to stop taking part in this clinical trial 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 clinical trial 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.

Printed Name of Patient	
Signature of Patient	*Date and time of Signature*
Signature of Legal Authorized Representative (if applicable)	*Date and time of Signature*
Signature of impartial witness (if applicable)	*Date and time of Signature*

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

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 sheet 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 and time of Signature*

Incapacitated patients enrolled in the clinical trial must sign the most recent ICF as soon as they are capable to do so.