RMP-A03-001 Informed Consent Form

NCT05794204

16 December 2022

INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Suzhou Raymon Pharmaceuticals / "A Phase 1/2a Study Evaluating the Safety and Efficacy of RMP-A03 Ocular Suspension in Healthy Volunteers and Patients with Pterygium"**
Protocol Number:	**RMP-A03-001**
Principal Investigator: **(Study Doctor)**	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

You are being invited to take part in a clinical research study conducted by Suzhou Raymon Pharmaceuticals (the Sponsor). This research study will test an investigational (experimental) drug named RMP-A03 as a possible treatment for pterygium. Pterygium is an eye disease that can cause irritation, redness, and blurry vision, which may get worse as the condition progresses.

Before you agree to take part in this study, it is important for you to read all of the information in this form. This consent form explains the purpose, procedures, risks, benefits, possible discomforts, and issues and protections of this study. It also explains what other treatments are available (if any) if you need treatment and choose not to be in this study. It is your right to choose not to be in this study and to leave this study at any time. The results of being treated with this study drug are not yet known, and you may not receive any medical benefits from taking part in the study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or

study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

PURPOSE OF THE INFORMED CONSENT FORM

Your participation in this research study is voluntary and includes only those who wish to take part. To help you decide whether you want to be part of this research, the risks and possible benefits of the study are described in this consent form so that you will understand more about the study before deciding. This process is known as informed consent.

This consent form gives you information about the study and what your participation in the study would require. You may want to talk with others about the study before you decide if you want to participate.

If you decide to take part in this study, you must provide your agreement (consent) by signing your name at the end of this form and dating it. By signing it you are telling us that you:

- Understand the information in this informed consent form.
- Agree to take part in the research study.
- Agree to follow the requirements and procedures of the study.
- Agree to have tests and study treatments that are described.
- Agree to use an effective method of birth control while you are participating in this study and for at least 30 days after all study procedures are completed.
- Grant permission for your personal and health information to be collected, used and disclosed as provided in this consent.

You will be given a signed and dated copy of this Participant Information and Consent Form to keep.

BACKGROUND AND PURPOSE OF THE STUDY

This research study is to study a potential new treatment that has never been tested in people. The potential new treatment is called RMP-A03. It is being tested to determine if it can help people with pterygium, which is an eye disease that can cause irritation, redness, and blurry vision, and which may get progressively worse.

What is the purpose of the study?

The main purpose of this research study is to test the safety and tolerability of RMP-A03 in subjects with the eye disease pterygium.

An additional purpose of the study is to determine how subjects with pterygium respond to treatment with RMP-A03 when compared with placebo. “Placebo” is the name given to eye drops that look just like the study eye drops, but do not contain any of the study drug ingredients. The placebo in this study is mostly water.

The use of RMP-A03 in this study is investigational. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). However, it has been

tested in animal studies, and an investigational new drug (IND) application has been submitted to the FDA to allow for the testing of the study drug in humans.

Since is there is no approved treatment for pterygium at this time point, if RMP-A03 is effective it may slow down the progression of pterygium in study subjects.

What study drug is being tested?

The study drug is RMP-A03, which is a kind of drug used to [redacted]. Scientific researchers who have studied RMP-A03 think it may be useful in treating people with pterygium. [redacted]

Approximately two-thirds of study subjects will be treated with RMP-A03, but the rest of the subjects will be treated with placebo. Placebo eye drops look just like the study eye drops, but do not contain any of the study drug ingredients and is mostly water.

The study is being sponsored by a company called Suzhou Raymon Pharmaceuticals Company, Ltd., Suzhou, Jiangsu, Peoples Republic of China.

Suzhou Raymon Pharmaceuticals Company Ltd. is referred to as the “Sponsor” in this document.

How is the study drug given?

You will receive study drug as eye drops placed in one eye. The eye that you treat with study drug (the study eye) will be chosen by the study staff and will have to meet the study criteria.

You will add eye drops to your study eye for 28 days. On the first day, the study staff will administer the first dose and show you how to do it. Then they will give you a plastic bottle with a dropper to use to administer the study drug at home. You will self-administer 1 drop of study drug (either RMP-A03 or placebo) to your study eye 3 times a day at least 3 hours apart.

How long do I have to take the study drug?

You will be randomly assigned by chance to receive RMP-A03 or placebo. You will have a 67% (2 in 3) chance of receiving RMP-03 and a 33% (1 in 3) chance of receiving placebo. Your first study treatment will be administered by the study staff in the clinic, and you will self-administer the eye drops in the study eye at home for the next 27 days.

This is a double-masked study, which means neither you nor your study doctor (and his/her study staff) will know to which of these study drug groups you are assigned. In case of an emergency, however, the study doctor can get this information.

Because this is a research study, the study drug will be given to you only during this study and not after the study is over.

Who may participate in this study?

This study will include adults with the eye disease known as pterygium. To participate, you must be eligible for and willing to participate in this study. In addition, if the study doctor reviews

your current and previous medical history (including such things as abnormal laboratory findings at screening or significant conditions that affect your heart, lungs or other body systems), the study doctor may determine you are not eligible for the study because it might be risky for you.

We expect about 75 subjects with pterygium will participate in this study.

How long will I be in the study?

You will undergo a screening period that occurs up to 60 days before the Baseline (Day 1) visit. During this time, you will be evaluated to see if you are eligible to participate in the study. If you are enrolled in the study, your participation will last approximately 84 days. Treatment with study drug will be for 28 days, and then you will have check-ups every 2-4 weeks for the rest of the study to see how you are doing.

WHAT WILL HAPPEN DURING THE STUDY?

Screening:

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent document. The following screening tests and procedures will then be performed by study staff to determine if you qualify to take part in this study:

- You will be examined to confirm you have pterygium.
- You will be evaluated to see if you are eligible to participate in the study.
- Your demographic information (your age, race, etc.) will be recorded.
- Your medical and ophthalmic (eye) history will be recorded.
- A list of any medications you are taking will be recorded.
- Your heart rate and blood pressure will be recorded.
- A urine sample will be collected to determine if you are pregnant (if applicable).
- A sample of your blood will be collected for routine tests to check your hematology, serum chemistry (sodium, potassium, glucose, etc.), blood clotting function, liver function, kidney function, and to see how well your organs are functioning.
- You will have a series of eye (ophthalmic) assessments.
- Your vision has to be 20/200 or better (with glasses or contacts) in both eyes.
- You will have photographs taken of your study eye.
- You will complete a questionnaire about your eyes (the Ocular Comfort Index [OCI] questionnaire).
- You will be given some eye drops to see how well you can tolerate taking them.
- You will be released from the study clinic to go home.

This study will use competitive enrollment. This means that the Sponsor will stop recruiting for the study when the target number of subjects have been enrolled. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued if the target number of subjects is met.

If you qualify to take part in this study and go on to receive the study treatment, then you will attend the following visits and the following assessments will occur.

Washout Period: You may be asked to stop taking eye medications 14 days before the start of the study, and the study staff may require that you stop other medications you are taking 7 days before the study starts. This is called a washout period, during which the effects of these medications leave your body. You will have to ask the study staff about how this applies to you.

Study Visits:

Day 1 – Before Administration of the First Dose of Study Treatment

- You will return to the study clinic on Day 1.
- You will be rechecked to confirm you are still eligible to participate in the study.
- Your medical and ophthalmic history will be updated.
- The list of medications you are taking will be updated.
- Your heart rate and blood pressure will be recorded.
- A urine sample will be collected to determine if you are pregnant (if applicable).
- You will complete a series of eye assessments like you did at Screening.
- You will have photographs taken of your study eye.
- You will complete the OCI questionnaire about your eyes.
- You will be evaluated to determine if you experienced any unpleasant medical occurrences (adverse events) either because you volunteered that information, you were asked about these events, or they were detected by the study staff.
- Your first eye drop of study drug will be administered by study staff.
- You will receive a plastic bottle with a dropper to use for administering study drug at home.
- You will be released from the study clinic to go home.

Day 7

- You will return to the study clinic on Day 7.
- Your medical and ophthalmic history will be updated.
- The list of medications you are taking will be updated.
- Your heart rate and blood pressure will be recorded.
- You will be evaluated for adverse events.
- You will have a series of eye (ophthalmic) assessments.
- You will complete the OCI questionnaire about your eyes.
- You will have photographs taken of your study eye
- Your study eye will be examined for the status of your pterygium.
- You will be released from the study clinic to go home.

Day 14 – Telephone Visit

- Your medical and ophthalmic (eye) history will be updated.
- A list of any medications you are taking will be recorded.
- You will be asked about the occurrence of adverse events.

Day 28 and Day 56

- You will return to the study clinic on Day 28 and again on Day 56.
- Your medical and ophthalmic (eye) history will be updated.
- A list of medications you are taking will be updated.
- Your heart rate and blood pressure will be recorded.
- You will be evaluated for the occurrence of adverse events.
- You will complete the OCI questionnaire about your eyes.
- You will have photographs taken of your study eye.
- Your study eye will be examined for the status of your pterygium.
- You will be released from the study clinic to go home.

Day 84 – Last Day

All the same assessments conducted at Day 28 and Day 56 will be repeated and the following tests also will be done.

- You will return to the study clinic on Day 84.
- A urine sample will be collected to determine whether you are pregnant (if applicable).
- A sample of your blood will be collected for routine testing.
- Any remaining (leftover) study drug you have will be collected by study staff.
- You will be released from the study clinic to go home.

What exactly are the eye (ophthalmologic) assessments to be done?

These are the eye (ophthalmologic assessments) that will be performed. For several of these tests, you will be given drops to numb your eyes.

- **Ocular Comfort Index (OCI) Questionnaire** – You will answer a series of questions about your eyes.
- **Best-corrected distance visual acuity (BCDVA)** - This exam tests your ability to read single letters on an eye chart like used for regular vision exams. It will be done on both of your eyes.
- **Intraocular pressure (IOP)** – Your eye pressure will be checked using a special instrument called a tonometer that looks like a pen and measures the pressure of the fluid inside your eye. You will be given drops to numb your eyes and then the tonometer will lightly touch the surface of your eye to measure the pressure inside your eye. Your IOP will be measured on both of your eyes.
- **Slit-lamp examination** - The study doctor will look at the front part of your eyes using a special microscope (slit lamp). This slit lamp is used to determine the overall health of your eyes. This is a painless exam where you place your chin in a chin rest and your forehead against the forehead strap of the slit lamp and the study doctor will shine a light in your eyes. This test will be done on both of your eyes.
- **Dilated fundus examination, also called Indirect Ophthalmoscopy** - This exam allows the study doctor to examine the back of your eye. This test will be done on both of your eyes.

- **Photographs** – Photographs will be taken from the middle of your forehead to the tip of the nose using a digital camera. A small sticker with a ruler will be placed on your forehead above your eyebrows to measure your eyes. Photographs will only be taken on your study eye.

Based on your eye exam and visual field results at screening, there is a chance that you may not be able to take part in this study.

EXPECTATIONS

If you participate in this study, you are expected to meet the following criteria:

- Attend each study visit; follow the instructions the study doctors give you and take the study drug as directed.
- Inform the study staff about any health issues you currently have, even if you think they are not important.
- Inform the study staff about all medications you are taking.
- Use an effective method of birth control while you are participating in this study and for at least 30 days after all study procedures are completed.
- If you wish to stop participating in the study, inform the study staff and return to the site to complete the final visit.
- Stop using tobacco products. Use of tobacco products is not allowed at all during this clinical trial.
- Avoid extreme exposure to the sun and avoid sunbathing during the whole clinical trial.
- You may be asked to stop taking a drug or supplement that you are taking. A drug you have taken in the past may prevent you from participating in the study. Please check with the study doctor for all the medicines or supplements you take.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

RMP-A03 is a new investigational drug, and this study is the first time it is being tested in people. The risks associated with RPM-A03 are not well understood at this time.

ALLERGIC REACTION

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting

- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

RMP-A03 may cause potential phototoxicity (skin sensitivity to sunlight or lamps) which may cause severe sunburn or skin rash. It is, therefore, strongly recommended to stay out of direct sunlight, to avoid the use of a sunlamp or tanning bed, to wear protective clothing, and to use a sun block preparation (SPF 30 or higher) following study drug administration.

RISKS OF STUDY PROCEDURES

Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

Photography of your study eye: Taking images and photographs of your eyes may cause temporary discomfort from bright lights and holding your eye wide open.

Some ocular assessments may result in headaches, dilated pupils that make it difficult to see or drive for a period of time, etc.

If you are taking medicines for your study eye, you will be asked to stop taking these medicines (washout period). During this time, your symptoms may not improve or may get worse. If your symptoms get worse, tell the study doctor immediately.

If you receive placebo (the inactive substance) as part of this study, your symptoms of pterygium may not improve and may get worse.

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 becomes pregnant.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

Acceptable methods of birth control for use in this study are condoms plus intrauterine devices or condoms plus oral hormonal contraceptives, double barrier methods (for example, condoms with spermicidal gel plus diaphragms). The study doctor or study staff will discuss this with you. If you or your partner becomes pregnant, she will be asked to sign and date a separate consent

form to allow the study staff to collect information about the pregnancy, its outcome, and the health of the child after birth.

Females:

To reduce the risk of pregnancy, women of childbearing potential (WOCBP) should use an effective method of birth control prior to study entry, while you are participating in this study and for at least 30 days after all study procedures are completed. If you become pregnant while you are participating in this study or within 30 days after completing all study procedures, tell your study doctor or study staff immediately. The study drug will be stopped and your participation in this study will be ended.

Males:

To reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study and for at least 30 days after all study procedures are completed. If your female partner becomes pregnant while you are participating in this study or within 30 days after you have completed all study procedures, tell your study doctor or study staff immediately.

Male participants should not donate sperm during the study or for at least 30 days after all study procedures are completed.

ALTERNATIVES TO PARTICIPATION

Currently, there are no FDA-approved medicinal treatments for pterygium. Therefore, there is a significant unmet medical need for the treatment of pterygium.

This research study is for research purposes only. Alternatives to participating include managing your symptoms with over-the-counter or prescription eye ointments/drops or undergoing surgery to remove the pterygium. Please speak with the study doctor about your treatment options.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS

You may benefit as a result of your participation in this study if the study drug is found to help treat your pterygium. However, there is no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

$xx.xx for Visits xxx.
$xx.xx for Visits xxx.
$xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ["after each visit," "annually," "bi-weekly," etc.]

If you have any questions regarding your compensation for participation, please contact the study staff.

[OR]

You will not receive any monetary compensation for your participation in this study.

[If applicable:] We will reimburse you for the cost of ***[describe: e.g., traveling to your study visits]***. You will be reimbursed approximately ***[e.g., 2 weeks, 1 month, etc.]*** after you submit your travel receipts to the study staff.

Note: If your payment exceeds [redacted], you will be responsible for reporting the payment received for this study to the Internal Revenue Service (IRS) as taxable income.

CONFIDENTIALITY

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. The study doctor, the sponsor, or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

COMPENSATION FOR INJURY

If you are injured as a direct result of taking the study drug or from procedures done for the purpose of this study, you should inform the study staff right away and get the medical treatment that you need. The sponsor will pay the reasonable costs of medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. No other payment is available from the sponsor or the study doctor in the event of injury. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

CLINICALLY RELEVANT RESULTS

Research results that are clinically relevant, including individual research results, **will not be disclosed to you.**

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 subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude 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 subjects. If you have any questions about your rights as a research subject, 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: [redacted].

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may contact you for the final follow-up and ask you to have some end-of-study tests for your safety.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study (please check yes or no).

❒**YES** (If yes, please complete the information below)

❒NO

Name and address of family doctor or primary health care provider:	Name:
	Address:
Telephone and Fax Number:	Tel:
	Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Your private data may be viewed from a remote location; however, the location will be secure, and the information will be limited to the same person(s) authorized to view your information while on site. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Suzhou Raymon Pharmaceuticals.
- Representatives of [redacted].
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, who work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if RMP-A03 works and is safe.
- To compare RMP-A03 to placebo.
- For other research activities related to RMP-A03.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.
Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

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.

If you decide not to sign and date this form, you will not be able to take part in the study.

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 and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date