Efficacy and Safety of Stapokibart for Primary Cutaneous Amyloidosis: A Randomized, Double-blind, Placebo-controlled Study

Dear Patient (Subject),

Hello!

As you are a patient with primary cutaneous amyloidosis, you are invited to participate in a study led by Dr. Chen Aijun at the First Affiliated Hospital of Chongqing Medical University. This is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Stapokibart in subjects with primary cutaneous amyloidosis, and it will last for 28 weeks. This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Your participation in this study is voluntary. This study has been reviewed and approved by the Ethics Review Committee of this research institution. If you agree to join this study, please read the following instructions carefully. If you have any questions, please ask the investigator responsible for this study.

Study Background

Amyloidosis is a group of diseases characterized by the abnormal deposition of amyloid substances in tissues and organs, which can be classified into primary and secondary forms, or focal and systemic types. Primary cutaneous amyloidosis (PCA) refers to a chronic metabolic skin disorder in

which amyloid proteins are deposited only in the dermis without involvement of internal organs. This condition is more common in middle-aged and elderly individuals and generally shows no gender predilection. Skin lesions are frequently found on the back, anterior tibia, and thighs, and may also be distributed on the upper lip, nasolabial folds, and penis. The main clinical manifestations of PCA include papules, macules, scales, lichenification, pigmentation, dryness and roughness of the affected skin, excoriations, and in some cases, local pruritus. Traditional treatment options are relatively limited, requiring daily medication use, which leads to poor patient compliance, and the therapeutic effects are often poor and prone to relapse. Because PCA shares certain similarities with another common dermatological condition—atopic dermatitis—in terms of clinical manifestations and traditional treatments, there have been a few case reports in recent years on the use of novel drugs for atopic dermatitis (biologics represented by IL-4 receptor antagonists and small-molecule drugs represented by JAK pathway inhibitors) to treat PCA, all of which have shown good therapeutic effects. Currently, clinical trials of JAK pathway inhibitors for the treatment of PCA are being conducted in China. However, there is still a lack of large-scale clinical studies exploring the efficacy and safety of novel drugs in PCA. Therefore, this trial is planned to investigate the efficacy and safety of Stapokibart (an IL-4 receptor antagonist) in patients with PCA.

Objective of the Study

To clarify the efficacy and safety of the IL-4 receptor antagonist Stapokibart in primary cutaneous amyloidosis.

Study Process and Methods

Duration and Design of the Study: The study is expected to last from September 15, 2025, to December 31, 2026. This study is a randomized, double-blind, placebo-controlled trial. A total of 40 subjects are planned to be enrolled and randomly assigned to two groups: the placebo group and the treatment group, with 20 subjects in each group. Subjects in the treatment group will receive Stapokibart Injection for 16 weeks, while those in the placebo group will receive placebo treatment for the same duration. After the treatment period, there will be a 12-week follow-up, making the total study duration 28 weeks. The investigational medicinal product is the IL-4 receptor antagonist Stapokibart Injection/Stapokibart Placebo Injection. The initial dose is 600 mg, followed by 300 mg every 2 weeks for a total of 16 weeks of treatment. Assessments during treatment include itch LASI75 response rate, PP-NRS score response rate, LASI50, LASI90 response rate, IGA score response rate, improvement in BSA score from baseline, and improvement in DLQI score from baseline.

Procedures During the Study: During the study, you will undergo the following assessments: Complete blood count, biochemical profile, and

urinalysis at visits V1, V2, V10, and V12; electrocardiogram (ECG), serum pregnancy test, and infectious disease screening at V1; and ECG at V10 and V12. Some subjects will undergo skin biopsy for histopathological examination at V1 and V12 (you will participate in/not participate in the assessments).

Potential Benefits of the Study

If you are randomized to the treatment group, you will receive 16 weeks of treatment with a novel biologic agent, which is expected to produce better therapeutic effects. However, we cannot guarantee the efficacy, meaning that your condition may improve, may not improve, or may even worsen. If, during the trial, at any visit after dosing, the treatment is deemed ineffective (e.g. persistent worsening of rash or pruritus that affects daily life and work), you will receive free drug treatment during the trial period. Participation in this study will allow you to receive the aforementioned examinations free of charge, providing more evidence for the diagnosis and treatment of your condition. A series of studies on the effects of Stapokibart after your injection will help further explore the efficacy and safety of this drug for primary cutaneous amyloidosis, offer necessary advice for your treatment, and provide valuable information for the research of primary cutaneous amyloidosis, which is beneficial for the comprehensive treatment of primary cutaneous amyloidosis. We will provide you with free follow-up consultations, as well as free medical consultations and health guidance for the comprehensive treatment of primary

cutaneous amyloidosis.

Risks and Discomforts of the Study

In this study, you will need to receive drug injections every two weeks, which will be administered by trained professionals. You may experience mild pain during the injection. At some visits during the study, you will need to undergo examinations, and you may feel slight pain or discomfort during blood draws. Some participants will undergo skin biopsies for histopathological examination, and the biopsy site may experience pain or infection. When collecting clinical case information during the study, you may be contacted by phone for follow-up, which may cause you some inconvenience. We will do our best to respect your wishes regarding follow-up.

Other Treatment Interventions

There are no other interventions or therapeutic measures apart from participation in this study.

Privacy Concerns

If you decide to participate in this study, your participation and personal information related to the trial will be kept confidential. All information about you will be kept confidential.For example, your assessment data will be identified by a study number rather than your name.Information that can

identify you will not be disclosed to anyone outside the research team unless you give your permission. All research team members are required to keep your identity confidential. Your records will be stored in the dermatology department's file cabinet and will be accessible only to the researchers. To ensure that the study is conducted as required,members of government regulatory authorities or ethics review committees may,as required, review your personal data at the research institution. When the results of this study are published,no personal information about you will be disclosed.

Costs and Compensation

The investigational medicinal product (Stapokibart) required for this study will be provided to you free of charge by the study team, and you will not be required to pay for it. All examinations planned within the study protocol during the screening and follow-up processes of this study are necessary for treatment and disease monitoring, and the costs will be covered by the study team. If you are injured as a result of participating in this study: in the event of harm related to this clinical study, you will be entitled to free treatment and corresponding compensation, with the relevant costs provided by the study team. The study team has purchased insurance for you. If you are randomized to the placebo group, you will receive a subsidy of 1,000 yuan upon completion of the trial. If efficacy is not satisfactory during the trial, you will receive free rescue treatment with the investigational medicinal product during the trial

period, with the relevant costs covered by the study team.

Voluntary Withdrawal

As a participant, you have the right to access all information related to this study and its progress at any time and can voluntarily decide whether to continue or discontinue participation. Once enrolled,regardless of whether any harm occurs or how severe it may be, you may choose to withdraw from the study at any time by notifying the study doctor. Your data will not be included in the study results, and your medical treatment and rights will not be affected. If continuing participation in the study would cause you serious harm, the study doctor may also terminate your involvement.

However, during your participation in the study, please provide accurate information about your medical history and current health status;inform the study doctor of any discomfort you experience during the study period; refrain from taking restricted medications,foods,etc.; and let the study doctor know if you have recently participated in other studies or are currently involved in any other studies. If you fail to comply with the study plan,experience study-related injuries, or for any other reason,the study doctor may terminate your continued participation in this study.

Contact Information

If you have any questions related to this study, experience any discomfort or injury during the study process, or have concerns about the rights of

participants in this study,you may contact the project contact person, _____, at phone number _____.

Post-Trial Benefit Sharing

The results of the study will be published in the form of a paper in an academic journal. It will not involve any commercial use.

Signature on the Informed Consent

I have read this informed consent form, and my doctor_____has provided me with a detailed explanation of the purpose, content,risks, and benefits of this clinical trial. All of my questions have been answered.I understand this clinical research study and voluntarily agree to participate in it.

Signature of the Subject：_____

Date：_____

Signature of the Investigator：_____

Date：_____

（Note:If the subject is illiterate,a witness signature is also required.If the subject lacks the capacity to act,consent from a representative is required.）