# Explanation for patients considering treatment with culture supernatant of human somatic mesenchymal stem cells (StemSup)

Azabu Central Clinic

#### Introduction

This document explains the components used in treating human somatic mesenchymal stem cell culture supernatant StemSup (StemSup) and describes how the treatment is performed for those considering it..

Patients who are considering undergoing this treatment should first listen to their doctor's explanation and fully understand the details. If you have any questions or find the explanation difficult to understand, please do not hesitate to ask your doctor.

StemSup is a research reagent, not a drug approved by the government. It is up to the patient's free will to decide whether or not to undergo the treatment, and the patient will never be disadvantaged in any subsequent medical treatment for choosing not to undergo the treatment. If you wish to undergo treatment, please sign the attached "Letter of Consent" in your own handwriting.

Please note that even after signing the Letter of consent, you may withdraw your consent at any time and discontinue any subsequent treatment. Please do not hesitate to contact us if you wish to withdraw your consent or if you have any concerns.

## What is "Mesenchymal stem cell culture supernatant: StemSup"?

Mesenchymal stem cells play a very important role in our body, repairing damaged tissues and reducing inflammation that damages our body. Mesenchymal stem cells exert their abilities by secreting active substances such as exosomes containing more than 100 types of cytokines and microRNAs. With recent advances in regenerative medicine, mesenchymal stem cells are now being administered to living organisms for the treatment of certain diseases. In addition, recently, cell-free therapies, in which a liquid containing active substances secreted by stem cells is administered without administering the stem cells themselves, have been attracting much attention. The mesenchymal stem cell culture supernatant called "StemSup," we use at our clinic, means "a liquid rich in natural active substances secreted by mesenchymal stem cells. Note that the stem cells themselves that secreted the active substances have been removed from the StemSup.

StemSup contains substances that help regenerate aged or damaged tissues, and its use is expected to improve symptoms such as male pattern baldness (AGA), thinning hair in women, loss of skin elasticity, rough skin, stiff shoulders, back pain, numbness in hands and feet, sensitivity to cold, tired eyes, fatigue, reduced sexual drive, and insomnia. However, the degree of effectiveness, the period of time until the onset of effects, and the duration of effects will vary in each case, depending on the degree of progression of symptoms, lifestyle, and other factors. Please visit your doctor regularly during the treatment.

## How is the treatment performed?

#### (1) Eligible patients

For those who wish to have their symptoms treated with StemSup, the doctor in charge will first confirm the symptoms they are suffering from in an examination and consider whether the symptoms can be expected to improve with the use of StemSup.

If they hear the explanation about the details and wish to undergo the treatment, the treatment can be performed for them.

However, before undergoing the treatment, you must understand the contents of this document, sign the Letter of consent, and agree that the use of StemSup and all medical examinations will be performed at your own expense.

Even if you wish to use StemSup, it may not be possible depending on the symptoms you are suffering from or the disease you have. Please inform your doctor of any illnesses you are currently being treated for, any illnesses you have had, and any medications you are using.

If you are undergoing any regular treatment at another clinic, please give priority to seeing and receiving the treatment from your primary doctor.

#### (2) Administration method

The method of administration for outpatients at the clinic is intravenous infusion and the infusion takes about 20 minutes.

Expected side effects of this treatment

Pain, swelling, and internal bleeding at the injection site may be observed in rare cases. Internal bleeding spots usually become less noticeable in 2 to 3 weeks.

Local injections may cause pain, swelling, and internal bleeding. Please advise us in advance if you are taking blood thinners, including warfarin, bai-aspirin (low-dose aspirin), and bufferin, as they increase the risk of internal bleeding.

#### (3) Risks of this treatment

It has been confirmed that StemSup is free of various known viruses and other pathogens. However, since it is obtained from human cells, we cannot rule out the possibility of infections caused by pathogens that cannot be confirmed by current testing techniques. With this in mind, we ask that those who have used StemSup refrain from donating blood at the Japanese Red Cross Society (this does not apply to blood donations made with the consent of both parties, such as

relatives).

# **Handling of Personal Information**

Although we may use the progress of your treatment with culture supernatant for presentation at academic conferences or in papers, your privacy will be kept strictly confidential. We will not use your name or personal identifying information in any of our reports. Your privacy, including information about your medical condition and name, will be strictly protected.

### **Treatment Costs**

Treatment with culture supernatant is self-funded and not covered by health insurance.

Treatment fees will be charged according to the treatment details.