Jinling Hospital, Nanjing University

CONSENT FORM

TITLE OF STUDY: Thymosin alpha 1 in the prevention of infected pancreatic necrosis following acute necrotizing pancreatitis

PRINCIPAL INVESTIGATOR: Weiqin Li, M.D.

We are conducting a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in the study. This consent form serves two purposes. First, it provides information on the procedures and risks involved in the clinical trial, so that you can decide if you want to take part in the study.

Second, this form will ask for your permission to use and release the medical information that we will get from you during this study. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. If you have any questions, you can ask the study doctor for more explanation.

This study is being sponsored by Jinling Hospital of Nanjing University. You are being asked to take part in this study because you were admitted to Jinling Hospital with acute necrotizing pancreatitis (ANP).

WHY IS THIS STUDY BEING DONE?

Infected pancreatic necrosis (IPN) and its related septic complications are the major causes of death in patients with ANP. Our previous study found that Thymosin alpha 1 is associated with improved cellular immunity and reduced infection rate in a group of ANP patients. However, no further study was published yet, and the clinical significance of this study is limited due to the small sample size and single-center nature. Therefore, we conduct a multicenter, randomized study with a sufficiently-powered sample size and proper design to evaluate the efficacy and safety of Thymosin Alpha 1 in treating ANP.

It is planned that a total of 520 people will take part in this study from 10-20 hospitals within China.

WHAT WILL HAPPEN IN THE STUDY?

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the study doctor will choose what group you will be in. You will have an equal chance of being placed in either group.

Group 1 will receive Thymosin Alpha 1(ZADAXIN) 1.6mg I.H q12h for the first seven days and 1.6mg I.H, qd for the following seven days. Group 2 will receive a matching placebo (normal saline) using the same mode of administration, as mentioned above. The administration will be terminated any day during the treatment when the patient deemed as qualified for discharge

You will be in the study until you are discharged from the hospital.However,You can stop being a part of this study at any time. Iif you decide to stop being in the study, please talk to the study doctor first.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for the following side effects. You should discuss these with the study doctor. We will be looking at your medical records up to 90 days after "randomization." If you are discharged before that, you will be contacted by phone.

Risks and side effects related to the study drug(Thymosin Alpha 1) and placebo(normal saline) include:

- primarily local discomfort at the injection site
- rare instances of erythema
- transient muscle atrophy
- polyarthralgia combined with hand edema,
- skin rash

There also may be other side effects that we cannot predict. These side effects are often manageable and reversible. You will be observed for side effects, and all medically appropriate efforts will be made to prevent and/or control them. If there are side effects that cannot be controlled or reversed, they may result in serious injury or death.You should report any of these problems to the study doctor immediately so that appropriate care can be given.Side effects other than those listed here may also occur.Talk to the study doctors about any side effects that seems unsual or that is especially bothersome to you.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, you are free to use the Thymosin Alpha 1(ZADAXIN)/placebo provided by Sciclone Pharmaceuticals (CHINA). Besides, you will experience improved access to medical care, more efficient medical evaluation, and management. The results of this study could help future patients with your condition.

WHAT ARE THE COSTS?

Taking part in this study will not lead to added costs to you or your insurance company. The trial drug and related immune system laboratory tests will be provided free of charge. The sponsor will not pay for routine costs required during hospitalization.

While you are in this study, you may receive tests, procedures, and exams that are standard medical care. This standard medical care may or may not be covered by your medical insurance.If your medical insurance does not pay for this standard medical care, you will be responsible for the cost of medical care related to your condition.

COMPENSATION?

You will receive no payment for taking part in this study.

WHAT ABOUT CONFIDENTIALITY?

Only the medical information that will be collected from you if you take part in this study.Date masking will be performed to protect your Identification information from divulging.The medical information are as follows:

- Information obtained from procedures used to determine your eligibility to take part in the study, including a routine medical history, physical exam, and laboratory data.
- Information that is created or collected from you during your participation in the study, including your overall medical condition and follow-up information up to 90 days after randomization.
- Information contained in your underlying medical records related to your medical history and treatment prior to this study

Only the hospitals envolved in the study may inspect and/or copy your research records for quality assurance and data analysis.

DO I HAVE THE RIGHT TO DECLINE AUTHORIZATION?

You have the right to decline to sign this authorization to use/disclose your medical information. If you decline, you will not be able to take part in this research study. Except as described herein, if you decline to sign this authorization, your rights concerning treatment, payment for services, enrollment in a health plan, or eligibility for benefits will not be affected.The authorization for use and disclosure of your information will remain in effect until the study is complete.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Your doctor has answered your questions. You can ask your doctor questions at any time. Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. We will tell you about the important new information that may affect your health, welfare, and willingness to stay in this study.

STATEMENT OF CONSENT AND AUTHORIZATION

I hereby freely and voluntarily consent to take part in the research study described above. This consent is given based on the verbal and written information provided and the understanding that I am medically and physically qualified to take part in this study. I am free to ask questions at any time.

I have the option to decline to take part or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available, including medical care at this institution.

My signature below indicates that I voluntarily agree to take part in this study and that I authorize the use and disclosure of my information in connection with the study. I will receive a signed copy of this consent and authorization form.

_____	_____	_____
Patient Signature*	Date	Time
_____	_____	_____
Research Coordinator Signature	Date	Time
_____	_____	_____
Investigator Signature	Date	Time

*If this consent is signed by a legal representative of the patient, check applicable box below explaining your authority to sign for the patient. For legal representatives acting in the capacity as a parent/guardian to the patient, attach a copy of documentation giving you the authority to sign this consent form on behalf of the patient.

- o Next of Kin
- o Parent (patient is a minor)
- o Guardian
- o Other relationship: _____

_____	_____	_____
Signature of Patient's Legally Authorized Representative	Date	Time
_____	_____	_____
Witness to consent process(if applicable)	Date	Time