Research Number: T18008-A

Subject informed consent

Dear patient,

We want to invite you to participate in a multicenter, double-blind, randomized controlled clinical study, which will evaluate the efficacy and safety of the recombinant human thrombopoietin (rhTPO) and eltrombopag for the treatment of immune thrombocytopenia (ITP) in Chinese adult patients. The purpose of this study is to verify whether the efficacy of rhTPO is better than eltrombopag after 14 days treatment in Chinese adults.

This informed consent form helps you decide whether or not to participate in the study. The content of this informed consent form should be fully understood before you agree to participate in the study. If you have any questions, please ask your doctor.

Name of the research project：Efficacy and Safety of rhTPO and Eltrombopag in the Treatment of Chinese Adults with Primary Immune Thrombocytopenia (ITP): a Multicenter, Double-blind, Randomized, Controlled Trial.

Research leader: Professor Yu Hu

Research unit: Union Hospital, Tongji Medical College, Huazhong University of Science and Technology

1. Research background and purpose:

The thrombopoietin drug is a second-line treatment drug for adult chronic primary thrombocytopenia recommended by Chinese experts, including recombinant human thrombopoietin injection (rhTPO) and Reefland

(eltrombopag ethanol tablets or eltrombopag). The rhTPO is a fully glycosylated thrombopoietin which can stimulate platelet production and increases peripheral blood platelet count. It used many years in China and has significant efficacy and safety for Chinese ITP patients. Eltrombopag is a newly marketed platelet-producing drug in China that stimulates platelet production by activating signaling pathways, but has little effect on platelet function. Meanwhile, pharmacokinetic studies indicate that the drug exposure rates are twice in Asians compared with non-Asians.

Currently, there is still a lack of efficacy and risk data for rhTPO and eltrombopag in Chinese ITP patients. This study intends to compare the efficacy and safety of rhTPO and eltrombopag in the treatment of primary immune thrombocytopenia in Chinese patients, and to determine whether the efficacy of rhTPO is better than eltrombopag. And explore the treatment options of chronic primary immune thrombocytopenia with Chinese characteristics, improve the level of treatment and reduce the cost.

2. Research content, methods and procedures:

You will be screened through detailed medical history, physical examination, laboratory examination and imaging examination. After passing the test, you will receive rhTPO+ eltrombopag simulator (tablet) or eltrombopag + rhTPO simulator (injection) treatment. During treatment, you will be followed up at 0 (baseline), 3 days, 6 days, 9 days, 12 days, and 15 days for physical examination, laboratory examination, etc. to evaluate the treatment effect. Concomitant medications and adverse events are recorded during the entire treatment period, and if there are any changes in the condition, the patient can visit the doctor at any time and the treatment plan will be adjusted if necessary.

3. Possible risks (or discomfort, inconvenience) and benefits (interested by individuals or social groups) to participate in the study:

The drugs in this study are provided for free: rhTPO 300 U/Kg, qd, subcutaneous injection; eltrombopag 25 mg/time/day, oral administration; rhTPO simulator (injection), 300 U/ Kg, qd, subcutaneous injection; eltrombopag simulator (tablet), 25 mg /time/day, orally administered. The indications for rhTPO and eltrombopag have been approved by the State Food and Drug Administration (CFDA).

There is a risk of adverse reactions in any drug. Mostly common adverse reactions that have occurred during the clinical application of rhTPO include: fever, muscle aches, dizziness, rash, injection site, high blood pressure, diarrhea, weakness, pain, etc. The more common side effects of eltrombopag include: nausea, diarrhea, upper respiratory tract infection, vomiting, muscle aches, urinary tract infections, and increased alanine aminotransferase. After the drug is stopped in time, the above abnormal conditions can return to normal and disappear. Each time you follow up, you can be sure to get a priority visit to the clinic. Your doctor will ask you about the adverse reactions at each visit. If you have any questions, please tell the doctor promptly. The common adverse reactions will be actively deal with. The vast majority of patients can benefit from this clinical observation and the condition will improve. The information obtained from this study will help you and other patients in the future.

4. Consultation on the content:

You have the right to consult on the research content and related risks.

5. Right to withdraw from research:

Your participation in this study is completely voluntary. If you are unwilling to participate or unwilling to continue in this study, you can withdraw without any reason, and will not have any impact on your rights. In addition, you have the right to withdraw from this study at any time. If you are not following your doctor's advice, or if your doctor thinks about your health and well-being, your doctor or researcher may ask you to quit.

6. Compensation for research:

If you have clinically relevant damages due to participation in this study, you will receive timely and necessary treatment. The financial support of this clinical observation, Shenyang Sansheng Pharmaceutical Limited Liability Company will bear the corresponding treatment costs and give you certain economic compensation according to relevant national regulations.

7. Confidential:

Your medical information for this study will be kept confidential. The results of the research will not reveal any personally identifiable information when published in academic journals. The Union Hospital of Tongji Medical College of Huazhong University of Science and Technology will keep all your records in this study and related hospital and office records, and no one can obtain this information without authorization.

8. The informed consent form is in duplicate, one for each subject and the researcher, and valid after signing by both parties.

Thank you for taking the time to read the above and consider whether to participate in this study!

Informed consent signature:

I have read the informed consent form, and my doctor has explained the purpose, content, risks and benefits of this clinical trial to me in detail, and also answered all the questions I asked. I have learned this clinical study and volunteered to participate in this study.

Subject signature: _____ ; Researcher signature:_____

Date:_____ ; Date:_____

Subject contact number: _____;Researcher contact number:_____

(Note: If the subject is illiterate, it needs to be signed by the witness, and if the

subject is incapacitated, the agent must agree)