

**A Phase III Double-Blind Placebo-controlled Study to
Evaluate Elfazab (Rapido) in Adults with
Moderate to Severe Plaque Psoriasis**

Doctor: Marcus Welby, M.D.

Informed Consent

You are being offered the opportunity to participate in a research study because you suffer from psoriasis. The purpose of the research study is to evaluate the effectiveness of Elfazab (Rapido) in the treatment of psoriasis. Please read this information carefully and ask your doctor any questions before deciding whether or not to participate in this study. Participation in this study may offer you the benefit of controlling your psoriasis. There may also be risks to you. This document will explain the study. Your participation in this study will last approximately 24 weeks.

What will happen to me on this study?

Rapido is an investigational agent designed to treat psoriasis. If you decide to participate in this study, the doctor will conduct a physical exam and blood tests to determine if you are eligible for the study. If you are eligible, you will be randomized to receive either placebo or Rapido. You have a 50% chance of receiving Rapido. Neither you nor your doctor will know which one you are receiving.

You will be required to discontinue any other medication which you have been taking for your psoriasis for 28 days prior to the first treatment. This period of time is called the “wash-out period” and is required in order to be able to evaluate the effectiveness of Rapido.

After the 28 day wash-out period, you will receive an injection once a week for 12 weeks. Your doctor will monitor your health and response to the treatment on your weekly visits. After the initial 12 weeks of treatment, you will be re-randomized to receive either a low dose or a higher dose of Rapido. You will receive weekly injections for 12 weeks.

How will I benefit from this study?

We do not know if you will benefit from participation in this study or not. You may benefit by receiving better treatment for your psoriasis with Rapido than with your previous medication. The information gained from this study could help future psoriasis patients.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Many side effects go away

soon after you stop taking Rapido. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the Rapido include those which are:

Likely

- headache
- chills
- fever
- nausea
- muscle aches

Less Likely

- back pain
- joint pain
- swelling of arms and legs

Reproductive risks: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. For more information about risks and side effects, ask your study doctor.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your psoriasis in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular psoriasis treatment.

If, during the study, Rapido, becomes approved for use in your psoriasis, you and/or your health plan may have to pay for drug needed to complete this study.

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Welby, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 423.234.7878.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor Dr. Marcus Welby at 423.234.7878.

For questions about your rights while taking part in this study, call the Southeastern Institutional Review Board (a group of people who review the research to protect your rights) at 423.234.7879.

How will my information be kept private?

Although study results may be published, your confidentiality will be maintained. Your name or information identifying you will not be released without written permission unless required by law. Under federal privacy regulations, you have the right to determine who has access to your personal health information (called “protected health information” or PHI). PHI collected in this study may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this consent form, you are authorizing the Dr. Welby to have access to your PHI collected in this study and to receive your PHI from any facility in which you have received treatment. In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including the (FDA) Food and Drug Administration, the Southeastern Institutional Review Board. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used indefinitely. You may cancel this authorization in writing at any time by contacting the Principal Investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your

PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

Signature

I have been given a copy of all pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant's Name (printed) _____

Participant's Signature: _____ Date _____