Do you have Cutaneous T-Cell Lymphoma?

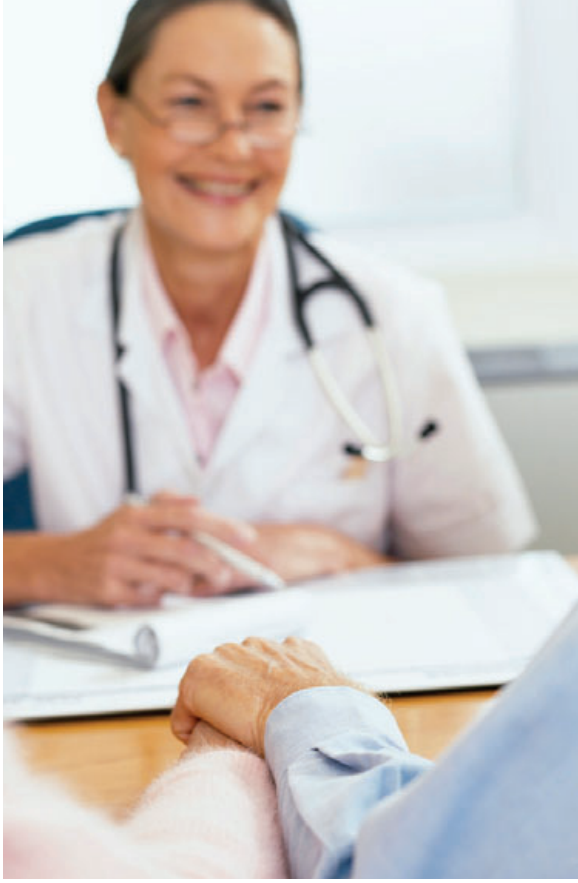
A Medical Research Study for Patients with Cutaneous T-cell Lymphoma (CTCL) Stage IB or IIB Disease and mSWAT <50 is Currently Accepting Patients*

Researchers are currently conducting a Phase II study of A-dmDT390-bisFv(UCHT1) called Resimmune®

Clinical Research Sponsored by:

Angimmune

www.angimmune.com



CTCL patients currently have limited treatment options that lead to long-term remissions.

Basic chemotherapy and more aggressive treatments may not be effective, or lead to dangerous side effects. CTCL patients need better treatment options, including potential medications that target cancerous T-cells. Study doctors are hoping that this research agent will be able to kill cancerous T-cells, and help the immune system to "reset" itself. Due to the slow disease progression, while initially presenting itself as a skin lesion, basic dermatology treatment may not provide desired results. Because previous study results have shown to be most encouraging when this disease is treated in its early stages,[A2,A3] it is important to seek evaluation and treatment as soon as the disease presents.

Pharmaceutical companies use medical research studies like this one to evaluate the safety and effectiveness of a research agent before it is made available to the public. By taking part in this study, you are making an important contribution to cutaneous T-cell lymphoma treatment research.

Study-related tests and medications will be provided to participants at no cost. In addition, compensation for travel and lodging may be provided.

Treatment with this study medication occurs over a period of 4 days, which is generally a shorter time period than current treatment options.

Cutaneous T-cell lymphoma and Resimmune.®

Cutaneous T-cell lymphoma (CTCL), is a form of cancer that impacts the skin before traveling to other parts of the body which causes a group or clone of T-lymphocytes, or T-cells, to multiply at an abnormal and uncontrollable rate. Unfortunately, CTCL does not always respond to available chemotherapy treatments. As a result, patients are often left without an effective treatment option.

Doctors and researchers have developed a CTCL research agent (study medication) that is being studied in human clinical trials, especially in the early stage of the disease. This study medication, known as Resimmune or A-dmDT390-bisFv(UCHT1), contains an immunotoxin, which is a type of protein that targets and depletes a high percentage of T-cells in the body, both malignant and normal.[A4] After the normal T-cells are depleted, they are able to grow back faster than malignant cells.

Treatment with this study medication occurs over a period of four days, which is generally a shorter time period than current treatment options, and is administered as an outpatient.

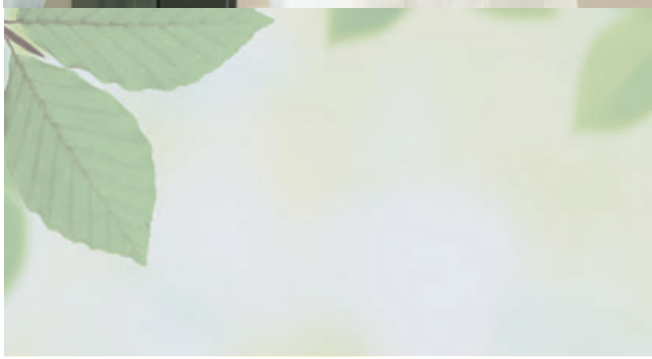
Who is eligible to participate in this study?

To pre-qualify for this study, you must:

- Be at least 18 years of age
- Have a medical diagnosis of cutaneous T-cell lymphoma* with skin coverage by lymphoma greater than 10% but less than 50% (with disease stage never exceeding IB/IIB, mSWAT <50%)
- Have had at least one prior systemic treatment (a pill or an injection or x-ray) for cutaneous T-cell lymphoma that was unsuccessful
- Not have a history of heart disease or prior treatment with Campath

If you qualify for study participation, some of your travel and lodging costs may be covered. You will also receive study-related medical care at no cost. Your dermatologist/oncologist can provide you with more information about this study, and additional information can be found online at www.ClinicalTrials.gov Identifier: NCT00611208 or www.ctclclinicaltrial.com

*All patients must have CTCL diagnosed by morphologic, histochemical or cell surface marker criteria with stage never exceeding IB / IIB disease and mSWAT ‹ 50%. CTCL patients with stage IA disease are not eligible for enrollment. CTCL patients with stage IB disease are eligible provided that they have failed a systemic treatment (this includes radiation). CTCL patients with bone marrow involvement but without lymph node involvement are eligible. Patients with a diagnosis of angioimmunoblastic T cell lymphoma are eligible, even with lymph node involvement.



Some of these tests and assessments include, but are not limited to:[A1]

— Physical exams
— Nervous system exams
— Vital signs measurements
— Blood samples
— Urine samples
— Echocardiogram (measures how well your heart is functioning as a pump)
— Electrocardiogram (measures the electrical activity of your heart)
— Chest x-rays
— Assessments of any viruses
— Skin assessments and pictures of skin
— Reviews of side effects

What happens during this study?

If you are eligible after screening is complete and you agree to participate, you will begin receiving IV infusions of the research agent 2 times a day for four days. Infusions will last about 15 minutes each. Prior to the IV infusion, you will be given medication to help prevent any infections as well as medications such as Tylenol,™ Zantac,™ and Benadryl™ to help limit any side effects you may experience from the study medication.[A1]

If your cancer is responding to this treatment, you will continue visiting the study clinic for observation.

During the study, you will visit the study clinic up to 18 times over approximately 72 months (6 years)[A1] to receive your infusions, as well as have various tests and assessments performed to evaluate your health and response to the research agent.

What are the risks and benefits related to this study?

Testing of this research agent is still in the early stages. As with any medical research study, this study medication may not have any effect on your cutaneous T-cell lymphoma. Side effects may also occur, such as fever, chills, sweats, nausea, vomiting, diarrhea, skin rashes, low or high blood pressure, and blood vessel issues that cause swelling.[A3] There is always a risk involved when taking a new medication. Participants will be closely monitored throughout the trial and are encouraged to report any side effects experienced.

What if I have questions?

To learn more about this study, staff is always available to answer any questions or concerns you may have.

Or visit: www.ctclclinicaltrial.com

www.ClinicalTrials.gov Identifier: NCT00611208

"A-dmDT390-bisFv(UCHT1) Immunotoxin Therapy for Patients with Cutaneous T-Cell Lymphoma (CTCL)"

Scientific Published References

A1 Protocol: A Phase II Study of A-dmDT390-bisFv(UCHT1) Fusion Protein in Patients with Cutaneous T Cell Lymphoma

A2 American Society of Clinical Oncology (ASCO) 2012 Annual Meeting, 06/04/2012. A.E. Frankel, J. H. Woo, M. Grable, A. Mankin, J.P. Mauldin, D.M. Neville (2012). "Anti-CD3 Diphtheria Immunotoxin Induces Remissions In Patients With Cutaneous T Cell Lymphoma." J Clin Oncol 30, 2012 (suppl; abstr 2505).

A3 The American Society of Hematology (ASH) Annual Meeting, December 2013 Abstract: Abstract #57379:
An Update On The Clinical Activity Of Resimmune, a Targeted Therapy Directed To CD3 Receptor, In Patients With Cutaneous T Cell Lymphomas–CTCL
Arthur E. Frankel, MD[1], Jung H Woo, PhD[2],*Jeremy P Mauldin, PhD[2],* Francine M. Foss, MD[3], Madeleine Duvic, MD[4] and David M Neville Jr., MD[5]*
[1] University of Texas Southwestern Medical Center, Dallas, TX,
[2] Scott & White Healthcare, Temple, TX
[3] Yale Cancer Center, New Haven, CT
[4] M.D. Anderson Cancer Center, Houston, TX
[5] Angimmune LLC, Rockville, MD

A4 Current Drug Targets, 2009, 10, 104-109, Anti-CD3 Recombinant Diphtheria Immunotoxin Therapy of Cutaneous T Cell Lymphoma.

Clinical Trial Centers

James Graham Brown Cancer Center

Brown Cancer Center Clinical Trials Office
Louisville, Kentucky, United States, 40202
Contact: David Figg, SC
Phone: 502-562-4006
Email: d.figg@louisville.edu
Principal Investigator: Cesar Rodriguez, MD

University of Texas MD Anderson Cancer Center

Houston, Texas, United States, 77030
Contacts: Carol Wilson, RN
Phone: 713-563-4655
Email: clwilson@mdanderson.org
Principal Investigator: Madeleine Duvic, MD

University of Texas Southwestern Medical Center

Dallas, Texas, United States, 75390
Contact: Adrian Avila, Study Coordinator
Phone: 214-648-5107
Email: adrian.avila@utsouthwestern.edu
Principal Investigator: Arthur Frankel, MD

Clinical Research Sponsored by:
Angimmune
www.angimmune.com