National Cancer Institute

CCR Clinical Trials at NIH

April 2014

Dear Colleague:

NCI's Center for Cancer Research (CCR) Clinical Immunotherapy Section of the Laboratory of Molecular Biology in Bethesda, Maryland, is participating in a CTEP-sponsored trial for the treatment of **relapsed or refractory hairy cell leukemia** in adults who have received at least two prior systemic therapies.

Patients who have been treated many times for hairy cell leukemia (HCL) often have poor responses to standard treatment. Moxetumomab pasudotox is a recombinant immunotoxin consisting of the Fv portion of the anti-CD22 antibody covalently fused to a 38 KDa fragment of Pseudomonas exotoxin-A (PE38). HCL cells that are resistant to chemotherapy display high levels of CD22, making them good targets for moxetumomab pasudotox, that binds to CD22, thereby delivering the toxin moiety PE38 directly to tumor cells. The recently published Phase I results in 49 patients included a complete remission rate of 57%, overall response rate 88%, and no dose limiting toxicity (http://www.ncbi.nlm.nih.gov/pubmed/22355053) and (https://ash.confex.com/ash/2013/webprogram/Paper64736.html). These results appear superior to other reported non-chemotherapy approaches for relapsed HCL. Our data suggest that hairy cells, which nearly always carry the BRAF V600E mutation, are effectively treated with moxetumomab pasudotox.

We invite your participation in furthering this research through patient referrals. For additional study information on this and other HCL trials, please click on the relevant link below:

Moxetumomab pasudotox trial info: http://clinicaltrials.gov/show/NCT01829711
My Website: http://ccr.cancer.gov/staff/staff.asp?profileid=5789
Our Trials: https://bethesdatrials.cancer.gov/clinical-trials-search-physician?field_investigator_name_value=kreitman&=Apply
Key eligibility criteria:

- Histologically confirmed diagnosis of HCL
- Requires treatment
- At least two prior systemic therapies

Please contact Dr. Kreitman (rk21n@nih.gov) at 301-648-7375 or one of our protocol nurse coordinators, Laura Wisch, R.N. (Laura.Wisch@nih.gov) at 301-594-1827, Elizabeth Maestri, R.N. (maestrie@mail.nih.gov) at 301-402-5633, or Sandra Brinkman-Denny, R.N.(sandra.brinkman-denney@nih.gov) at 301-496-9458, to learn more about this study or to find out how you can send samples to determine protocol eligibility of potential study participants.

Your support of clinical research and your patient referrals are vital to our efforts to find new and better ways to treat patients with leukemia. That's why we're committed to keeping you informed of the clinical research taking place within our branch. As part of our commitment, we promise to keep you, the referring physician, informed of your patient's progress, study developments, and updates. We look forward to working with you, and we welcome the opportunity to discuss treatment options for your patients or answer any questions you may have about our study.

Patients are not charged for the medical care they receive as participants in a clinical trial at NCI. Once enrolled in a study, they also receive support for travel costs associated with study-related visits; however, patients will be responsible for travel costs for their initial screening visits. In addition, it will be important for them to maintain their current insurance plan to cover all medical care that is provided away from the NIH Clinical Center. For more information on CCR clinical trials conducted at the NIH Clinical Center, please visit http://bethesdatrials.cancer.gov.

Thank you for your commitment to the fight against cancer.

Sincerely,

Kreitman MD

Robert J. Kreitman, M.D.
kreitmar@mail.nih.gov
Chief, Clinical Immunotherapy Section
Laboratory of Molecular Biology, CCR, NCI, NIH