

REPORT ON MEETINGS ON TRADITIONAL MEDICINE HEALTH RESEARCH

Date: February 10, 2006

Location: Paramaribo

Participants: University of Suriname Faculty of Medicine representatives D. Mans Ph.D. and J. Hasrat MD. From Amazon Conservation Team: Health Coordinator Melvin Uiterloo, Program Director Gwen Emanuels-Smith.

Purpose: Collaboration for traditional medicine testing.

Details: Both parties acknowledge the need for medicine development for the tribes for income generation and healthcare. The ultimate goal is to prepare a research proposal where the Faculty will provide their trail experience, contacts and infrastructure, and ACT will work with the Trios to establish a coded system for medicine delivery. The first experiments will be done with external medicines, predominately for dermatology problems. We will continue the meeting by exchanging expectations by e-mail and return on the first week of March.

Date: March 14, 2006

Location: Paramaribo

Participants: University of Suriname Faculty of Medicine representatives D. Mans Ph.D., J. Hasrat MD, Tulsie MD, Bipat MD. From Amazon Conservation Team: Health Coordinator Melvin Uiterloo, Director Gwen Emanuels-Smith.

Purpose: Collaboration for traditional medicine testing.

Details: Because of safety issues, both parties decided to conduct dermatology research. The researchers will deliver a protocol in which the research of ACT with the Medische Zending Suriname (comparing western and traditional disease concepts in clinics in the indigenous villages of Kwamalasamutu and Tepu) will be incorporated. Follow-up was provided through e-mail, and a protocol was developed for "Evaluation of a plant-based traditional preparation for moderate to severe chronic plaque psoriasis".

Summary

Title. Evaluation of a plant-based traditional preparation for its efficacy and safety in patients with moderate to severe chronic plaque psoriasis.

Background. Chronic plaque psoriasis, the most common form of psoriasis, is a T-cell-mediated autoimmune disease of the skin characterized by erythematous plaques with a silvery scale. Psoriasis affects 0.6 to 4.8% of the U.S. population. Steroids and vitamin D derivatives, either alone or simultaneously, are the mainstays of topical therapy, inducing 50 to 75% improvement in approximately 40% of patients. Patients who do not respond to topical therapy, or those with more than 20% of their skin involved, can receive light therapy, or systemic therapy with cytotoxic or immunomodulatory drugs such as methotrexate and alefacept, respectively. Thus far, results with all these forms of treatment are unsatisfactory.

Objective. In this one-armed, two-stage phase II clinical trial designed according to the Fleming method¹, a plant-based, traditional preparation called Substance S will be evaluated for efficacy and safety in patients with moderate to severe chronic plaque psoriasis.

Patients and methods. Patients will be recruited from the Department of Dermatology of the Academic Hospital Paramaribo. Eligible patients are at least 18 years of age; suffer from chronic plaque psoriasis defined by a score of at least 8 on the Psoriasis Area and Severity Index (PASI); respond unsatisfactorily to standard forms of treatment; and must have given informed consent. Patients with a history of allergy; skin cancer, and/or yeast or fungal skin infections; as well as pregnant and lactating women, are not allowed to participate in the study. Efficacy, defined as at least 50% disease improvement (PASI 50) in at least 40% of patients, will be assessed after four weeks of daily topical application of Substance S. In the first stage of the trial, six patients will be entered. If there are no responses in this group, Substance S will be declared inactive and the trial will be terminated. If there are three or more responses, Substance S will be declared active and the trial will be terminated. In the case of 1-2 responses, five additional

patients will be enrolled in the second stage of the trial. Depending on the number of responses in the total number of participants (less, equal, or more than 40%), the level of activity of Substance S against psoriasis will be established. Safety will be evaluated after at least one week of therapy as described².

¹Fleming TR. Biometrics 38: 143-151, 1982.

²Bruner CR, et al. Dermatol Online J 9: 2, 2003.