MEDICAL THERAPIES AND PHARMACOLOGY

EXTRACORPORAL PHOTOPHERESIS WITH 5-AMINOLEVULINIC ACID IN PATIENTS WITH CHRONIC GRAFT-VERSUS-HOST DISEASE – PRELIMINARY RESULTS FROM A PILOT STUDY

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Introduction: The current standard 8- methoxypsoralen (MOP)-extracorporal photopheresis (ECP) is long-lasting, thus expensive, and only provides partial response in the majority of treated patients. Possible benefits of 5-aminolevulinic acid (ALA –ECP) includethat it specifically targets diseased cells and more diseased cells are killed by treatment with 5-ALA than those treated with 8-MOP. Thus, ALA may improve ECP efficacy significantly, so that the number of treatments may be reduced.

Objective: Primary aim was to assess safety and tolerability after single and multiple treatments using 5-ALA– ECP in patients with chronic graft-versus-host disease (cGvHD). The primary safety parameters were frequency, seriousness and intensity of adverse events, ECG, recordings, vital signs and safety laboratory parameters. Secondary, distinctive skin manifestations of cGVHD was recorded over time with baseline as reference.

Materials and Methods: Patients with cGvHD and considered to respond inadequately to 8-MOP-ECP therapy were considered for inclusion. A standard approved, fully integrated photopheresis system with ALA at a dose of 10 mM instead of 8-MOP was used. Patients were treated with one cycle (two treatments on two consecutive days) at various intervals for up to 10 cycles with follow-ups at 3., 6-, 9- and 12 months after treatment.

Results: So far, three patients are included and have received a total of 40 ALA-ECP treatments. For each patient, safety tests taken before and after treatments are comparable. No serious adverse events have been reported, although some episodes of transient infections, headache and nausea are recorded. Manifestation of skin disease became less extensive during treatment.

Conclusion: Patients tolerated ALA-ECP very well. No toxicity has been shown. The

treatment may help improve cGvHD skin manifestations.