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Title: Safety and efficacy of ectoine inhalation solution in patients with inflammation and airway obstruction: The EFECT study

Dr. Roman 29234 Berndt berndt@bitop.de ¹, Dr. Ulrich 29235 Sydlik ulrich.sydlik@uni-duesseldorf.de ², Dr. Andreas 29236 Bilstein bilstein@uni-duesseldorf.de ¹, Dr. Alessandra 29237 Marini Alessandra.Marini@uni-duesseldorf.de MD ², Dr. Thomas 29238 Jaenicke Thomas.Jaenicke@uni-duesseldorf.de ², Mrs. Gabriele 29273 Seitner-Sorge seitner@uni-duesseldorf.de ², Mrs. Sabine 29285 Stolz Sabine.Stolz@uni-duesseldorf.de ², Prof. Jean 29287 Krutmann krutmann@uni-duesseldorf.de MD ¹, Prof. Ursula 29292 Krämer ukraemer@uni-duesseldorf.de ¹ and Dr. Klaus 29298 Unfried Klaus.Unfried@uni-duesseldorf.de ¹. ¹ R & D, bitop AG, Witten, Germany, 58453 and ² Leibniz Research Institute of Environmental Health, IUF, Duesseldorf, Germany, 40225 .

Body: Introduction Ectoine is a compatible solute used for symptomatic treatment of rhinitis allergica, inflammatory dermatoses and irritated epithelia. Results from different studies demonstrated the efficacy of ectoine in reducing inflammation in the airways. Based on the positive results of a trial with asthmatic patients a study was set up to evaluate Ectoine Inhalation Solution (EIL) in subjects with mild airway obstruction and inflammation. Methods The study was designed as double blind, placebo-controlled cross-over trial. Subjects were randomly assigned to EIL or placebo (0.9% saline). Primary endpoint was defined as reduction of inflammatory markers IL 8 and % neutrophilic granulocytes in sputum. Other sputum and breath condensate biomarkers were analysed. QoL and spirometry data were collected on visit days. Results Reduction of inflammatory markers IL8 and granulocytes was greater after treatment with Ectoin compared to placebo (12% for IL8, 29% for neutrophils). Statistical significance could not be demonstrated. However, total Nitrogen from sputum showed a significant reduction after Ectoin (35%, p=0.02). Other biomarkers included in the investigation indicated advantages for Ectoin (granulocytes), or placebo (TNF α , LTB4, CRP). Analysis of QoL and spirometry data did not show significance to support superiority of one of the treatment arms. No indication for increased health risks could be detected. Conclusions Inhalation of Ectoin can reduce inflammatory markers and shows an excellent safety profile. The results of the EFECT study support the outcome of other studies that the membrane stabilizing Ectoin reduces epithelia derived inflammatory processes.