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Title: Review of health -related quality of life and patient-reported outcome in patients receiving EPs 7630 treatment for acute bronchitis

Prof. Dr Heinrich 6482 Matthys hmatthys@t-online.de MD ¹ and Dr. Wolfgang 6483 Kamin wkamin@evkhamm.de MD ². ¹ Medical Director emeritus, Department of Pneumology, University Hospital, Freiburg i. Br., Germany and ² Clinic for Paediatrics, Evangelic Hospital Hamm, Hamm, Germany .

Body: BACKGROUND: Health-related quality of life (HRQL) and patient-reported outcome (PRO) are important outcome parameters for the evaluation of both medical treatment within clinical trials and efficiency in clinical practice. For EPs® 7630 (Umckaloabo®) treatment, clinically relevant improvements in HRQL/PRO have been reported recently (Matthys, H. et al. Wien Med Wochenschr 2010;160:564-70; Matthys, H. et al. Eur Respir J 2011;38(Suppl 55):18s-19s). AIMS: We systematically reviewed randomised controlled trials (RCTs) in order to assess the impact of EPs 7630 treatment on HRQL and PRO of patients with acute bronchitis (AB). METHODS: Trials published 2010 or earlier were included for the review if they were RCTs investigating EPs 7630 vs placebo (PL) in adults or children suffering from AB and assessing HRQL and PRO by means of the EQ-5D questionnaire and the Integrative Medicine Patient Satisfaction Scale (IMPSS). RESULTS: 6 trials with a total of 1164 patients (EPs 7630: 586, PL: 578; 53% 1-18 yrs) were identified. After 7 days of treatment, clear and mostly statistically significant advantages were seen for EPs 7630 compared to PL in the 5 EQ-5D dimensions (mobility, usual activities, pain/discomfort and anxiety/depression: $p<0.01$; self-care: $p=0.02$) and in the health status of patients (EQ VAS; $p<0.01$). With EPs 7630, twice as many patients were satisfied or very satisfied with treatment outcome compared to PL (82.1% vs. 40.0%; $p<0.01$). CONCLUSIONS: There is encouraging evidence from currently available data derived from placebo-controlled trials that EPs 7630 treatment improves HRQL and PRO in both children (>1 year) and adults with acute bronchitis.